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COMMITTEE NAME **CFP – ISSC Joint Shellfish Committee Final Report**

DATE OF FINAL REPORT: 12/28/2022

COMMITTEE ASSIGNMENT: ☒ ***Council I*** ☐ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Barry Parsons and Joe Graham

COMMITTEE CHARGE(S):

Issue # 2020-I-004

1. Continue work to develop guidance documents for foodborne illness outbreak investigation for State and Local retail food inspectors and documents for best practices related to compliance for traceability for retail food establishments.
2. Report the committee's findings and recommendations at the next CFP Biennial Meeting

COMMITTEE WORK PLAN AND TIMELINE:

1. We divided the full committee into a regulatory subcommittee and an industry subcommittee to simultaneously develop the documents need to accomplish our charges.
    a. Regulator subcommittee focused on the guidance documents for foodborne illness outbreak investigation.
    b. Industry subcommittee focused on the best practice documents for retail to assist with shellstock tag compliance.
    c. Ultimately, the full committee would provide the retail industry and food safety regulators with the ability for proper traceback of shellstock product if a foodborne illness event would occur.
2. Our full committee met on Wednesday's, while the subcommittees met separately on Thursday's. Both groups collaborated to complete the various tasks to successfully achieve the charges set forth.

COMMITTEE ACTIVITIES: DATES OF COMMITTEE MEETINGS OR CONFERENCE CALLS:

- Full Committee meetings: 11/4/2021, 1/5/2022, 2/2/2022, 3/2/2022, 4/6/2022, 5/4/2022, 6/1/2022, 7/6/2022, 9/7/2022, 11/2/2022
- Regulator and Industry subcommittee meetings: 1/20/2022, 2/17/2022, 3/17/2022, 4/19/2022, 5/19/2022
- Regulator subcommittee meetings: 7/21/2022, 8/18/2022, 9/9/2022

1. ***Overview of committee activities:***
    a. The industry committee developed documents for use in retail establishments. The documents utilize colorful and eye-catching aspects with reduced wording and graphics to visually engage food employees.
        1. **"Shellstock Tags"** is for person in charge and explains a three-step process to properly Keep, Record and File the tags. It provides a graphics, explains why the tags are to be kept for 90 days, and a QR code to access the Interstate Certified Shellfish Shippers List.
        2. **"Shellstock Tag Procedures"** is simplified for the food worker and provides the three-step process to Keep, Record and File the tags. Graphics show a tag and where to record the date when the last product was used.
        3. Both documents are available in English and Spanish. To achieve a broader outreach an **"Shellstock Tag Procedures"** infographic with dual languages was also created.
    b. The regulator committee developed a toolkit for regulators. The committee developed **five documents** for the toolkit.
        1. **"Anatomy of Shellstock Tags"** has an image of a large shellstock tag with explanatory language for the various fields on the tag.

2. A document called **"Molluscan Shellfish the Basics"** provides simple, clear information for regulators who are unfamiliar with shellfish.
3. A **"Shellfish Code Language Table"** is a "one-stop" document with the FDA Food Code requirements for shellstock and shucked shellfish.

The next two documents help investigators with environmental assessments (EAs) of shellfish-related outbreaks.

4. The **"Molluscan Shellfish Environmental Investigation Field Worksheet"** is a multi-page document investigators can use to record information collected during EAs.
5. The **"Molluscan Shellfish Retail & Food Service Investigation Field Checklist"** is designed for investigators to determine what they will focus on during EAs.

2. ***Charges COMPLETED and the rationale for each specific recommendation:***

a. The documents the Industry committee created were developed specifically for the retail frontline worker and Manager/Chef. The documents have fewer and simplified words utilizing bullet points, strong, eye-catching colors, and are rooted in the basic three concepts of Keep, Record, and File to properly maintain shellstock tags for traceability purposes.

1. The industry committee's research found a scarcity of documents translated into Spanish or other languages. To have the broadest outreach possible, the infographic was created for the wide spectrum of languages that retailers employ throughout the country.
2. The intent is to assist the retailer and improve compliance with maintaining shellstock tags. This can assist regulators to complete a speedy traceback, speeding up area closures and potentially reducing foodborne illnesses from adulterated shellstock.

b. The documents the regulator committee are submitting meet the part of the charge to "develop guidance documents for foodborne illness outbreak investigation for State and Local retail food inspectors." The toolkit concept goes a bit beyond the charge, but the documents together provide important information retail food inspectors need to effectively regulate shellfish and investigate outbreaks.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. Committee Issue #1: Report - CFP - ISSC Joint Shellfish Committee

a. **List of content documents submitted with this Issue:**

(1) Committee Member Roster: Committee Member Roster: ☒ No changes to previously approved roster

(2) Other content documents: Guidance Documents and Best Practice Documents from the Committee

i. Shellstock Tag Procedures English (see attached PDF)
ii. Shellstock Tag Procedures Spanish (see attached PDF)
iii. Shellstock Tag Procedures Infographic (see attached PDF)
iv. Shellstock Tags English (see attached PDF)
v. Shellstock Tags Spanish (see attached PDF)
vi. Anatomy of Shellstock Tags (see attached PDF)
vii. Molluscan Shellfish the Basics (see attached PDF)
viii. Shellfish Code Language Table (see attached PDF)
ix. Molluscan Shellfish Environmental Investigation Field Worksheet (see attached Word document)
x. Molluscan Shellfish Investigation Field Checklist (see attached PDF)

b. List of supporting attachments: ☐ *Not applicable*

i. **Alaska shellfish retail guide**
ii. **Assess_AMC Shellfish**
iii. **Hawaii_retail shellfish requirements**
iv. **Molluscan Shellfish**
v. **Molluscan Shellfish Handling**
vi. **Record Keeping**
vii. **Retail Shellfish Requirements**
viii. **Shellfish at Retail 5_08**

2. *Committee Issue #2: CFP-ISSC Joint Shellfish Committee Guidance Documents*

a. **List of content documents submitted with this Issue:**

(1) Other content documents: Guidance Documents and Best Practice Documents from the Committee

i. Shellstock Tag Procedures English (see attached PDF)
ii. Shellstock Tag Procedures Spanish (see attached PDF)
iii. Shellstock Tag Procedures Infographic (see attached PDF)
iv. Shellstock Tags English (see attached PDF)
v. Shellstock Tags Spanish (see attached PDF)
vi. Anatomy of Shellstock Tags (see attached PDF)
vii. Molluscan Shellfish the Basics (see attached PDF)
viii. *Shellfish Code Language Table (see attached PDF)*
ix. Molluscan Shellfish Environmental Investigation Field Worksheet (see attached Word document)
x. Molluscan Shellfish Investigation Field Checklist (see attached PDF)

b. List of supporting attachments: ☐

i. **Alaska shellfish -retail-guide**
ii. **Assess_AMC Shellfish**
iii. **Hawaii_retail shellfish requirements**
iv. **Molluscan Shellfish**
v. **Molluscan Shellfish Handling**
vi. **Records_training 3_18_19**
vii. **Retail Shellfish Requirements**
viii. **Shellfish at Retail 5_08**

Committee Name: CFP-ISSC Committee on Shellfish

Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Parsons	Barry	Chair	Food Industry Support	Paster Training, Inc	Gilbertsville	PA	717-419-5103	barry.parsons@pastertraining.com
Graham	Joe	Co-Chair	Regulatory - State	WA State DOH	Olympia	WA	360-338-2717 W 360-349-9005 M	joe.graham@doh.wa.gov
Good	Sarah	Member	Regulatory - State	VA Dept. of Ag	Virginia Beach	VA		sarah.good@vdh.virginia.gov
Goodman	Alan	Member	Regulatory - State	SCDHEC	Columbia	SC	803-331-0073	goodmaae@dhec.sc.gov
Stryker	Kimberly	Member	Regulatory - State	Alaska Department of Environmental Conservation	Alaska	AK	907-269-7583	kimberly.stryker@alaska.gov
Baker	Merriah	Member	Regulatory - State	Georgia Dept. of Public Health	Atlanta	GA		merriah.baker@dph.ga.gov
Motta	Myrna	Member	Regulatory - State	Arizona Dept of Health Services	Phoenix	AZ	602-364-0929	myrna.motta@azdhs.gov
Wagendorf	Julie	Member	Regulatory - State	North Dakota Dept. of Health	Bismark	ND	701-328-2523	jwagendorf@nd.gov
Gilliland	Robert	Member	Regulatory - Local	Clay County Public Health	Liberty	MO	816-595-4253	rgilliland@clayhealth.com
Zarati	Enrique	Member	Regulatory - Local	Pima County Health Department	Tuscom	AZ	520-445-1650	enrique.zarate@pima.gov
Munaretto	Christy	Member	Regulatory - Local	Southern Nevada Health District	Las Vegan	NV	702-259-5810	munaretto@snhd.org
Jensen	Sarah	Member	Regulatory - Local	Franklin County Public Health	Columbus	OH	614-525-4537	SarahJensen@franklincountyohio.gov
Martin	Jeff	Member	Regulatory - Local	Multnomah County Health Department	Portland	OR	503-988-6972	jeffrey.martin@multco.us
Jackson	Keith	Member	Distribution	Performance Food Group	Richmond	VA	407-701-0997	keith.jackson@pfgc.com
Dewey	Bill	Member	Industry - Food Processing	Taylor Shellfish Company	Shelton	WA	360-790-2330	billd@taylorshellfish.com
Brown	Crissida	Member	Industry - Retail Food	H-E-B	San Antonio	TX	210-643-4418	brown.crissida@heb.com
Temke	Laura	Member	Industry - Retail Food	Sendik's Food Market	Milwaukee	WI	414-732-7585	laura.temke@sendiks.com
Wildy	Laura	Member	Industry - Retail Food	National Environmental Health Association (NEHA)	Denver	CO	302-668-5403	lwildey@neha.org
Noller	Aubrey	Member	Industry - Retail Food	Food Lion	Salisbury	NC	864-640-2760	Aubrey.Noller@retailbusinessservices.com
Bongo-Box	Christina	Member	Industry - Food Service	Church's Chicken / Texas Chicken	Atlanta	GA	1-502-594-5915	cbongo@churchs.com
Nardone	Angela	Member	Industry - Support	share-ify	Longwood	FL		nardone@share-ify.com
Detweiler	Darin	Member	Academia	Northeastern University	Long Beach	CA	425-232-5743	d.detwiler@northeastern.edu
Wilson	David	Member	Consumer	After School Matters	La Grange	IL	708-582-0022	d.wilson180@my.chicago.chefs.edu

Non-Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Williams	Laurie	Consultant	Regulatory - Federal				240-402-2938	**Laurie.Williams@fda.hhs.gov**
Burditt	Raymond	Consultant	Regulatory - Federal				240-402-1562	floyd.burditt@fda.hhs.gov
Johnson	Ann	Alternate	Regularoty - State	FL Department of Agriculture and Consumer Services	Tallahassee	FL	407-416-5401	anna.johnson@FDACS.gov
Diersen	Nancy	Alternate	Regulatory - State	Virginia Dept. of Health	Richmond	VA	804-307-6443	nancy.diersen@vdh.virginia.gov
Dinauer	Lauren	Alternate	Regulatory - Local	Pima County	Tucson	AZ	502-724-7873	Lauren.Dinauer2@pima.gov
Wiedmeyer	Lindy	Alternate	Regulatory - Local	City of Racine Public Health Department	Racine	WI	262-636-9567	Lindy.Wiedmeyer@cityofracine.org
O'Donnell	Kathleen	Alternate	Industry - Retail Food	Wegmans Food Markets, Inc.	Rochester	NY	585-734-3909	kathleen.odonnell@wegmans.com
No appointee		USDA Consultant	Regulatory - Federal					
No appointee		CDC Consultant	Regularoty - Federal					

Note: *Minimum council committee size is 11 (as noted above): 1-Chair; 1-Vice Chair; 1-State; 1-Local; 2-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise;*
Maximum council committee size is 23 voting members: 1-Chair; 1-Vice Chair; 4-State; 4-Local; 8-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise; 36 -Non-voting alternates.
Membership on standing committees is defined by the Executive Board. On all CFP committees, the committee chair, co-chair(s), and vice chair(s) all count towards constituency balance.

SHELLSTOCK TAG PROCEDURES
(Oysters, Scallops, Mussels, & Clams)

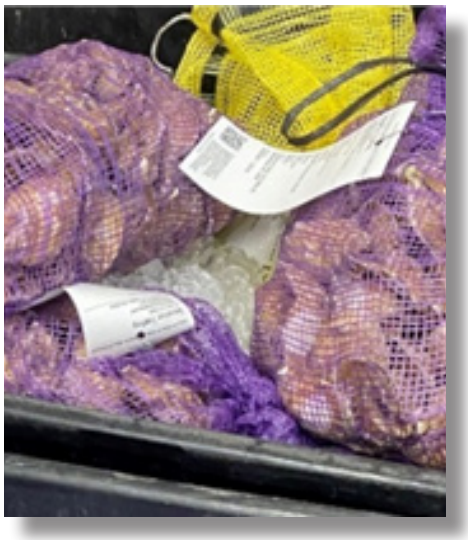
Retail Staff – It is a part of your job when selling shellstock to protect your customer. Failure to **keep, record and file** tags makes it impossible for inspectors to identify where the shellstock came from in the event of a foodborne illness, notify other retailers of safety issues, and protect the public from further foodborne illnesses.

Here are three easy steps needed to protect the health and safety of your customers:

KEEP

- The original tag must always remain with the shellstock container
- When splitting the container between storage and display a second tag / label must be used at the display. Options must be acceptable by your local regulator and could include:
  - o Make a photocopy of the tag to keep with the display
  - o Mark the display using a permanent marker, sticker, or similar identifier (example letter, date, number, color code)
  - o Use a second identical tag from the supplier to put with the display

****Never mix shellstock from different containers****



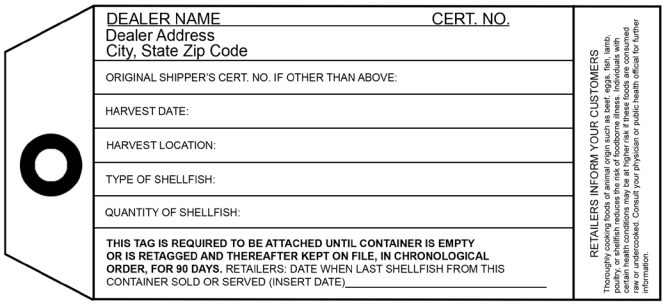
RECORD

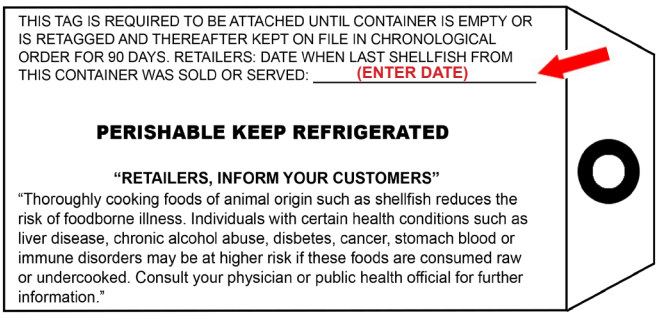
When the last shellstock from the bag / box has been sold, served, or discarded, **record the date** on the blank line / space on the tag with a permanent marker. If no line / space is provided, place the date anywhere on the tag.

FILE

- File the ***original*** tag in order by the date recorded on the tag when the last shellstock was **sold, served, or discarded.**
  - o Use a record keeping system such as a file box, binder, spreadsheet, notebook, or digital/electronic system to organize tags
- Keep the tags for **90 days**
- An inspector can ask to see tags during a routine inspection, and will ask to see tags in the event of a foodborne illness.

****If a foodborne illness occurs**, the properly completed tags provide critical information that can minimize further illnesses and protect your customers and your business**





Procedimientos de etiquetado de mariscos
(Ostras, Vieiras, Mejillones y Almejas)

Personal minorista – Parte de su trabajo cuando vende mariscos es proteger a su cliente. Si no se **mantienen, registran y archivan** las etiquetas, es imposible que los inspectores identifiquen de dónde provienen los mariscos en caso de una enfermedad transmitida por los alimentos, notifiquen a otros minoristas sobre problemas de seguridad y protejan al público de otras enfermedades alimentarias.

Aquí hay **3 pasos** fáciles que usted necesita saber para proteger la salud y la seguridad de sus clientes:

MANTENER

- La etiqueta original siempre debe permanecer con el contenedor de mariscos
- Al dividir el contenedor entre el almacenamiento y la exhibición, se debe usar una segunda etiqueta con los mariscos que están en exhibición. Las opciones deben ser **aceptables por su regulador** local y podrían incluir:
  - **Hacer una fotocopia** de la etiqueta para guardarla con los mariscos que se exhiben
  - **Marque los mariscos** que se exhiben con un marcador permanente, una etiqueta adhesiva o un identificador similar (por ejemplo, carta, fecha, número, código de color).
  - **Use una segunda** etiqueta idéntica del proveedor para colocarla con los mariscos que se exhiben

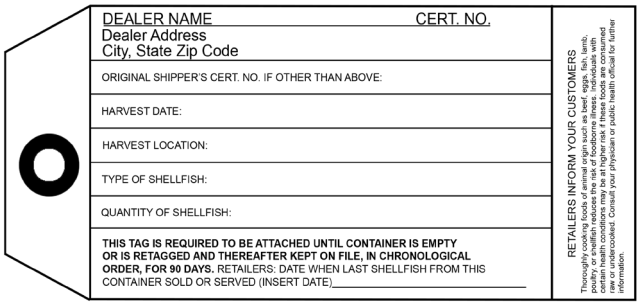
****Nunca combine los mariscos de diferentes contenedores****

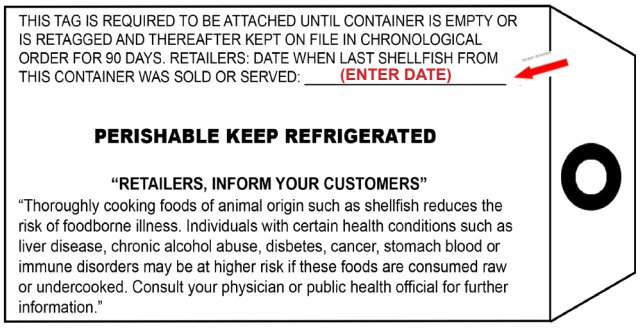
REGISTRAR

Cuando se haya vendido, servido o desechado el último marisco de la bolsa/caja, **registre la fecha** en la línea/espacio en blanco de la etiqueta con un marcador permanente. si no se proporciona una línea o espacio, coloque la fecha en cualquier lugar de la etiqueta.

ARCHIVAR

- Archive la **etiqueta original** en orden según la fecha registrada en la etiqueta cuando se vendió, sirvió o descartó el último marisco.
  - Use un sistema de mantenimiento de registros, como una caja de archivos, una carpeta, una hoja de cálculo, un cuaderno o un sistema digital/electrónico para organizar las etiquetas
- Guarde las etiquetas durante **90 días**
- Un inspector puede solicitar ver las etiquetas durante una inspección de rutina y solicitará ver las etiquetas en caso de una enfermedad transmitida por los alimentos.


DEALER NAME CERT. NO.
Dealer Address
City, State Zip Code
ORIGINAL SHIPPER'S CERT. NO. IF OTHER THAN ABOVE:
HARVEST DATE:
HARVEST LOCATION:
TYPE OF SHELLFISH:
QUANTITY OF SHELLFISH:
THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS. RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE)_____
RETAILERS INFORM YOUR CUSTOMERS
Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, pork, shellfish or poultry reduces the risk of foodborne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information.


THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE IN CHRONOLOGICAL ORDER FOR 90 DAYS. RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER WAS SOLD OR SERVED: (ENTER DATE)
PERISHABLE KEEP REFRIGERATED
"RETAILERS, INFORM YOUR CUSTOMERS"
"Thoroughly cooking foods of animal origin such as shellfish reduces the risk of foodborne illness. Individuals with certain health conditions such as liver disease, chronic alcohol abuse, disbetes, cancer, stomach blood or immune disorders may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information."

****Si se produce una enfermedad transmitida por los alimentos**, las etiquetas que se completaron correctamente brindan información crítica que puede minimizar futuras enfermedades y proteger a sus clientes y su negocio.**

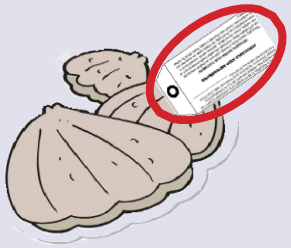
SHELLSTOCK TAG PROCEDURES

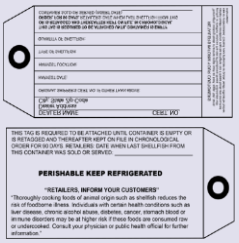
Procedimientos de etiquetado de mariscos

(Oysters, Scallops, Mussels, & Clams)

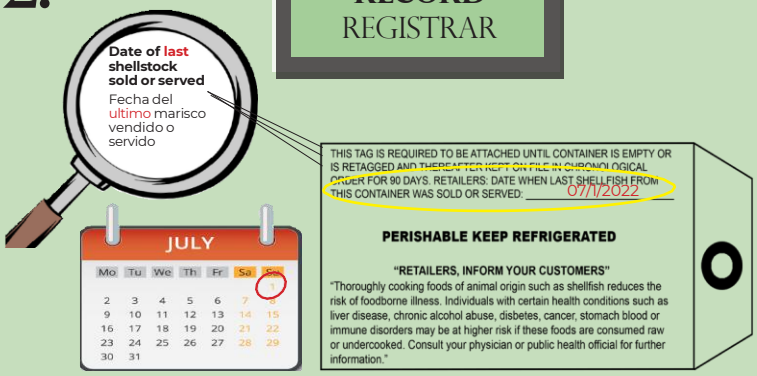
(Ostras, Vieiras, Mejillones y Almejas)

1. KEEP
MANTENER

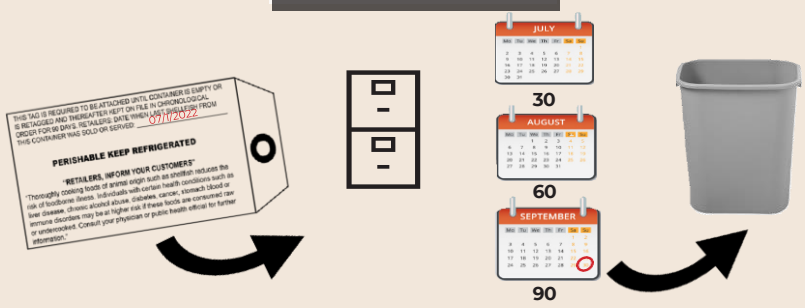




2. RECORD
REGISTRAR



3. FILE
ARCHIVAR



SHELLSTOCK TAGS
(Oysters, Scallops, Mussels, & Clams)

Shellstock tags (tags) provide a record of where the shellstock came from. If you do not **KEEP, RECORD, and FILE** tags the right way, this can make it hard for a food inspector to find out where the shellstock came from, alert the harvester and tell other businesses of food safety issues.

Here are three steps needed to protect your customers:

KEEP the tag with the shellstock in storage and on display
RECORD the date on the tag when the last of the shellstock from the bag / box is sold, served, or thrown away
FILE the original tag in order by the date you wrote on the tag

KEEP

- **Keep** the original shellstock tag with the shellstock
- When splitting the container between storage and display a second tag / label must be used at the display. Options **must be acceptable by your local regulator** and could include:
  - **Make** a photocopy of the tag to keep with the display
  - **Mark** the display using a permanent marker, sticker or similar identifier to trace to the original bag / box
  - **Put** a second identical tag from the supplier with the display

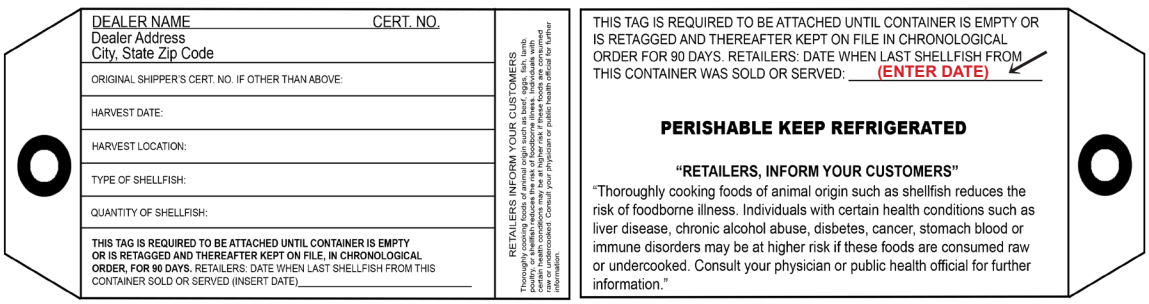
RECORD

- **Write** the date on the blank line / space on the tag when the last shellstock from the bag / box has been sold, served, or thrown away
  - **Use** a permanent marker to record the date
  - **Record** the date anywhere on the tag if there is no line / space

FILE

- **File** the original tag in order by date written on the tag when the last shellstock was **sold, served, or thrown away**
  - **Organize** tags with a file box, binder, spreadsheet, note book, or digital / electronic system
  - **Keep** the tags for **90 days**
- An inspector can ask to see tags during their inspection and will ask to see tags in the event someone gets sick

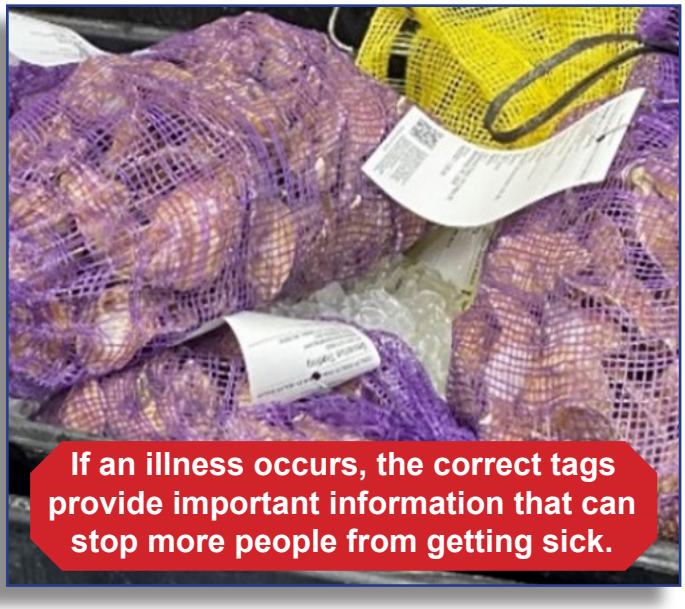
DO NOT MIX SHELLSTOCK!
Commingling, or mixing shellstock collected on different days, packed on different days, or collected from different growing areas is not allowed.



Definitions:

- **Shellstock -** live molluscan shellfish (raw oysters, clams, mussels and scallops) in the closed shell
- **Shellstock tags –** a record proving the shellstock was legally harvested and when, where and by whom they were harvested

SHELLSTOCK TAGS
(Oysters, Scallops, Mussels, & Clams)



DID YOU KNOW???

Hepatitis A is a serious virus that can hurt your liver. Sometimes, shellstock can have Hepatitis A in it, especially if the shellstock is from polluted water. It can take **56 days** for someone to start feeling sick from eating shellstock. Keep the tags on file for **90 days** due to the amount of time it could take to know someone is sick from eating shellstock and investigate the illness.

WHY following tag procedures is important?

- ✓ **Protect** your customers and your business
- ✓ **Provide** important information during a shellfish related illness investigation
- ✓ **Can help prevent** more people from getting sick
- ✓ **An inspector can ask** to see tags to make sure you are in compliance

All shellstock must be from an approved source

How do you know your shellstock provider is approved?

By checking the Interstate Certified Shellfish Shippers List, that's how.

Simply **Scan this QR code** to find out if your vendor is on the monthly approved provider list?

Etiquetado De Mariscos
(Ostras, Vieiras, Mejillones, & Almejas)

Etiquetado de Mariscos (Etiquetas) Proporcione un registro de la procedencia de los mariscos. Si no se MANTIENEN, REGISTRAN Y ARCHIVAN las etiquetas de una manera correcta esto puede dificultar que los inspectores de alimentos identifiquen de donde provienen los mariscos, no puedan alertar al cosechador y que no puedan informar a otras empresas sobre problemas de salud alimentaria.

Aquí hay tres pasos que deben seguir para proteger a los clientes:

MANTENER la etiqueta con los mariscos en almacenamiento y en exhibición.
REGISTRE la fecha en la etiqueta cuando se vendió, sirvió o desecho los mariscos
ARCHIVAR la etiqueta original en el orden según la fecha que usted escribió en la etiqueta.

MANTENER

- **Mantenga** la etiqueta original del marisco con el marisco
- Al dividir el contenedor entre el almacenamiento y la exhibición, se debe usar una segunda etiqueta en la exhibición. Las opciones **deben ser aceptables por su regulador local** y podrían incluir las siguientes:
  - **Hacer** una fotocopia de la etiqueta para guardarla con los mariscos que se exhiben
  - **Marque** los mariscos que se exhiben con un marcador permanente, una etiqueta adhesiva o un identificador similar para rastrear la bolsa/caja original
  - **Ponga** una segunda etiqueta idéntica del proveedor con los mariscos que se exhiben

REGISTRAR

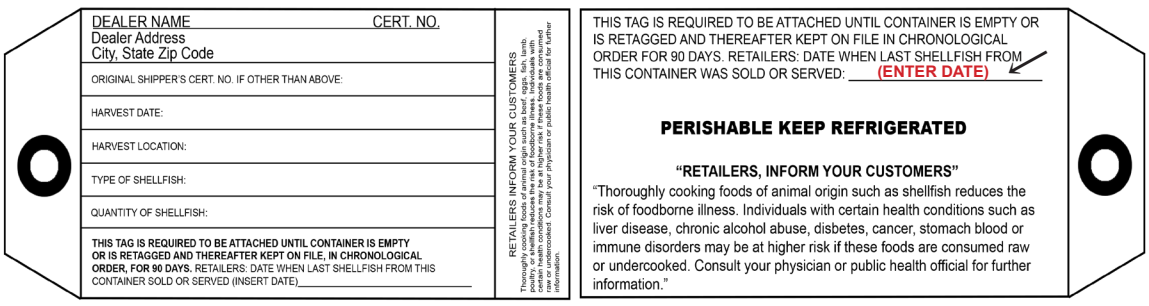
- **Escriba** la fecha en la línea/ espacio en blanco de la etiqueta cuando se vendió, sirvió o se desecho el ultimo marisco de la bolsa/caja
  - **Use** un marcador permanente para poner la fecha
  - **Escriba** la fecha en cualquier lugar de la etiqueta si no hay línea o espacio en blanco

ARCHIVAR

- **Archivar** la etiqueta original en orden según la fecha registrada en la etiqueta cuando se vendió, sirvió o se descartó el ultimo marisco
  - **Organizar** la etiqueta en una caja de archivos, una carpeta una hoja de cálculo, un cuaderno o un sistema digital/electrónico para organizar las etiquetas
  - **Guarde** las etiquetas durante 90 días
- **Un inspector** puede solicitar ver las etiquetas durante la inspección de rutina y solicitar ver las etiquetas en caso de que alguien se enferme

NO MEZCLE LOS MARISCOS!

No se permite mezclar o combinar los mariscos recolectados en diferentes días, empacados en diferentes días o recolectados de diferentes áreas de cultivo



DEALER NAME _____ CERT. NO.
Dealer Address
City, State Zip Code

ORIGINAL SHIPPER'S CERT. NO. IF OTHER THAN ABOVE:

HARVEST DATE:

HARVEST LOCATION:

TYPE OF SHELLFISH:

QUANTITY OF SHELLFISH:

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS. RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE)_____

RETAILERS INFORM YOUR CUSTOMERS
Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, pork, poultry or shellfish reduces the risk of foodborne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information.

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE IN CHRONOLOGICAL ORDER FOR 90 DAYS. RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER WAS SOLD OR SERVED: _____ (ENTER DATE)

PERISHABLE KEEP REFRIGERATED

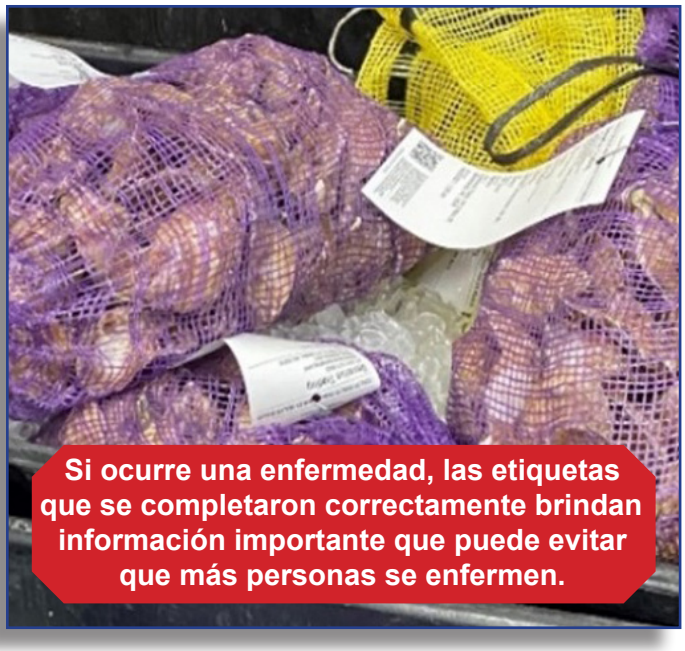
"RETAILERS, INFORM YOUR CUSTOMERS"

"Thoroughly cooking foods of animal origin such as shellfish reduces the risk of foodborne illness. Individuals with certain health conditions such as liver disease, chronic alcohol abuse, disbetes, cancer, stomach blood or immune disorders may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information."

Definiciones:

- **Mariscos –** moluscos vivos (ostras crudas, almejas, mejillones y vieiras) en la concha cerrada
- **Etiquetas de mariscos –** Un registro que prueba en donde, cuando y quien cosecho los mariscos legalmente

Etiquetado De Mariscos
(Ostras, Vieiras, Mejillones, & Almejas)



¿Sabías qué?

La Hepatitis A es un virus grave que puede dañar el hígado. A veces los mariscos pueden tener Hepatitis A, especialmente si el marisco proviene de agua contaminada. Puede tomar hasta 56 días para que alguien comience a sentirse enfermo por comer mariscos. Mantenga las etiquetas de los mariscos archivados durante 90 días debido a la cantidad de tiempo que podría pasar para saber si alguien está enfermo e investigar la enfermedad.

¿Porque es tan importante seguir los procedimientos de etiquetado?

- ✓ **Protege** a sus clientes y su negocio
- ✓ **Proporciona** información importante durante una investigación de enfermedades relacionadas con maricos
- ✓ **Puede ayudar a evitar** que más personas se enfermen
- ✓ **Un inspector puede solicitar** ver las etiquetas para asegurarse que usted esta en cumplimiento con la ley

Todos los mariscos deben provenir de una fuente aprobada

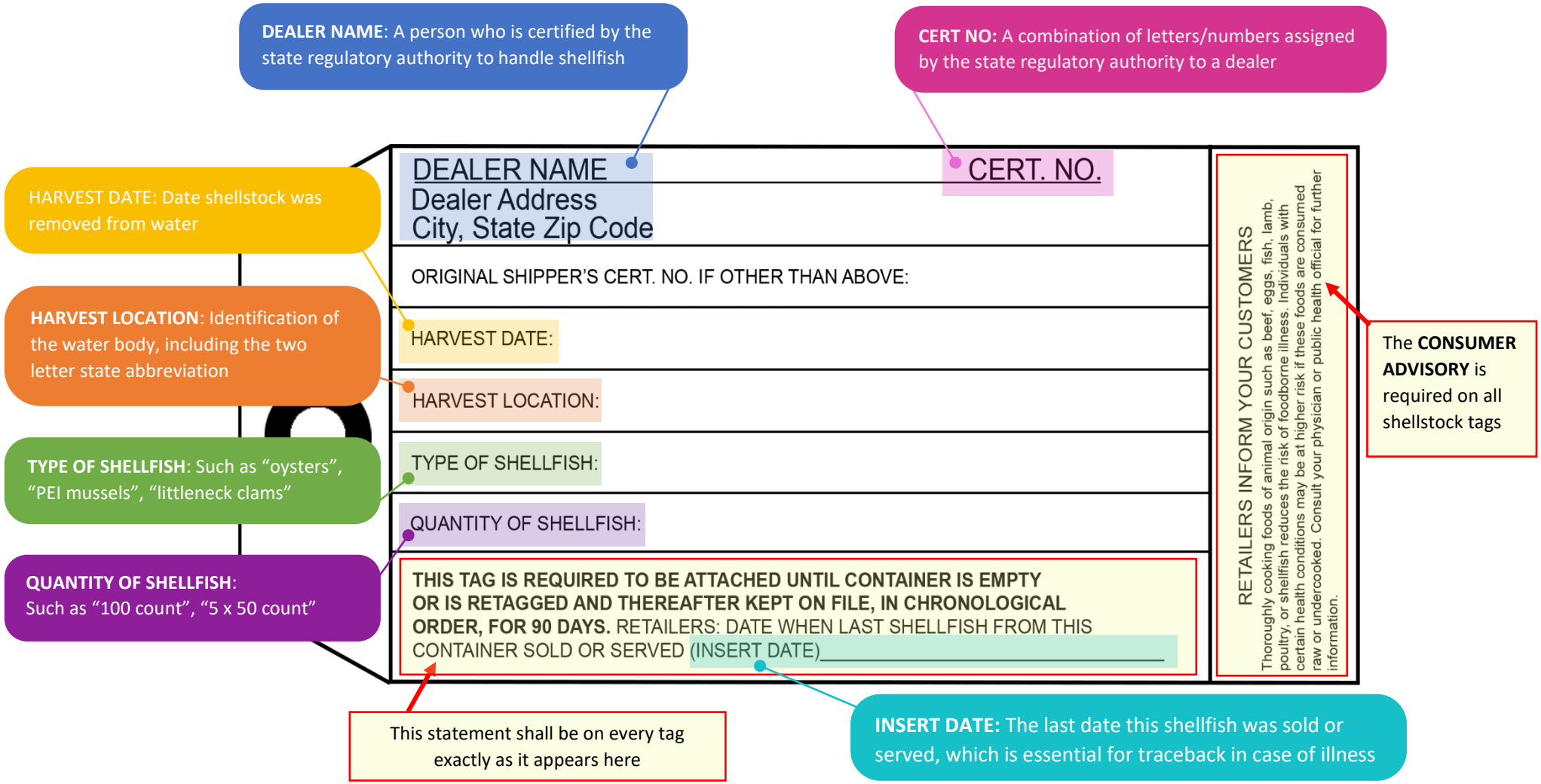
¿Como saber que su proveedor está aprobado?

Consultando la lista de transportistas de mariscos interestatales certificados.

Simplemente **escanee este código QR** para saber si su proveedor está en la lista mensual de proveedores aprobados.

ANATOMY OF SHELLSTOCK TAGS

Shellstock must be received from businesses listed on the ICSSL* and accompanied by tags



*Interstate Certified Shellfish Shippers List (ICSSL): https://www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list

Molluscan Shellfish—The Basics

What is molluscan shellfish?

An aquatic animal that lives in a shell. They are bivalve filter feeders that can contain pathogens in the surrounding water.

By which names are molluscan shellfish known?

Oyster, Clam, Mussel, or Scallop.

What is shellstock?

Raw, in-shell molluscan shellfish. For more information, see the bivalve shellfish identification resource: www.doh.wa.gov/community-and-environment/shellfish/recreational-shellfish/illness-prevention/identification

How might they be found in a restaurant, grocery store, truck, or roadside stand?

Fresh or frozen, removed from both their shells (shucked), one shell removed (shucked/half-shell), or contained in both shells (shellstock).

What is not molluscan shellfish?

Finfish (salmon, tilapia, tuna), crustaceans (lobster, crab, shrimp), snails, conch, octopus, sea urchin.

Why so much emphasis on molluscan shellfish?

Oysters, clams, and mussels grow in water that naturally contains pathogenic bacteria, such as *Vibrio* species. Many molluscan shellfish are consumed without a cooking step to kill those pathogens. In addition, some molluscan shellfish may contain toxins from algae in the growing water.

For more information, see *The Bad Bug Book* available for download: www.fda.gov/food/foodborne-pathogens/bad-bug-book-second-edition.

Other quick facts:

- Molluscan shellfish are time/temperature control for safety foods
- Date marking DOES NOT apply to shellstock
- Molluscan shellfish are often consumed raw, especially oysters
- Tag requirements do not apply to commercially packaged frozen or shucked shellfish, such as shucked scallops
- Molluscan shellfish are not included in the major food allergens because they are not crustacean

SHELLFISH CODE LANGUAGE TABLE

		SPECIFIC STANDARDS	
	2022 Food Code Reference	**SHELLSTOCK – Raw In-Shell Molluscan Shellfish**	**SHUCKED – Molluscan Shellfish with One/Both Shells Removed**
Receiving	**Approved Source** 3-201.15 Molluscan Shellfish	▪ ICSSL Interstate Certified Shellfish Shippers List ▪ 3-202.18 Shellstock Identification • Tag, Label, Invoice	▪ ICSSL Interstate Certified Shellfish Shippers List ▪ 3-202.18 Shucked Shellfish, Packing ID • Label, Invoice
	Temperature 3-202.11 Temperature	Per NSSP, adequately iced or ≤45˚F ambient air temp ***or*** as specified in LAW governing its distribution	Per NSSP, adequately iced or ≤45˚F ambient air temp ***or*** as specified in LAW governing its distribution
	Condition	Alive; reasonably free of mud, dead shellfish/broken shells. 3-202.17 Shellstock	Packages in good condition and protect the integrity of the shellfish. 3-202.15 Package Integrity
Storage	**Original Containers and Records** 3-203.11 Molluscan Shellfish, Original Container	▪ May not be removed from original container ▪ For display purposes, may be removed from the container	▪ May not be removed from original container except • For display purposes • When repacked in consumer self-service containers
	No Commingling 3-203.11 Shellstock, Maintaining ID	No commingling from one tagged/labeled container with ones from different harvest dates, growing areas	No commingling from one tagged/labeled container with ones from different harvest dates, growing areas
	Temperature 3-501.16 Time/Temp Control	41˚F or below	41˚F or below
Prep	**Food Employee** 2-2 Employee Health 2-3 Personal Cleanliness 3-301.11 Preventing BHC 3-302.11 Preventing contamination	▪ Employee health policy ▪ Hand washing ▪ Avoiding bare hand contact ▪ Cross contamination	▪ Employee health policy ▪ Hand washing ▪ Avoiding bare hand contact ▪ Cross contamination
Service	**Tag** 3-203.12 Shellstock, Maintaining ID 3-203.11 Molluscan Shellfish, Original Container (shucked ID)	▪ Tags/label remain attached to container until empty ▪ Record date on tag when last shellstock sold ▪ Tags retained for 90 days	▪ May be removed from the container in which they were received and repacked in Consumer self-service containers • Labeling information for the shellfish is on each Consumer self- service container • Labeling is retained and correlated with the date when, or dates during which, the shellfish are sold or served • Labels kept for 90 days
	Consumer Advisory 3-603.11 Consumer Advisory	▪ Served raw or undercooked • Disclosure • Reminder	▪ Served raw or undercooked • Disclosure • Reminder

Molluscan Shellfish Environmental Investigation Field Worksheet

Facility Name	Investigation Date(s)
Facility Contact Name	**Field Investigator Name**
Contact Information	

Type of Facility

☐ Oyster Bar or Restaurant ☐ Truck or Roadside Vendor ☐ Food Store ☐ Seafood Market ☐ Unknown

☐ Other:

Complaint Information

Consumption Date	Consumption Time	Amount Consumed
Suspect Shellfish Species		

Preparation & Service

Preparation Method (Product Form) for Suspect Shellfish at Service:

☐ Raw ☐ Baked ☐ Boiled ☐ Broiled ☐ Fried ☐ Steamed ☐ Unknown

☐ Other:

Service:

☐ Table Service ☐ Buffet ☐ Self- Service

☐ with Utensils Provided ☐ Serving Tongs ☐ Sneeze Guards

☐ On Half Shell with Ice

Documentation Checklist

(If collected, check and provide)

☐ **Suspect Meal Menu** (type list of fresh available, photo for days in question)

☐ **Other Parties/Special Events** (title, contact name, phone)

☐ **Shellfish Tags**

☐ **Receipts, Shopper Card Information** (to contact customers – name, phone number)

☐ **Reservation Lists** (name, phone, party size, occasion)

☐ **Production Sheets/Logs** (where different shellfish are available – to Identify types/origins of all oysters available with different meal services)

☐ **Delivery Invoices** (showing date of delivery, company, type of shellfish, lot, quantity)

Supplier Information

Supplier(s) Name(s)

Date(s) Suspect Lot Received

Imported From Another Country

☐ No ☐ Yes ***If Yes***, write import country:

Processor Treatment

☐ None ☐ Pasteurization ☐ Unknown

☐ High pressure processing ☐ Irradiation ☐ Other:

Product Form at Receipt by Retail/Food Service

☐ **In Shell** (non-living, processed shellfish with one or more shells present)

☐ **Shellstock** (raw, in-shell molluscan shellfish)

☐ **Shucked Meat**

☐ Other:

Flow Chart of Suspect Items

Receiving

Storage

Prep (including shucking)

Handling after shucking

Service

Shellfish Temperatures & Cold-Holding Method

	Mechanical	Ice	Ambient & Internal Temps & Notes
During Shipping			
At Receiving			
Storage			
Cold-Holding			

Questions

1. **Does facility display shellfish? (*If Yes*, answer 2.)**	☐ Yes ☐ No
2. **how facility prevents cross-contamination:**	***If Yes*, explain**
3. Does facility offer a variety of sources at one time (mixed plate of shellfish from variety of sources)?	☐ Yes ☐ No
4. Does facility offer a variety of oysters for order?	☐ Yes ☐ No
5. How do servers prevent commingling?	
6.	If facility shucks: ☐ N/A
a. Are cut-resistant gloves used? (*If Yes¸ answer 6b. If No, continue to 6c.)*	☐ Yes ☐ No
b. *If Yes*, are gloves smooth, durable, and nonabsorbent or covered by a glove that is smooth, durable, and nonabsorbent or single-use?	☐ Yes ☐ No
c. Is a towel used? (*If Yes¸ answer 6d. If No, continue to 6e.)*	☐ Yes ☐ No
d. *If Yes*, explain use:	
e. Do food workers handle shellfish with bare hands?	☐ Yes ☐ No
f. Does facility utilize separate sanitizer bucket for shucking?	☐ Yes ☐ No
g. Are shells used for other entrees?	☐ Yes ☐ No
h. Do the number of tags in the records match the number of animals delivered as per invoice records (are all received animals accounted for with tags)?	☐ Yes ☐ No

MOLLUSCAN SHELLFISH RETAIL & FOOD SERVICE INVESTIGATION FIELD CHECKLIST

SUSPECT AGENT/PATHOGEN OF CONCERN & CORRESPONDING FIELD FOCUS		RISK FACTORS & INTERVENTIONS FIELD FOCUS	METHODS, REMEDIATION & CONTROL MEASURES
TOXINS	**FIELD FOCUS**	**SOURCE (S)**	*Consider items and check each used.*
☐ Paralytic shellfish poisoning	S	☐ Copies of delivery receipts/invoices	**INVESTIGATION METHODS**
☐ Diarrhetic shellfish poisoning		☐ Shellfish tags, ICSSL (Interstate Certified Shellfish Shippers List)	☐ Food, Environmental Samples
☐ Neurotoxic shellfish poisoning		**ILL FOOD WORKERS (ILL FW)**	☐ Stool Samples
☐ Amnesic shellfish poisoning		☐ Exclusion policy	☐ Photographs
		☐ Check work schedules (employee list)	☐ Suspect Meal Menu
BACTERIAL INFECTIONS	**FIELD FOCUS**	☐ Determine employee health status	☐ Reservation Lists, Receipts
☐ *Vibrio cholerae O1*	S	☐ Determine roles of food workers for suspected meals and ingredients	☐ Special Events, Parties
☐ *Vibrio cholerae non-O1*	Ill FW	**BARE HAND CONTACT (BHC)**	☐ Invoices, Inventory, Traceback
	BHC	☐ Gloves/utensils available & indications of usage	☐ Multiple Establishments Investigated
	HW	☐ History of BHC control in facility	☐ Additional Case Finding
	CH	**HANDWASHING (HW)**	**CONTROL MEASURES**
	XC	☐ Handwash sinks available & have soap/towels	☐ Behavior Change
	CA	☐ Observe proper HW	☐ Procedure Change
BACTERIAL INFECTIONS*	**FIELD FOCUS**	**COLD HOLDING (CH)**	☐ Exclude Ill FW
☐ *Vibrio parahaemolyticus*	S	☐ Proper CH	☐ Food Destruction
☐ *Vibrio vulnificus*	CH	☐ History of proper temperature control practices	☐ Detention Order
	XC	☐ Discussion of food prep steps	☐ Cleaning & Sanitizing
*Not typically transmitted person to person	CA	☐ Advanced preparation	☐ Suspension/Closure
		CROSS-CONTAMINATION (XC)	**MOVING FORWARD**
		☐ Proper storage during cold-holding, display	☐ Follow-up Visit Scheduled
		☐ Separation of utensils used for raw product	☐ Follow-up Visit with Interpreter
		☐ Cleaning/sanitizing of equipment/utensils	☐ Increased Inspections
		☐ Shells used for other entrees	☐ Menu Reduction
		☐ Shucking gloves, towels, sanitizer buckets	☐ Required Education/Training
		CONSUMER ADVISORY (CA)	☐ Office Conference
		☐ Menu disclosure and reminder	**COMMUNICATION**
			☐ State Shellfish Authority

SAFE HANDLING OF SHELLFISH AT RETAIL

Alaska molluscan shellfish, specifically live fresh oysters, are often eaten raw or undercooked. To reduce the risk of foodborne illness in molluscan shellfish, follow the Alaska Food Safety & Sanitation Program's practices for safe handling. For more information on seafood safety at retail in Alaska, please visit the State of Alaska website at https://dec.alaska.gov/eh/fss/food/food-service-markets.

RECEIVING

1 APPROVED SOURCE

- Check ICSSL list for certified supplier*

2 LIVE SHELLSTOCK

- No open shells
- Mist or tap to check if shell closes

3 SAFE TEMPERATURES & GOOD CONDITIONS

- Receiving temps should be below 45F°
- No off odor smells
- Shells are not starting to open and no broken shells

4 PROPER TAGGING

- Dealer's name, address, and certification number
- Data/location of harvest
- Type and quantity of shellfish
- Statement that tag needs to stay attached to the container until emptied and then retained for 90 days

DISPLAY & STORING

1 MONITOR FOR SAFE DISPLAY

- Temperature is at 41F° or less
- Discard any dead shellstock
- Rotate on display—First in First out
- Make sure displayed shellfish returns to the same container w/ original tag

2 SAFE STORAGE

- If stored on ice, use a drip pan system
- Never place in air tight container or fresh water
- Don't store near foods that can leak or that could be contaminated
- Keep shellstock tags on original container until empty

SHELLFISH SALE

1 SAFE RECORDKEEPING

- Fill out tag once container is empty
- File tag in chronological order
- Keep tag for 90 days after container is emptied

2 COMMUNICATE SAFETY

- Display consumer advisory for raw or undercooked seafood.
- Advise on storing and handling practices

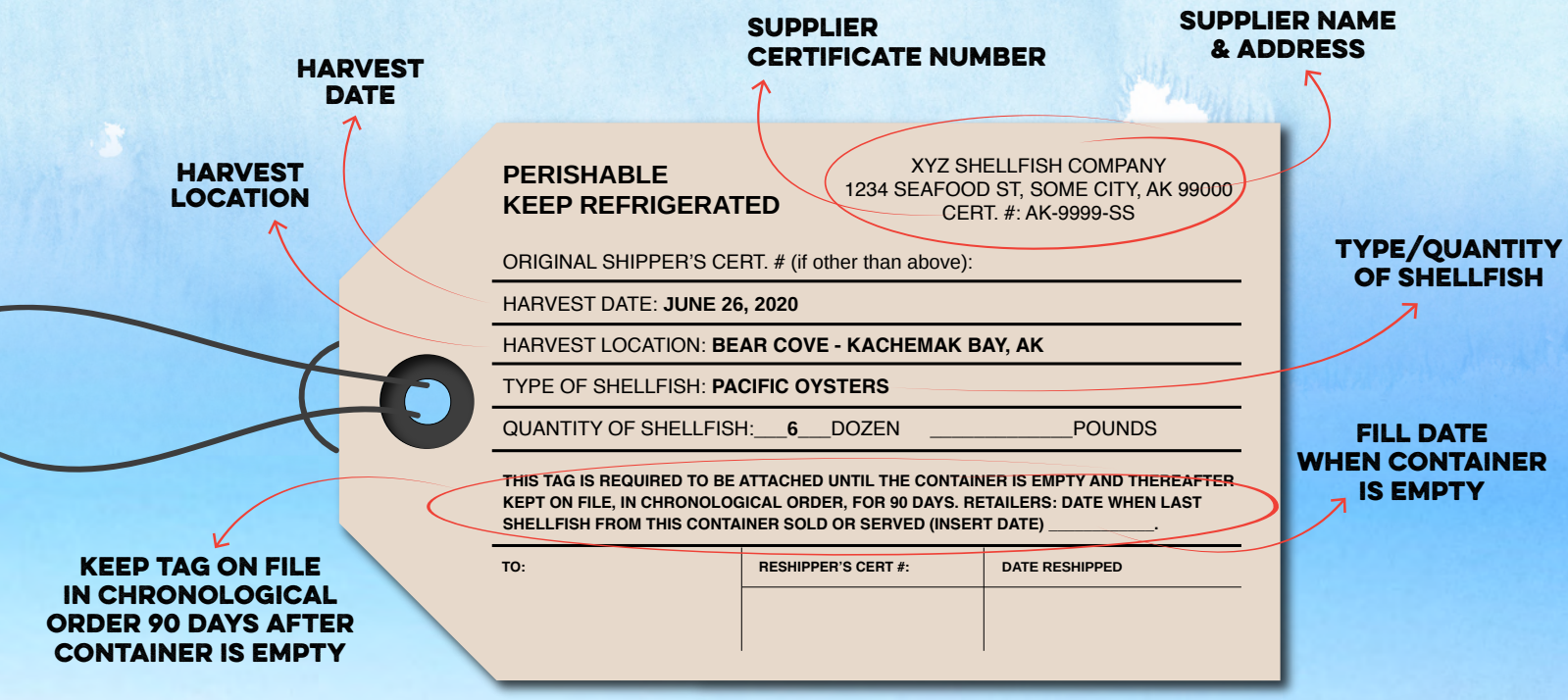
ADEC Food Safety & Sanitation Program

555 Cordova Street,
Anchorage, AK 99501

P: 907.269.7501
dec.alaska.gov/eh/fss.aspx

*https://www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list

SHELLSTOCK TAG INFORMATION



CONSUMER ADVISORY INFORMATION

Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions.

Refrigerate purchased shellfish as soon as possible to 41F° or less. Do not mix the raw seafood with other seafood or foods in storage.

QUICK FACTS

SHELLSTOCK

Live shellfish that remain in their shells

MOLLUSCAN SHELLFISH

Fresh or frozen oysters, clams, mussels, and scallops

SHELLFISH SAFETY CONCERN

Due to where molluscan shellfish live, how they feed, and how they're eaten, these shellfish can contain bacteria and viruses that can cause illness if not handled properly

SHELLFISH SAFETY ACTION

To minimize risk, the Alaska Food Safety and Sanitation Program works to implement FDA measures to ensure refrigeration controls are practiced to prevent foodborne illness, all shellfish are properly tagged, all shellfish are harvested from safe and permitted areas, and harvest facilities and operations meet appropriate sanitary standards

For more information on shellfish safety and handling, please visit the Alaska Food Safety and Sanitation Program website: https://dec.alaska.gov/eh/fss/shellfish

APPROVED SOURCE

1. Approved Source Critical Limits

APPROVED SOURCES & RECEIVING

- Delivery vehicle clean, free from insects / vermin; no evidence of cross contamination
- Time-Temperature Control for safety foods delivered under refrigeration are 41ºF or below
- Frozen foods do not show evidence of thawing or freezing
- Evaluations indicate no signs of spoilage; off odors; discoloration; thawing of frozen foods; ice crystals; etc.
- Product packaging is not damaged exposing food to contamination

SHELLSTOCK

- Shellstock obtained from source identified on the Interstate Certified Shellfish Shippers List (ICSSL) http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/default.htm
- Shellstock shall be obtained in container bearing legible source identification tags or labels:
  - ✓ Harvester's tag or label
    - Harvester's identification number that is assigned by the shellfish control authority
    - The date of harvesting
    - Most precise identification of harvest location including the abbreviation of the name of the state or country in which the shellfish are harvested
    - Type and quantity of shellfish
    - Statement in bold, capitalized type: *THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTIED OR RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS*
  - ✓ Dealer's tag or label
    - Dealer's name and address, and the certification number assigned by the shellfish control authority
    - The original shipper's certification number including the abbreviation of the name of the state or country in which the shellfish are harvested
    - The same information as specified for the harvester's tag or label (above)
    - Statement in bold, capitalized type: *THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTIED AND THEREAFTER KEPT ON FILE FOR 90 DAYS*
  - ✓ Shellfish tag maintenance:
    - Tags remain attached to container in which the shellstock are received until the container is empty;
    - The date when last shellstock from the container is sold/served must be recorded on the tag or label;
    - Tags must be retained in chronological order for 90 days from date recorded on the tag or label (the date when the last shellstock from the container is sold or served).
  - ✓ National Shellfish Sanitation Program also requires the following statement on tags: *RETAILER INFORM YOUR CUSTOMERS. Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, poultry or shellfish reduces the risk of foodborne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information.* http://www.issc.org
- Shucked Shellfish
  - ✓ Shipped in nonreturnable containers
  - ✓ May be removed from original containers for displaying/dispensing if the labeling information is retained and correlated to the date when, or dates during which, the shellfish are sold or served
  - ✓ Labeled with name, address and certification number of the shucker-packer or repacker; and
    - "sell by" date for < ½ gallon or
    - "date shucked" for ≥ ½ gallon

2. Questions to Assess AMC of Approved Source

- How do you verify that the food you receive is from an approved source?
- Do you have purchase specifications for specific food items?
- Do you any food products that require the suppler to sign a certificate of conformance with your operation?
- What method do you use to verify the source of your shellfish?
- How frequently do have food delivered to your facility?
- Have you established specific times of the days when food is to be delivered to your facility or do you work within the parameters of the supplier's schedule?
- Who is responsible for checking food delivered to the facility?
- What do you check when food is delivered to your establishment?
- How do you know if the food is at proper temperature when it is received?
- Do you maintain any receiving logs?

3. Tips to Assess AMC of Approved Source

- The time and day of the inspection is important when assessing whether foods are received from safe sources and in sound condition. Food may be received in the food establishment on set days. Ask questions to ascertain the day or days that deliveries are received and also the receiving procedures in place by the food establishment. Schedule inspections at times when it is known that product will be received by the food establishment.
- If food is being delivered during the inspection, you should:
  - ✓ Verify internal product temperatures
  - ✓ Examine package integrity upon delivery
  - ✓ Look for signs of temperature abuse (e.g., large ice crystals in the packages of frozen products)
  - ✓ Examine the delivery truck and products for potential for cross contamination
  - ✓ Observe the food employees behaviors and practices as they relate to the establishment's control of contamination and holding and cooling temperatures of received products
  - ✓ When evaluating approved sources for shellfish, such as clams, oysters, and mussels, you should ask whether shellfish are served at any time during the year. If so, review the tags or labels to verify that the supplier of the shellfish is certified and on the most current Interstate Certified Shellfish Shippers List
  - ✓ Note whether all required information is provided on the tags or labeled and that these records have been retained for 90 days and stored in chronological order.

IMPROPER HOLDING / TIME & TEMPERATURE CONTROL

CONTROL AREAS

A. Cold Holding of Temperature Control for Safety (TCS) Foods
B. Date Marking of Ready to Eat (RTE), TCS Foods
C. Time Used as a Microbial Growth Barrier

A. COLD HOLDING & DATE MARKING

1. Critical Limits of Cold Holding & Date Marking

A. COLD HOLDING OF TCS FOODS	
Process / Product	**Critical Limit**
Cold holding of TCS foods	41ºF (5ºC) or less

B. DATE MARKING OF RTE, TCS FOODS	
Process / Product	**Critical Limit**
Refrigerated RTE, TCS Foods: ✓ prepared in the establishment ✓ opened package from a commercial processing plant ✓ held for more than 24 hours	✓ 7 days at 41ºF (5ºC) or less ✓ Marked to indicate the date or day the food must be consumed on the premises, sold, or discarded ✓ Day of "preparation" or "opening is counted as "Day 1" ✓ Date mark not to exceed manufacturer's use by date
RTE, TCS Foods Subsequently Frozen:	✓ Marked at the time of freezing as to the days already held at refrigeration and upon removing from the freezer, the new "date" is 7 days minus the time held before freezing
**Date Marking is not required by Alaska Food Code*	

2. Questions to Assess AMC of Cold Holding & Date Marking

- How do you monitor your refrigeration units to ensure they are maintaining proper temperature?
- Are there any refrigeration/cold food storage units located outside of the kitchen area (salad bars, food transportation units, etc.)?
- Do you use methods, other than storing under refrigeration, to maintain foods cold (e.g. storage in ice)?
- What kind of monitoring procedures do you implement for ensuring food is at the proper cold holding temperature?
- What type of equipment is used to check the food product temperatures? How often is this done? How do you know the temperature measuring devices are accurate?
- Do you keep temperature logs? Do you record the temperature of the refrigeration units, product temperatures, or both? (not required per the Alaska Food Code)
- How do employees know what food is to be used first (first in, first out)?
- What is your date marking procedure for ready-to-eat, TCS Food? (not required in Alaska Food Code)
- How does the manager/food employees handle situations when they discover prepared food that has been stored in the walk-in cooler or other refrigeration unit without date marking or that has expired dates?

3. Tips to Assess AMC of Cold Holding & Date Marking

- Check cold holding temperatures with a thermocouple, thermistor, or other appropriate temperature measuring device. This includes the temperature of TCS food during transport (receiving trucks, cold holding carts being used to transport food to patient room in a hospital, satellite kitchens, or off-site catering events).
- DO NOT USE an infrared thermometer for verifying cold holding temperatures. Relying on surface temperatures may mask potential problems related to improper internal product temperatures and will not provide enough information to make an accurate assessment of cold holding procedures. In addition, inspectors should not stir cold soups and the like since it is important to know the temperature before the food is agitated.
- Open top refrigerated display cases and sandwich prep units may present significant cold holding challenges. When located across from cooking equipment or hot holding devices, these units may have a difficult time maintaining product temperatures. For refrigerated display cases, packaged food products may be stored directly on top of refrigerated air vents or placed in the case in a manner that blocks the flow of refrigerated air. Determine the system the establishment has in place for monitoring these units to ensure product temperatures are maintained at 41ºF or less. An alarm system (commonly used by large grocery store chains) may not be sufficient alone in ensuring product temperatures are maintained at 41ºF or less.
- Cold holding temperature control does not stop once the product leaves the kitchen. How does the facility ensure cold holding temperatures are maintained for products sent to satellite schools, patient rooms, or other food distribution points that may be off-site? Who is responsible for monitoring the temperature once it leaves the kitchen areas? Is it the kitchen foodservice personnel or is it the nursing staff in hospital facilities? Are satellite school facilities responsible for checking temperatures when the food arrives? How is this done and reported back to the main commissary kitchen?
- Date marking systems may use calendar dates, days of the week, color-coded marks, or another type of system. When the person in charge explains the system, is it clear to you what is expected and does it meet the Food Code requirements? Can food employees explain the system and is their version consistent with management's expectation?

C. TIME USED AS A MICROBIAL GROWTH BARRIER

1. Critical Limits for Time Used as Microbial Growth Barrier

C. TIME USED AS A MICROBIAL GROWTH BARRIER FOR TCS FOODS

Written procedure must be available on-site and:

- ✓ Identifies the foods to be held using time only as a public health control
- ✓ Describes the procedures for implementing time without temperature as a public health control (procedures, training, monitoring, documentation)

Time without temperature control is used as the public health control up to a MAXIMUM OF **4 HOURS**

- ✓ Food must have an initial temperature of:
  - ❖ 41ºF (5ºC) or less when removed from cold holding temperature control, OR
  - ❖ 135ºF (57ºC) or above when removed from hot holding temperature control
  - ❖ TCS Food marked or identified with the maximum 4 hour period when removed from temperature control
  - ❖ After 4 hours any remaining food product is discarded
  - ❖ Unmarked containers or packages or containers marked that exceed a 4 hour limit are to be discarded

Time without temperature control is used as the public health control up to a MAXIMUM OF **6 HOURS**

- ✓ Food must have an initial temperature of:
  - ❖ 41ºF (5ºC) or less when removed from cold holding temperature control
  - ❖ Food temperature may not exceed 70ºF (21ºC) during the 6 hour period
  - ❖ The food shall be monitored to ensure the warmest portion of the food does not exceed 70ºF (21º) during the 6-hour holding period
  - ❖ TCS Food marked to indicate time when the food is removed from 41ºF (5ºC) or less cold holding temperature control
  - ❖ TCS Food marked or identified with the maximum 6 hour period when removed from temperature control
  - ❖ TCS Food is discarded of the temperature of the food exceeds 70ºF (21ºC) OR
  - ❖ After 6 hours any remaining food product is discarded
  - ❖ Unmarked containers or packages or containers marked that exceed a 6 hour limit are to be discarded

2. Questions to Assess AMC

- How long is TCS Food being held out of temperature before or after cooking?
- How do you monitor how long products are out of temperature control?
- Do you have specific food products for which you use time instead of temperature as a food safety control?
- What type of system do you have in place to monitor the time?
- Who is responsible for ensuring that time frames for holding product out of temperature control are not exceeded?
- What happens to food that exceeds the time frames for holding?
- For the products that you hold using time rather than temperature, what action do you take after 2 hours if it appears that all the product will not be sold or served within the 4 or 6 hour time frames?

3. Tips to Assess AMC

- Each temperature scenario for using time only as a microbial growth barrier incurs different risks in regard to the type of foodborne pathogens able to grow and the rate of growth likely to occur. For both cooling and warming conditions, growth depends on the amount of time the food spends in an optimum growth temperature range and its equilibration with its surroundings.
- Several factors influence the rate of temperature changes in a food such as the type of food, thickness of food, and the temperature differential between the food and its surroundings. When evaluating the safety of a 4-hour limit for food with no temperature control, products and environmental parameters must be selected for a worst-case scenario for pathogen growth and possible toxin production.
- Consider the type of operation that is using time as a microbial growth barrier. Are the establishment's written procedures easy to implement? Monitoring the time period for the food may be a greater challenge if the product is displayed in an area of the store that is located outside of the food preparation area such as rotisserie chicken displayed in the aisle section outside the deli area in a retail food store.
- Determining how the operation maintains clear marking of the 4 hour period of time may be difficult if multiple batches are made during the course of the day and are stored, commingled, in a display case. In this scenario, each individual product would have to be clearly marked or a system that provides distinct separation of lots would have to be established within a display or holding case.
- Having written procedures and appropriate product marking will only be effective if the individuals responsible for the procedure are properly implementing them. The individuals responsible for monitoring (and when appropriate, discarding the product) must be clearly identified.
- Holding cold food without temperature control has some additional consideration. An assessment of the products start temperature must be made to ensure it was maintained at 41ºF or below prior to being removed from temperature control. Determine where these products are stored prior to using time as a public health control and evaluate the product temperature within these refrigeration units. The type of refrigeration unit and its capacity should also be considered when assessing these products.
- Holding cold food without temperature control must include a system for assuring the product temperature never exceeds 70ºF. The ideal scenario would be to have a product temperature measuring device constantly recording or displaying the warmest part of the food. In many cases, an establishment may want to use alternative monitoring such as the ambient air temperature of a refrigeration unit. What steps have they taken to validate that this type of procedure is effective, and how do they verify that the system is implemented at all times?
- Keep in mind that using time as a microbial growth barrier is an intentional use of time rather than temperature to control growth of pathogens. Corrective action of a cold holding problem may use the same principles as when time alone is used but it is different in that when time is used, the establishment needs to have a distinct system in place. The assessment should not only be on the written procedures in place, but the rotation of the product. Does the facility add product to a container under time control in busy periods or does the system incorporate procedures for completely changing out the containers? Are foods intended to be held cold without temperature control, stored or commingled with foods intended to be temperature-controlled?

PERSONAL HYGIENE

CONTROL AREAS

*Active Managerial Control for the Personal Hygiene risk factor must include **all three of the elements identified A-C below**. Concurrent use of each of these three control measures will help prevent the transmission of viruses, bacteria, and protozoan oocysts from food employees to customers through contaminated food*

A. Ill Food Workers (Ill FW)
B. Handwashing (HW)
C. Bare Hand Contact (BHC)

A. ILL FOOD WORKERS

1. Critical Limits for Ill Food Workers (Employee Health)

A. ILL FOOD WORKERS (

- **Employee Health Program must address:**
  - **5 pathogens** (due to low infectious dose, contamination of the gastrointestinal system after ingestion, and shed in feces):
    1. Norovirus
    2. *Salmonella* Typhi (typhoid-like fever)
    3. *E. coli* O157:H7, Enterohemorrhagic or Shiga toxin-producing *E. Coli*
    4. *Shigella* spp.
    5. Hepatitis A virus
  - **5 symptoms**
    1. Vomiting
    2. Diarrhea
    3. Jaundice (yellow skin or eyes)
    4. Sore throat with fever
    5. Infected cuts and burns with pus on hands and wrists
- The manager or Person-in-Charge (PIC) ensures that food employees **trained in 4 subjects**
  1. Cause of foodborne illness
  2. Relationship between the food employee's job task, personal hygiene, and foodborne illness
  3. Importance of and requirement for reporting
  4. Specific symptoms, diagnoses, and exposures that must be reported to the Person-in-Charge
- **Report to Management**:
  1. **5 symptoms**: Vomiting, diarrhea, jaundice, sore throat with fever, or any exposed boil or open, infected wounds or cuts on hands or arms
  2. **Diagnoses of 5 pathogens:** An illness diagnosed by a health practitioner that was caused by: *Salmonella* Typhi; *Shigella* spp.; Norovirus; Hepatitis A; or E coli O157:H7 or other Enterohemorrhagic or Shiga toxin producing *E. coli*
  3. **Past illness** with typhoid-like fever within the past 3 months unless treated with antibiotics
  4. **Exposure** to typhoid-like fever, shigellosis, Norovirus, Hepatitus A virus, *E. coli* O157:H7 or other Enterohemorrhagic or Shiga toxin-producing *E. coli*, by eating or serving food that was implicated in a foodborne illness outbreak or if residing with a diagnosed individual.

► Exclusion and restriction policies must adhered to those provided in the decision tree tables contained in the FDA Employee Health and Personal Hygiene Handbook

2. Questions to Assess AMC of Ill Food Workers (Employee Health)

- What kind of policy do you have in place for handling sick employees?
- Is there a written policy? (Note: a written policy is not required in the Food Code, but having a written policy may give an indication of the formality of the policy being discussed.)
- Describe how managers and food employees are made knowledgeable about their duties and responsibilities under the employee health policy.
- Are food employees asked if they are experiencing certain symptoms or illnesses upon conditional offer of employment? If so, what symptoms or illnesses are food employees asked about? Is there a written record of this inquiry?
- What are food employees instructed to do when they are sick?
- What conditions or symptoms are reported?
- What may some indicators be of someone who is working while ill?
- When are employees restricted from working with exposed food or food contact surfaces? When are they excluded from working in the food establishment?
- For employees that are sick and cannot come to work, what policy is in place for allowing them to return and for notifying the regulatory authority?

3. Tips to Assess AMC of Ill Food Workers (Employee Health)

- In general, most individuals do not like discussing subjects related to illnesses such as diarrhea and vomiting. It will be important to put the Person-in-Charge at ease. Explaining that the Centers for Disease Control and Prevention (CDC) has identified that employees coming to work when ill is a primary contributor of foodborne illness will provide rationale to establish a common ground for communication. Including a discussion of the difficult economy and the pressure on employees to work in order to have income often helps on operator relate to the business side of the issue.
- Establishing a dialogue with the operator requires more than asking questions. In fact, an operator may feel they are being interrogated if too many questions are asked in succession. Be cognizant of the types of questions you are asking the operator. Not all the questions included in the previous Employee Health questions section need to be asked to assess the extent of an operation's employee health program or policies.
- Though it is important to look for visible signs of illnesses of wound infections at any time during the inspection, asking questions regarding an operation's employee health policy may be better addressed later in the inspection rather than the beginning. Often times this is a gap area for an operator because they haven't really thought about it in the past and regulatory agencies did not make it a priority during their inspections. Stressing a gap area in an establishment's food safety management system early on in the inspection may make the operator defensive and guarded.
- Employee Health can be a complex and intimidating subject for most operators who are first and foremost business people. Do not be mistaken, it is a subject they care about and know it is important to prevent ill employees from working to protect their customers and business. Much of the information pertaining to employee health will not be retained by the operator if it is based merely on an open discussion at the end of the inspection. It is important to leave a simple reference sheet or other written materials that will assist them in developing a sound employee health program. Two useful tools in this endeavor are the FDA Employee Health and Personal Hygiene Handbook or CD. These tools contain comprehensive Standard Operating Procedures and include forms for documenting food employees training and responsibilities pertaining to foodborne illnesses and their symptoms.
- If an operator has concerns about employee privacy, ADA, or HIPPA, a good resource is

B. HANDWASHING

1. Critical Limits for Handwashing

B. HANDWASHING Critical Limits

- When food employees should wash their hands:
  - ✓ Immediately after engaging activities that contaminate hands
  - ✓ When entering a food preparation area
  - ✓ Before putting on clean, single-use gloves for working with food and between glove changes
  - ✓ Before engaging in food preparation
  - ✓ Before handling clean equipment and serving utensils
  - ✓ When changing tasks and switching between handling raw foods and working with ready-to-eat foods
  - ✓ After handling soiled dishes, equipment, or utensils
  - ✓ After touching bare human body parts, for example, parts other than clean hands and clean, exposed portions of arms
  - ✓ After using the toilet
  - ✓ After coughing, sneezing, blowing the nose, using tobacco, eating, or drinking
  - ✓ After caring for or handling service animals or aquatic animals such as molluscan shellfish or crustacean in display tanks

- Handwashing procedure
  - ✓ Clean hands and exposed portions of arms, including surrogate prosthetic devices for hands and arms, for at least 20 seconds using the following procedure:
    1. Rinse under clean, warm running water
    2. Apply soap and rub all surfaces of the hands and fingers together vigorously with friction for at least 10 to 15 seconds, giving particular attention to the area under the fingernails, between the fingers/fingertips, and surfaces of the hands, arms, and surrogate prosthetic devices
    3. Rinse thoroughly with clean, warm running water
    4. Thoroughly dry the hands and exposed portions of arms with single-use paper toweling, a heated-air hand-drying device, or a clean, unused towel system that supplies the user with a clean towel
    5. Avoid recontamination of hands and arms using a clean barrier, such as a paper towel, when turning off hand sink faucets or touching the handle of a restroom door

2. Questions to Assess AMC of Handwashing

- How do employees know when to wash their hands and what method to use?
- What type of system do you have in place to ensure employees wash their hands when you expect them to do so?
- Who is responsible for checking to see that employees practice good handwashing procedures?
- What action is taken when an employee is observed not washing their hands when you expect them to do so?
- What type of system do you have in place to ensure that handsinks are continually stocked with hand soap and paper towels (or hand drying devices)?
- Do you use any techniques or methods to encourage employees to wash their hands?
- Do you maintain any type of documentation that attempts to monitor employees' handwashing within the kitchen area?

3. Tips to Assess AMC of Handwashing

- Conducting an assessment of proper and adequate handwashing procedures in an establishment requires patience. A snap shot observation of a poor employee practice may not provide enough information to gain an understanding of the root cause of the problem. The lack of handwashing and improper handwashing methods are not always directly attributed to an employee failing to follow good practices. Observations of the entire food preparation procedure can uncover environmental antecedents to poor handwashing such as: the volume of foods being prepared, activity level in the establishment, location of handwashing facilities and an employee's ability to reach them, and lack of training or monitoring by food service management. In order to change employee behavior, it is essential to identify the root cause of the problem.
- It is important to know what the management's handwashing policy is. Not only can an assessment be made as to whether the establishment's policy adequately addresses all aspects of proper handwashing, but it can provide an indication as to whether the employees are following the procedure as described by management. This can provide an indication as to the level of awareness and training employees are receiving regarding the importance of handwashing.
- Having the foodservice manager or person-in-charge with you during the assessment of handwashing can help establish a common understanding of the root causes that might be contributing to poor practices. Management can observe first-hand the employee practices that have the potential to put their business at risk. The person-in-charge will begin to recognize that they need to reinforce the importance of proper handwashing procedures on a continual basis and have a method for providing feedback to all employees on how well they are doing.
- Having the person-in-charge/manager with you during the inspection provides an opportunity to assess what corrective actions are in place to address poor handwashing practices. If management observes poor handwashing, do they implement the type of corrective action they have described? If not, why not?

C. BARE HAND CONTACT (BHC)

1. Critical Limits for Bare Hand Contact

C. <u>NO BARE HAND CONTACT WITH READY-TO-EAT FOODS</u>

- Bare hand contact with a ready-to-eat food such as sandwiches and salads can result in contamination of food and contribute to foodborne illness outbreaks. Food employees should always use suitable utensils such as spatulas, tongs, single-use gloves, or dispensing equipment when handling ready-to-eat foods.
- Single-use gloves used along with handwashing can be an effective barrier to decrease the transfer of microorganisms from the hand to the food. Gloves are not total barriers to microbial transmission and will not be an effective barrier alone for food workers without education on proper glove use and handwashing requirements.
- Procedures for the use of single-use gloves include:
  - ✓ Always wash hands before donning gloves
  - ✓ Change disposable gloves between handling raw products and ready-to-eat products
  - ✓ Do not wash or reuse disposable gloves
  - ✓ Discard torn or damaged disposable gloves
  - ✓ Cover an infected lesion with pus (e.g. cut, burn, or boil) with a waterproof covering and disposable glove
  - ✓ Wear disposable gloves over artificial nails, nail polish, or uncleanable orthopedic support devices
    - The Food Code only allows bare hand contact with ready-to-eat food when the regulatory authority has granted prior approval for alternative procedure. The alternative procedure must address the management of food employees and related food handling activities to prevent food contamination, including the enforcement of thorough handwashing practices after toilet use.
    - The 2011 Supplement to the 2009 Food Code allows bare hand contact with ready-to-eat foods that are being added as an ingredient to a food that:
      - ✓ contains a raw animal food and is to be cooked in the establishment to required minimum temperatures, OR
      - ✓ does not contain raw animal food but is to be cooked in the food establishment to heat all parts of the food to 165ºF (74ºC)

2. Questions to Assess AMC of Bare Hand Contact

- Where do you prepare your shellfish?
- At what times of day do you prepare shellfish?
- What procedures are employees expected to follow when working with ready-to-eat foods?
- Can you describe the system you have in place to ensure employees that work with ready-to-eat foods follow your operational procedures?
- What action would be taken if you observed one of your food employees handling ready-to-eat foods with their bare hands?
- Do you conduct any ready-to-eat food processes for which an alternative procedure is in place to no bare hand contact? Is this alternative procedure in written form? Can you describe the alternative procedure? Have you submitted it to the health department for review?
- How do you know which foods can be touched with bare hands?

3. Tips to Assess AMC of Bare Hand Contact

- Identifying the location where ready-to-eat foods are prepared will provide an opportunity to observe food preparation procedures. Much like handwashing, it is important to observe the entire procedure/process in order to identify potential root causes for the occurrence of bare hand contact with ready-to-eat foods.
- It is also important to know what methods management has established in their procedures to ensure no bare hand contact with ready-to-eat foods. In many foodservice operations, multiple methods such as the use of single-use gloves, utensils, paper wraps, etc. are employed to prevent bare hand contact with ready-to-eat foods. Often, these are task-specific. Some operations may provide options for the employee (single-use gloves or utensils). Understanding the expected methods to prevent bare hand contact with ready-to-eat foods will provide a foundation for assessing how well employees have been trained and give an indication as to whether a system is in place to ensure operational procedures are being followed.
- Keep in mind that no bare hand contact with ready to eat foods is only one component of active managerial control of poor personal hygiene. An assessment of handwashing and employee health must always be conducted in conjunction with no bare hand contact.

CROSS CONTAMINATION (XC)

CONTROL AREAS

A. Separation of Raw Animal Foods from RTE Foods
B. Separation of Raw Animal Foods of Different Species
C. Cleaning Frequency
D. Cleaning & Sanitation of Food-contact Surfaces

A. SEPARATION OF RAW ANIMAL FOODS FROM RTE FOODS
B. SEPARATION OF RAW ANIMAL FOODS OF DIFFERENT SPECIES

1. Critical Limits for Preventing Contamination of Food

A. <u>SEPARATION OF RAW ANIMAL FOODS FROM READY-TO-EAT FOODS</u>

- Food shall be protection from cross contamination by separating raw animal foods during storage, preparation, holding, and display from:
  - ✓ Ready-to-eat foods, including other raw animal food (such as fish for sushi or **molluscan shellfish)** or other ra ready-to-eat food (such as fruits and vegetables)
  - ✓ Cooked, ready-to-eat food

NOTE: *Frozen commercially processed and packaged raw animal food may be stored or displayed with or above frozen, commercially processed and packaged, ready to eat food*

B. <u>SEPARATION OF RAW ANIMAL FOODS OF DIFFERENT SPECIES</u>

- Food shall be protection from cross contamination by separating types of raw animal foods from each other such as beef, fish, lamb, pork, and during storage, preparation, holding, and display by:
  - ✓ Using separate equipment for each type, or
  - ✓ Arranging each type of food in equipment so that cross-contamination of one type with another is prevented, and
  - ✓ Preparing each type of food at different times or separate areas
  - ✓ Not storing and displaying comminuted or otherwise non-intact meats above whole-muscle intact cuts of meat unless they are packages in a manner that precludes the potential for cross contamination

2. Questions to Assess AMC of Preventing Contamination of Food

- Describe your system for storing raw animal foods in the walk-in cooler?
- Where are ready-to-eat foods that require refrigeration stored before service?
- How do food employees know which food products go on what shelves in the walk-in cooler?
- What steps do you use to prevent cross-contamination in the food preparation area?
- How do you verify that foods are being stored, prepared, held, and displayed to prevent cross-contamination? How often is this verification done?

3. Tips to Assess AMC of Preventing Contamination of Food

- Ask questions about the locations for the preparation of ready-to-eat foods and raw foods of animal origin. Gaining an understanding of the flow of food as it is prepared in the food establishment may uncover potential opportunities for cross-contamination. Most establishments have a system or production schedule for preparing different products during the course of the day.
- One of the preparation focus points should be the food preparation sink. Most foodservice operations have only one designated food preparation sink that is often used to wash ready-to-eat vegetables/fruits AND thaw raw animal food items, such as fish or other seafood items. What system does the facility have in place to prevent cross-contamination for the multiple varieties of foods that are processed using the food preparation sink?
- High volume areas like grill lines sometimes require food employees to work with both ready-to-eat and raw animal foods. What system or procedures does the operation have in place to prevent cross-contamination from utensils such as tongs and spatulas? How are work responsibilities delegated between employees? Has the management of the operation given any thought to segregating out work responsibilities based on preventing cross-contamination (Example: one employee only works with ready-to-eat foods and another with raw animal food products)?
- Observing the entire preparation procedure can provide a more complete picture of the establishment's active managerial control for preventing cross-contamination. What happens to the containers and utensils that have been used to transport and dispense raw animal food products to preparation areas? Are the same utensils or containers used to remove and store the cooked product?
- Observe whether practices are in place to eliminate the potential for contamination of food, utensils, equipment, or single-service items from environmental contamination. For example, handwashing sinks and fixtures may be located where splash may contaminate food contact surfaces or food. Splash guards may need to be installed or food contact surface relocated to prevent contamination.
- Raw animal foods stored on shelves in refrigeration units should be separated by cooking temperatures such that food requiring a higher cooking temperature like chicken is stored below or away from foods requiring a lower cooking temperature like pork and beef. If foods are not being cooled, they should be covered or packaged while in storage.

C. CLEANING FREQUENCY
D. CLEANING & SANITATION OF FOOD-CONTACT SURFACES

1. Critical Limits for Preventing Contamination of Equipment

C. CLEANING & SANITIZING OF FOOD CONTACT SURFACES

Food contact surfaces and utensils must be cleaned and sanitized each time:

- ✓ There is a change from working with raw animal foods to ready-to-eat foods
- ✓ Between uses with raw fruits and vegetables and with time-temperature control for safety foods
- ✓ Before using or storing food temperature measuring devices
- ✓ Contamination may have occurred, such as dropping a utensil on the floor
- ✓ Before each use of raw animal food (except in contact with a succession of different raw animal foods each requiring a higher cooking temperature than the previous food, such as raw fish followed by cutting / preparation or raw poultry

Cleaning Frequency, Based on Ambient Temperature of a Refrigerated Room or Area

Preparation Room Temperature	Cleaning Frequency	
41ºF (5ºC) or less	24 hours	Refrigerated room temperatures and cleaning frequency to be documented
> 41ºF (5ºC) to 45ºF (7.2ºC)	20 hours	
> 45ºF (7.2ºC) to 50ºF (10.0ºC)	16 hours	
> 50ºF (10.0ºC) to 55ºF (12.8ºC)	10 hours	
> 55ºF (12.8ºC) unrefrigerated rooms	4 hours	

- ✓ Cleaning frequency **time-temperature control for safety foods** – food contact surfaces:
  - In storage, containers of time-temperature control for safety foods (maintained at proper refrigeration temperatures and date marked) are cleaned when emptied.
  - Containers in serving situations such as salad bars that maintained and refilled with time-temperature control for safety foods, are cleaned at least every 24 hours.
  - In-use utensils intermittently stored in a container of hot water at ≥ 135ºF are cleaned every 24 hours or more frequently to preclude accumulation of soil residues.

- ✓ Cleaning frequency **non-time temperature control for safety foods** – food contact surfaces:
  - Utensils and equipment – at any time when contamination may have occurred
  - At least every 24 hours for ice tea dispensers and consumer self service utensils
  - Before restocking consumer self-service equipment and utensils
  - In or enclosed components of equipment such as ice bins, ice makers, beverage nozzles and syrup dispensing lines/tubes, cooking oil storage tanks and distribution lines, coffee bean grinders, and water vending equipment; as specified by the manufacturer or as necessary to preclude accumulation of soil residues.

D. CLEANING AND SANITIZING OF FOOD CONTACT SURFACES

Warewashing: Chemical
Sanitation: Concentration, pH, Temperature, Hardness and Contact Time

Minimum Concentration (ppm or mg/L	**pH ≤ 10.0 and Minimum Temperature**	**pH ≤ 8.0 and Minimum Temperature**	**Contact Time**
Chlorine 25	120ºF (49ºC)	120ºF (49ºC)	≥ 10 seconds
Chlorine 50	100ºF (38ºC)	75ºF (24ºC)	≥ 7 seconds
Chlorine 100	55ºF (13ºC)	55ºF (13ºC)	≥ 10 seconds
Iodine ≥ 12.5 to 25	pH ≤ 5.0 or per label; 75ºF (24ºC)		≥ 30 seconds
Quaternary Ammonium (per label)	water hardness ≤ 500 ppm or mg/L or per label; ≥ 75ºF (24ºC)		
Hot Water Sanitize 3 compartment sink w/ Integral heating device	≥ 171ºF (77ºC) immersed in rack or basket		

NOTE: *All chemical sanitizers shall be listed in 21 CFR 178.1010 Sanitizing Solutions and used in accordance with EPA-approves manufacturer's label use instructions*

Warewashing: Mechanical and Manual			
		Minimum Wash Temperature	**Minimum Sanitizing Temperature**
SPRAY TYPE WAREWASHERS Single Tank, Hot Water Sanitize	Stationary rack, single temperature	165ºF (74ºC)	165ºF (74ºC)
	Stationary rack dual temperature	150ºF (66ºC)	180ºF (82ºC)
	Conveyor, dual temperature	160ºF (71ºC)	
Multi-tank, Hot Water Sanitize	Conveyor, multi temperature	150ºF (66ºC)	
Chemical Sanitize	Any warewashing machine	120ºF (49ºC)	Sanitization levels as stated in the above table, or per labeled manufacturer's instructions on the container
3 Compartment Sink	Cleaning agent labeling may allow for lower washing temperatures	110ºF (43ºC)	

2. Questions to Assess AMC of Equipment

- Can you demonstrate how the 3-compartment sink is set-up when equipment and utensils are soiled and need to be cleaned?
- How do you know that the sanitizer concentration is correct?
- What procedures do you have in place to ensure that the dishmachine is operating properly?
- Describe the method you use to clean the meat slicer?
- Who is responsible for cleaning the food preparation sink? What procedure is used?
- How does an employee know that the food preparation sink was previous cleaned and sanitized before they use it to prepare food?
- Do you have a cleaning schedule for food equipment that cannot be sent thorough the dishmachine or cleaned in the three compartment sink?

3. Tips to Assess AMC of Preventing Contamination of Equipment

- Special attention needs to be given to the cleaning and sanitizing procedure for work stations where both raw animal food products and ready-to-eat foods are processed during the course of the day. Is there a planned system or schedule for what types of foods are prepared during the course of the day? For example, are ready-to-eat food processed before raw animal foods OR is preparation done on an as-needed basis. While this assessment is important for all operations, it is especially critical for smaller establishments that may have limited space for food preparation.
- In addition to the schedule and flow of food preparation, it is important to obtain an understanding of who is responsible for ensuring that a food preparation surfaces has been cleaned and sanitized. Is it the responsibility of the person who completed preparing food on the work surface/sink or is it the responsibility of the person who will be using the surface to clean and sanitize it before placing foods on a work table or in a preparation sink? Understanding these types of systems will provide insights as to how well the cleaning and sanitizing procedure is monitored throughout the facility.
- An assessment of wiping cloths used for food contact surfaces requires more than just checking the sanitizer concentration of the solution in the wiping cloth buckets. Observe how, when, and on what surfaces food employees use the wiping cloth. Is it being used to clean surfaces that have accumulated heavy amounts of organic material or may have been used to process raw animal foods? Keep in mind that sanitizers will only be effective if the surface has been cleaned /rinsed first. High volume work areas like grill lines may create challenges for employees to effectively clean and sanitize food contact surfaces.

Suggested Immediate Corrective Actions and Intervention Strategies for Achieving Long-Term Compliance of Out-of-Control Procedures

Out-of-Control Procedure	Associated Hazards	Immediate Correction Action(s)	Intervention Strategies for Achieving Long-term Compliance
Approved Source	Bacteria, Viruses	Reject or Discard.	Change Buyer Specifications, Train Employees
Receiving Temperatures	Bacteria	Reject or Discard.	Change Buyer Specifications, Train Employees, Develop SOP/ HACCP/ Recipe
Cold Holding	Vegetative Bacteria, Toxin-forming and Spore-forming Bacteria	Conduct Hazard Analysis.	Change Equipment, RCP, Train Employees, Develop SOP/ HACCP/ Recipe
Bare Hand Contact with RTE Food	Bacteria, Viruses	Conduct Hazard Analysis.	RCP, Train Employees, SOP/HACCP Development
Ill Food Worker	Bacteria, Viruses	Exclude Ill Workers, Conduct Hazard Analysis	Train Employees, Develop SOP
Handwashing	Bacteria, Viruses	Wash Hands Immediately; Conduct Hazard Analysis.	Change Equipment Layout, Train Employees, RCP, Develop SOP/ HACCP
Contaminated Food	Bacteria, Parasites, and Possibly Viruses	Discard or Reheat RTE Food.	Change Equipment Layout, RCP, Train Employees, Develop SOP/ HACCP/Recipe
Contaminated Equipment	Bacteria, Parasites, and Viruses	Clean and Sanitize Equipment; Discard or Reheat RTE Food.	Train Employees, Change Equipment or Layout, Develop SOP

Retail Shellfish Requirements

Hawaii Administrative Rules (HAR) Chapter 11-50 Food Safety Code

DEFINITIONS:

Commingle

To combine shellstock harvested on different days or from different growing areas.

Dealer

A person certified by DOH as a shellstock shipper, shucker-packer, re-packer, shipper or depuration proccesor.

Shellstock

Raw, in-shell molluscan shellfish.

Shucked shellfish

Molluscan shellfish that have one or both shells removed.

Shucker-packer

A person certified by DOH to shuck and pack shellfish.

REQUIREMENT FOR IDENTIFICATION OF SHUCKED SHELLFISH

Raw shucked shellfish must be obtained in nonreturnable packages which bear a legible label that identifies the name, address, and certification number of the SHUCKER-PACKER. The label must include "sell by" or "best if used by" date for packages of less than one-half gallon or the date shuck for packages larger than one-half gallon.

REQUIREMENT FOR IDENTIFICATION OF SHELLSTOCK

Each container of SHELLSTOCK must have the certified shellfish DEALER'S tag with required harvest information. The tag or label must have the following information in order:

1. Dealer's name, address and certification number
2. Original shipper's certificate number
3. Date of harvest
4. Harvest location, including water body and specific site designation
5. Type and quantity of shellfish
6. The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days"

REMOVAL FROM THE ORIGINAL CONTAINER FOR DISPLAY

For dispensing to the consumer, SHUCKED SHELLFISH or SHELLSTOCK may be removed from the original container and displayed on drained ice or held in a display container if:

- The required label or tag information is retained and correlated to the dates when the shellfish is sold or served; and
- Products are protected from contamination

COMMINGLING

COMMINGLING of SHELLSTOCK is prohibited, except containers of SHELLSTOCK harvested on the same day and from the same growing area may be combined.

RECORD KEEPING REQUIREMENTS

Tags must remain on the SHELLSTOCK container until the container is empty and must be retained for 90 calendar days. Tags must be kept in an orderly, chronological system and available to the Department of Health (DOH) regulatory authority for review.

food code facts

Alaska Food Code Guidance
Food Safety & Sanitation Program
Alaska Department of Environmental Conservation

Molluscan Shellfish at Retail

"Because shellfish is often consumed raw, it must be sourced from clean water under sanitary conditions."

Food Code References:
18 AAC 31.200(c)(6)
18 AAC 31.200(d)
18 AAC 31.990

Definitions:

Commingle
To combine shellstock harvested on different days or from different growing areas; or to combine shucked shellfish from containers with different container codes or shucking dates.

Dealer
A person certified by FSS or certified by another regulatory authority as a shellstock shipper, shucker-packer, re-packer, re- shipper, or depuration processor.

Molluscan Shellfish
An edible species of fresh or frozen oysters, clams, mussels, or scallops (except a scallop that consists only of the shucked adductor muscle.

Shellstock
Raw, in-shell molluscan shellfish.

Shucked Shellfish
Molluscan shellfish that have one or both shells removed.

Shucker-Packer
A person certified by FSS to shuck and pack shellfish

IDENTIFICATION OF SHUCKED SHELLFISH
Raw SHUCKED SHELLFISH must be obtained in containers which bear a legible label that identifies the name, address, and certification number of the SHUCKER-PACKER. The label must also include the "sell by" date for packages of less than one-half gallon or the date shucked for packages larger than one-half gallon.

IDENTIFICATION OF SHELLSTOCK
Each container of SHELLSTOCK must have the certified shellfish DEALER'S tag with required harvest information. The tags must have the following information in order:

1. DEALER name, address, and certification number
2. Original shipper's certification number
3. The date of harvest
4. The harvest location, including water body and specific site designation
5. The type and quantity of shellfish
6. The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days"

REPACKAGING OF PRODUCT AT FOOD ESTABLISHMENTS
SHELLSTOCK may be repackaged in consumer self-service containers if each self-service container is plainly marked with the type and quantity of shellfish, harvest location, date of harvest, and DEALER certification number, or otherwise marked with a code that links the product with the tag or label information. SHUCKED SHELLFISH may ***not*** be removed from the original container and repacked by the food establishment into consumer self-service containers.

REMOVAL FROM THE ORIGINAL CONTAINER FOR DISPLAY
For dispensing to the consumer, SHUCKED SHELLFISH or SHELLSTOCK may be removed from the original container and displayed on drained ice or held in a display container if:

- the required label or tag information is retained and correlated to the dates when the shellfish is sold or served; and
- the products are protected from contamination.

COMMINGLING
COMMINGLING of SHELLSTOCK is prohibited, except containers of SHELLSTOCK harvested on the same day and from the same growing area may be combined.

RECORD KEEPING REQUIREMENTS
A SHELLSTOCK tag must remain on the SHELLSTOCK container until the container is empty and must be retained for 90 calendar days. The record keeping system for maintaining SHELLSTOCK tags must be an orderly, chronological system that correlates with the dates of product sale or service and is acceptable to the regulatory authority.

NOTE: This fact sheet is a compilation of major food safety rules regarding the given topic and is not designed to replace reading the Alaska Food Code.
Rev 5/16

food code facts

Alaska Food Code Guidance
Food Safety & Sanitation Program
Alaska Department of Environmental Conservation

Molluscan Shellfish at Retail

"Because molluscan shellfish is often consumed raw, it requires special handling to reduce risk of illness."

Food Code References:
18 AAC 31.060
18 AAC 31.215
18 AAC 31.220
18 AAC 31.222
18 AAC 31.226
18 AAC 31.300
18 AAC 31.310
18 AAC 31.990

Definitions:

Highly Susceptible Population
A group of persons more likely than another group to experience foodborne illness because they are immunocompromised, preschool aged, or older adults AND are obtaining food at a facility that provides services, such as custodial care, assisted living, or health care.

Disclosure
A written statement identifying shellfish that is or can be ordered raw, undercooked, or otherwise processed to eliminate pathogens.

Reminder
A written statement concerning risk of consuming raw or undercooked shellfish.

Diseases Communicable by Food
1. Salmonella
2. Shigella
3. E coli
4. Hepatitis A
5. Norovirus

RAW MOLLUSCAN SHELLFISH AT CERTAIN FACILITIES
Unless prepared in response to a specific adult consumer's request, raw molluscan shellfish may not be served or offered in a ready-to-eat form in a facility that serves a HIGHLY SUSCEPTIBLE POPULATION.

PRACTICE GOOD PERSONAL HYGIENE
- Do not handle ready-to-eat MOLLUSCAN SHELLFISH with bare hands.
- Report symptoms of illness (diarrhea, vomiting, fever, jaundice, sore throat with fever) or diagnosis of a disease communicable by food to the person-in-charge and do not handle food.
- Wash hands before and after handling raw MOLLUSCAN SHELLFISH.

PREVENTING CONTAMINATION DURING STORAGE AND DISPLAY
- Store SHUCKED SHELLFISH or SHELLSTOCK off the floor.
- Separate different species of raw, ready-to-eat during storage and display.
- Separate raw animal foods from cooked, ready-to-eat food and raw, ready-to-eat SHUCKED SHELLFISH or SHELLSTOCK during storage and display.
- Do not store SHELLSTOCK below foods that may drip or leak.
- If displayed on ice, the ice must be drained.
- Rotate from storage to display using the FIFO (First In, First Out) system based on the date of receipt.

CONSUMER SELF-SERVICE
Except when offered at a buffet or salad bar, or individual portions for immediate cooking, raw, unpackaged MOLLUSCAN SHELLFISH may not be offered for consumer self-service.

TEMPERATURE AND TIME CONTROL
SHUCKED SHELLFISH or SHELLSTOCK must be received and held at 41˚ F

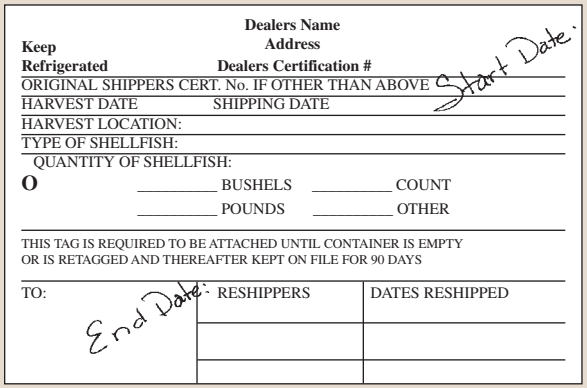
SALE AND SERVICE
A brochure, deli case or menu advisory, label statement, table tent, placard, or other effective means must contain a consumer advisory. The two parts of this consumer advisory are:

1. disclosure by either a description of the food, such as "oysters on the half shell (raw oysters), or identification of the food using an asterisk by the name of the food that refers to a footnote that states the item is raw or undercooked; and
2. a reminder that refers to the description or asterisk that states:
   - o "Regarding the safety of these foods, written information is available upon request."
   - o Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness." OR
   - o "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

NOTE: This fact sheet is a compilation of major food safety rules regarding the given topic and is not designed to replace reading the Alaska Food Code.
Rev 5/16

Recordkeeping

- Keep shellfish tags or labels with the product until the containers are empty.
- Keep shellfish tags or labels on file for 90 days after the container has been emptied.
- Keep shellfish tags and labels in chronological order of dates sold or consumed.
- For easy traceability keep a log of tags and labels and record the date the container is emptied on the tag (example below)



Dealers Name
Address
Keep Refrigerated — Dealers Certification #
Start Date
ORIGINAL SHIPPERS CERT. No. IF OTHER THAN ABOVE
HARVEST DATE — SHIPPING DATE
HARVEST LOCATION:
TYPE OF SHELLFISH:
QUANTITY OF SHELLFISH:
O _____ BUSHELS _____ COUNT
_____ POUNDS _____ OTHER
THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS
TO: End Date — RESHIPPERS — DATES RESHIPPED

Resources:

For a current listing of shellfish shippers that have been certified by regulatory authorities in the United States and abroad, visit Interstate Certified Shellfish Shippers List:

http://www.cfsan.fda.gov/~ear/shellfis.html

For more information about safe food handling practices at retail and foodservice, visit FDA Food Code:

http://www.cfsan.fda.gov/~dms/fc05-toc.html

For more information contact:

HANDLING FRESH AND FROZEN RAW

U.S. Food and Drug Administration

MOLLUSCAN SHELLFISH HANDLING

Receiving

- Verify shellfish shipments are from sources listed on the Interstate Certified Shellfish Shippers List at *http://www.cfsan.fda.gov/~ear/shellfis.html*.
- Check product temperature upon receiving. Verify that:
  - Live shellfish are at 50°F (10°C) or below.
  - Air temperature in delivery vehicle or shipping container is 45°F (7.2°C) or below.
  - Frozen product is received frozen.
- Verify that the quality and quantity in your product order is correct. Place shellfish under temperature control immediately.
- Accept only shellfish that are clean, alive and with whole unbroken shells.
- Keep tags and labels with the containers of live product.

Storage and Display

- Keep storage and display refrigerators cold enough to maintain product at 41°F (5°C) or less.
- Do not co-mingle (mix) different lots or species of shellfish.

Scallops

Mussels

Clams

Oysters

- Store shellfish above or away from other raw animal foods that could drip or leak onto the shellfish.
- Protect shellfish from contamination, such as refrigerate condensation, that could drip onto the product.
- Store raw shellfish away from and below ready-to-eat foods.
- Monitor product daily. Remove any dead shellfish and badly broken shellfish.
- Clean and sanitize equipment and food contact surfaces regularly.

Personal Hygiene

- Wash your hands before handling or preparing food.
- Wash your hands during food preparation to prevent cross contamination.
- Wash your hands when switching between working with raw food and ready-to-eat food.
- Wash your hands after engaging in other activities that contaminate the hands.
- Use utensils or gloves to handle ready-to eat shellfish. Never use your bare hands.

Record Keeping

Vital for Illness Outbreak Trace Back

2019 Pacific Rim Shellfish Sanitation Association Regional Meeting

What We'll Cover

- Records as Foundation of Shellfish Traceability
- Traceback and Traceforward
- Retail Food & Food Service Requirements
- Dealer Requirements
  - Tagging
  - Shipping and Transaction Records

Identification is Key to Traceback

Retail / Food Service

Dealer(s)

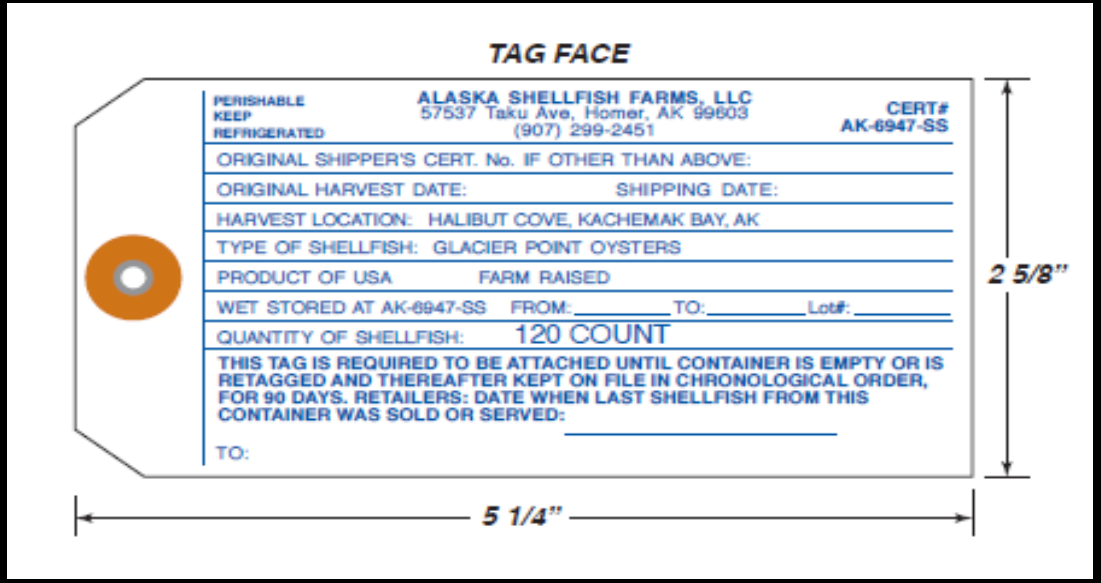
Harvester

Core principle of NSSP

- Harvest by licensed harvesters * Shipped & processed by licensed dealers
  * Trace product at each step * Lot-by-lot traceability
  * Correlate lot to growing area

Records as Evidence

- Accurate records are principal mechanism for tracing shellfish to source
- Provide evidence to support public health and regulatory decisions and support closure
- Support removal of product from distribution



Traceback vs. Traceforward

Response

- Starts with the consumer or the point-of-service and traces the distribution of the product **back** to the source.

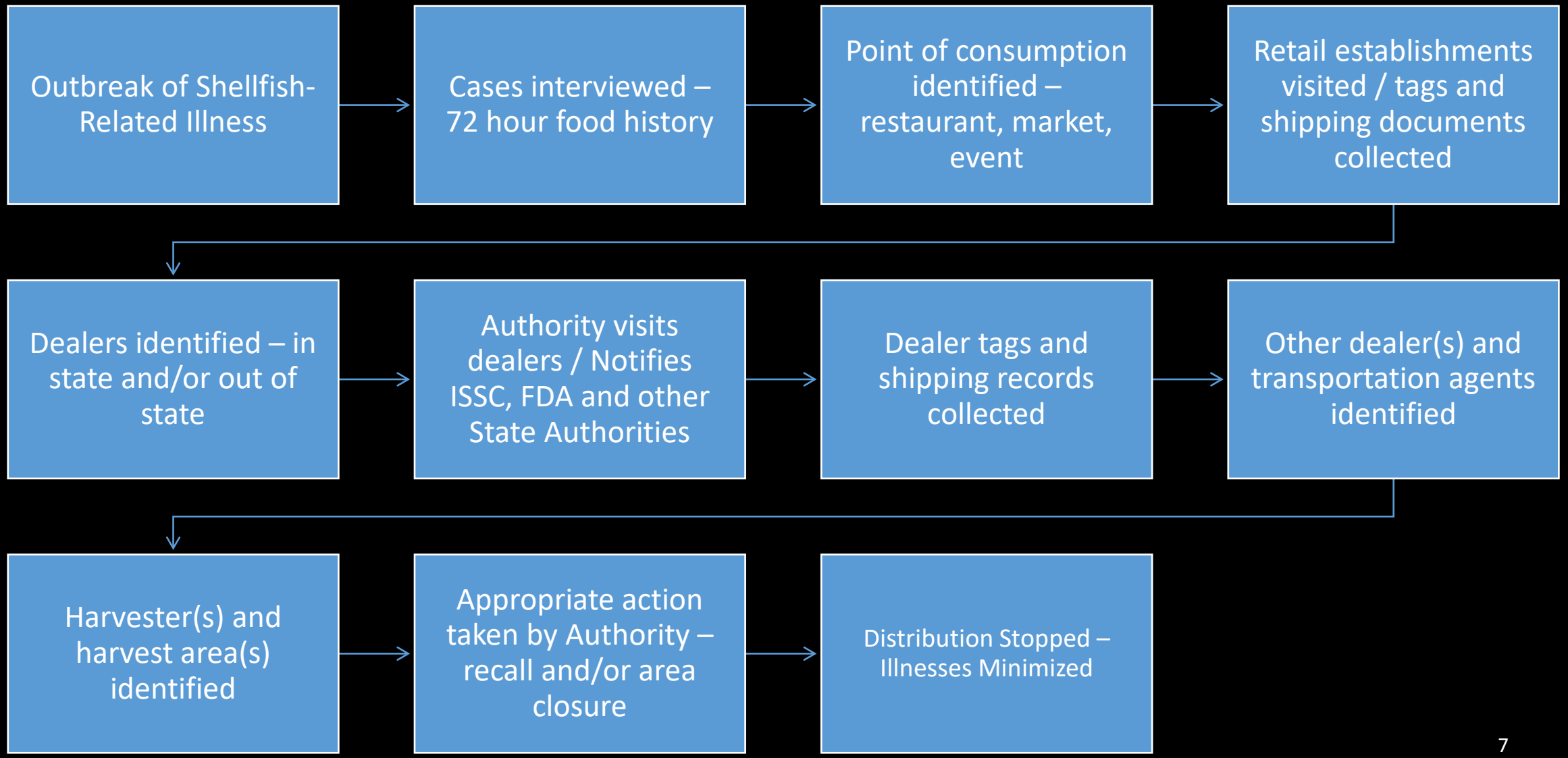
Recall

- Begins with source and traces **forward** to consumer

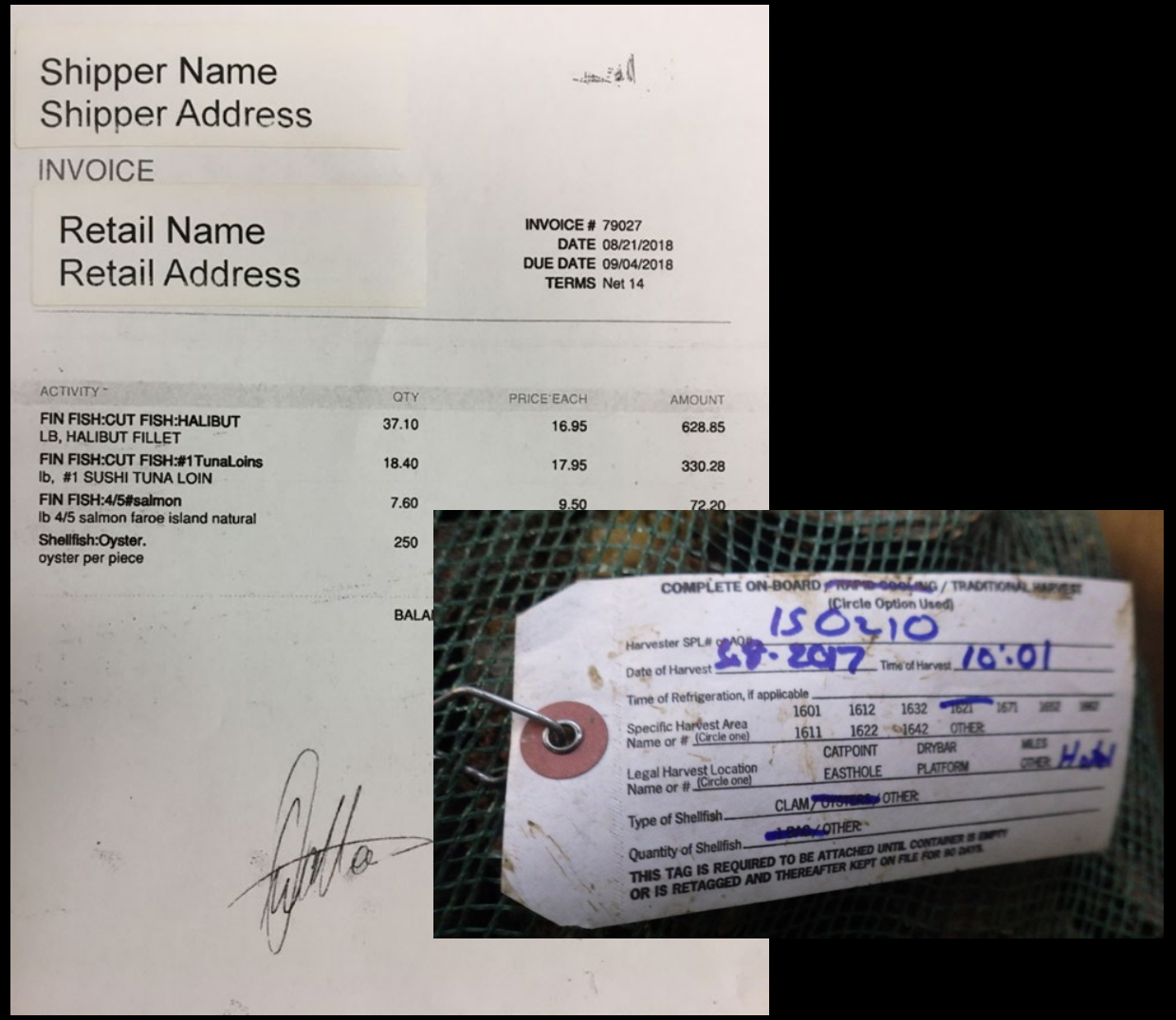
Traceback Objectives

1. Identify Source
2. Immediately Close Area
3. Remove Product from Marketplace
4. Prevent Further Illness

Investigation Flow Chart



Regulatory Traceback


Shipper Name
Shipper Address

INVOICE

Retail Name
Retail Address

INVOICE # 79027
DATE 08/21/2018
DUE DATE 09/04/2018
TERMS Net 14

ACTIVITY	QTY	PRICE EACH	AMOUNT
FIN FISH:CUT FISH:HALIBUT LB, HALIBUT FILLET	37.10	16.95	628.85
FIN FISH:CUT FISH:#1TunaLoins lb, #1 SUSHI TUNA LOIN	18.40	17.95	330.28
FIN FISH:4/5#salmon lb 4/5 salmon faroe island natural	7.60	9.50	72.20
Shellfish:Oyster. oyster per piece	250		

BALA

Documents the distribution through the supply chain, and the source(s) of a product that has been implicated in illness investigation.

Traceback Process

Retail / Food Service

- Collect Tags, Invoices Based on Exposure Dates
- Determine Shipments & Dealer(s)

Dealer(s)

Determine Source

- Tags
- Shipping Documents
- Transaction Documents

Growing Area

Take Action

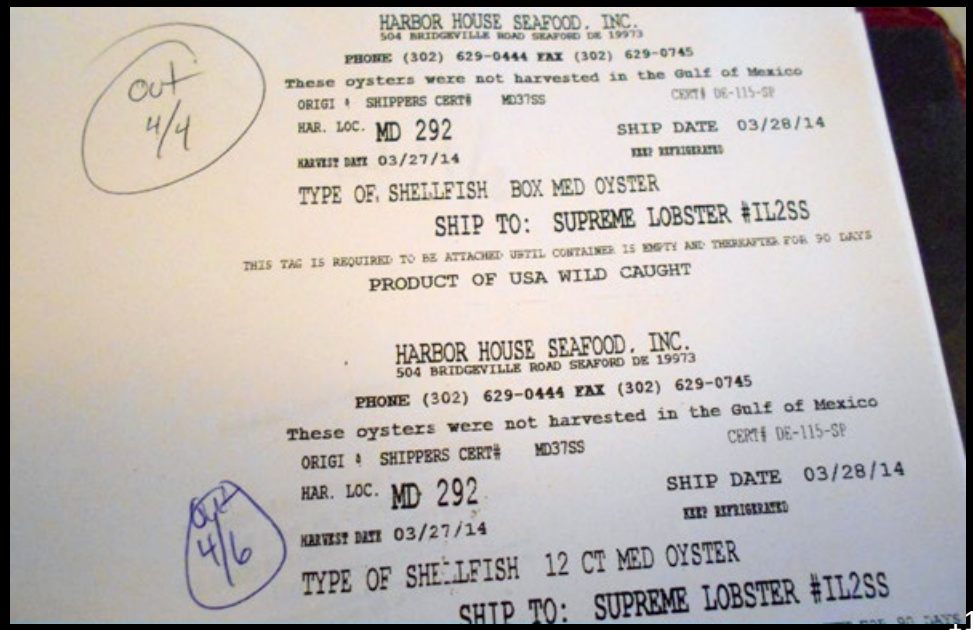
Retail

Retail Requirements

Every package has required tag

When last shellstock sold, date, and keep 90 days

No commingling during display


HARBOR HOUSE SEAFOOD, INC.
504 BRIDGEVILLE ROAD SEAFORD DE 19973
PHONE (302) 629-0444 FAX (302) 629-0745
These oysters were not harvested in the Gulf of Mexico
ORIGI ♦ SHIPPERS CERT# MD37SS
CERT# DE-115-SP
HAR. LOC. MD 292
SHIP DATE 03/28/14
HARVEST DATE 03/27/14
KEEP REFRIGERATED
TYPE OF SHELLFISH BOX MED OYSTER
SHIP TO: SUPREME LOBSTER #IL2SS
THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER FOR 90 DAYS
PRODUCT OF USA WILD CAUGHT

out 4/4

HARBOR HOUSE SEAFOOD, INC.
504 BRIDGEVILLE ROAD SEAFORD DE 19973
PHONE (302) 629-0444 FAX (302) 629-0745
These oysters were not harvested in the Gulf of Mexico
ORIGI ♦ SHIPPERS CERT# MD37SS
CERT# DE-115-SP
HAR. LOC. MD 292
SHIP DATE 03/28/14
HARVEST DATE 03/27/14
KEEP REFRIGERATED
TYPE OF SHELLFISH 12 CT MED OYSTER
SHIP TO: SUPREME LOBSTER #IL2SS

OK 4/6

FDA Food Code 3-203.11, 3-203.12

Dealers

Tag Basics

- Harvester's tag must remain with each container of shellstock until shipped or container emptied
- Durable
- Waterproof
- Approved by Authority
- 13.8 square inches in size
- Indelible ink, legible
- Keep Refrigerated
- Consumer Advisory (if raw)

- Restricted use tags should not include retailer language
- When both dealer & harvester tags on container, dealer not required to duplicate
- If retail containers of 5 lbs or less shipped in master carton, each container need not be tagged
- "For shucking by certified dealer" statement – shellstock must be sold to or processed by certified shucker-packer for shucking only

Dealer

"Keep Refrigerated"

XYZ Shellfish Company
1195 Commercial Way, Metropolis, WA 98000
Cert. # WA-9999-SS

ORIGINAL SHIPPER'S CERT. NO. (if other than above):

HARVEST DATE: *November 17, 2010*

HARVEST LOCATION: *WA-Totten Inlet* Harvest Site ID: *Bed/BIDN/Parcel#*

TYPE OF SHELLFISH: *Manila Clams*

QUANTITY OF SHELLFISH: _____ dozen _____ pounds

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL THE CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS

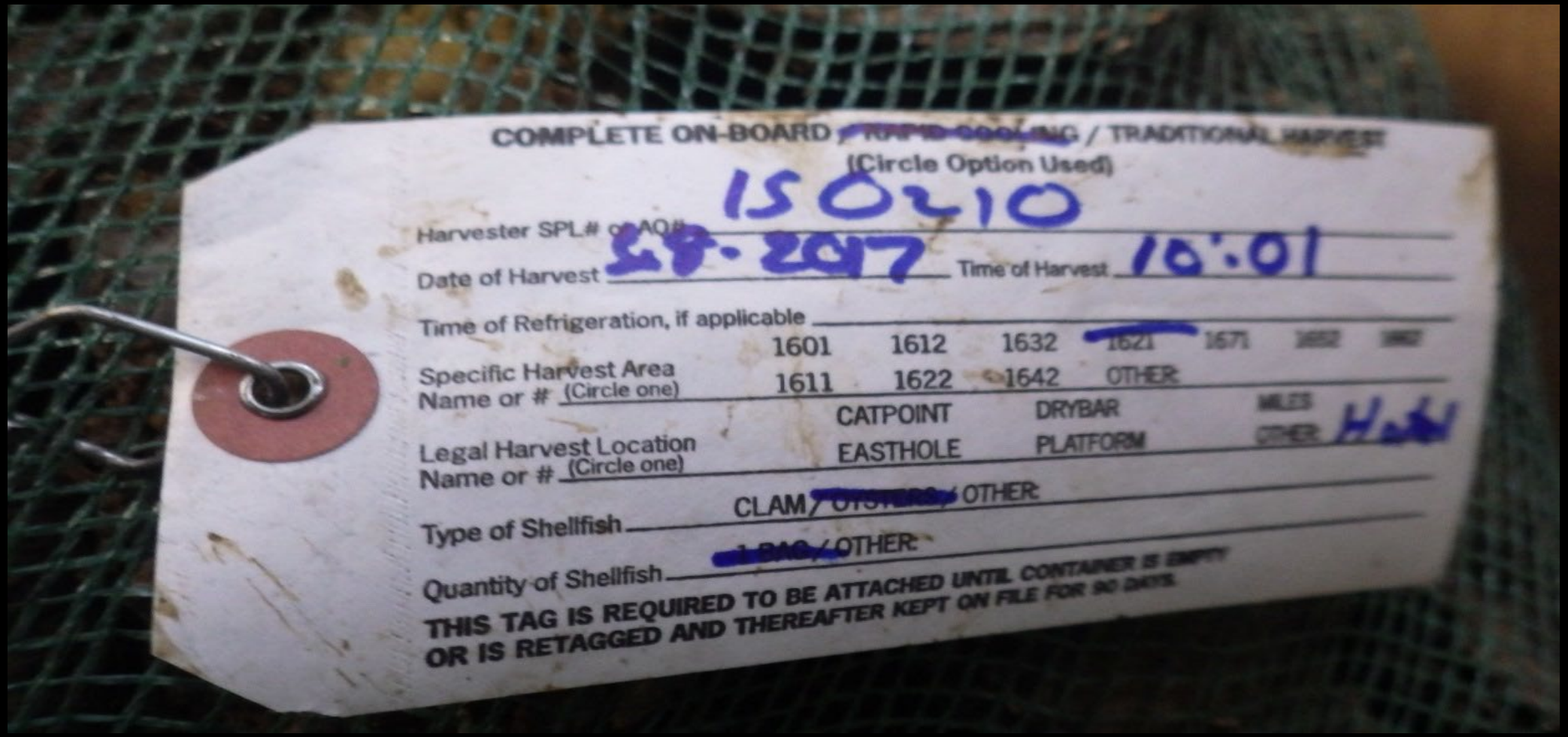
TO:	RESHIPPER'S CERT. No.	DATE RESHIPPED

Not required if depurated

If depurated, date of depuration and cycle or lot number

https://www.doh.wa.gov/Portals/1/Documents/4400/332-128-Dealer-Tag-Example.pdf

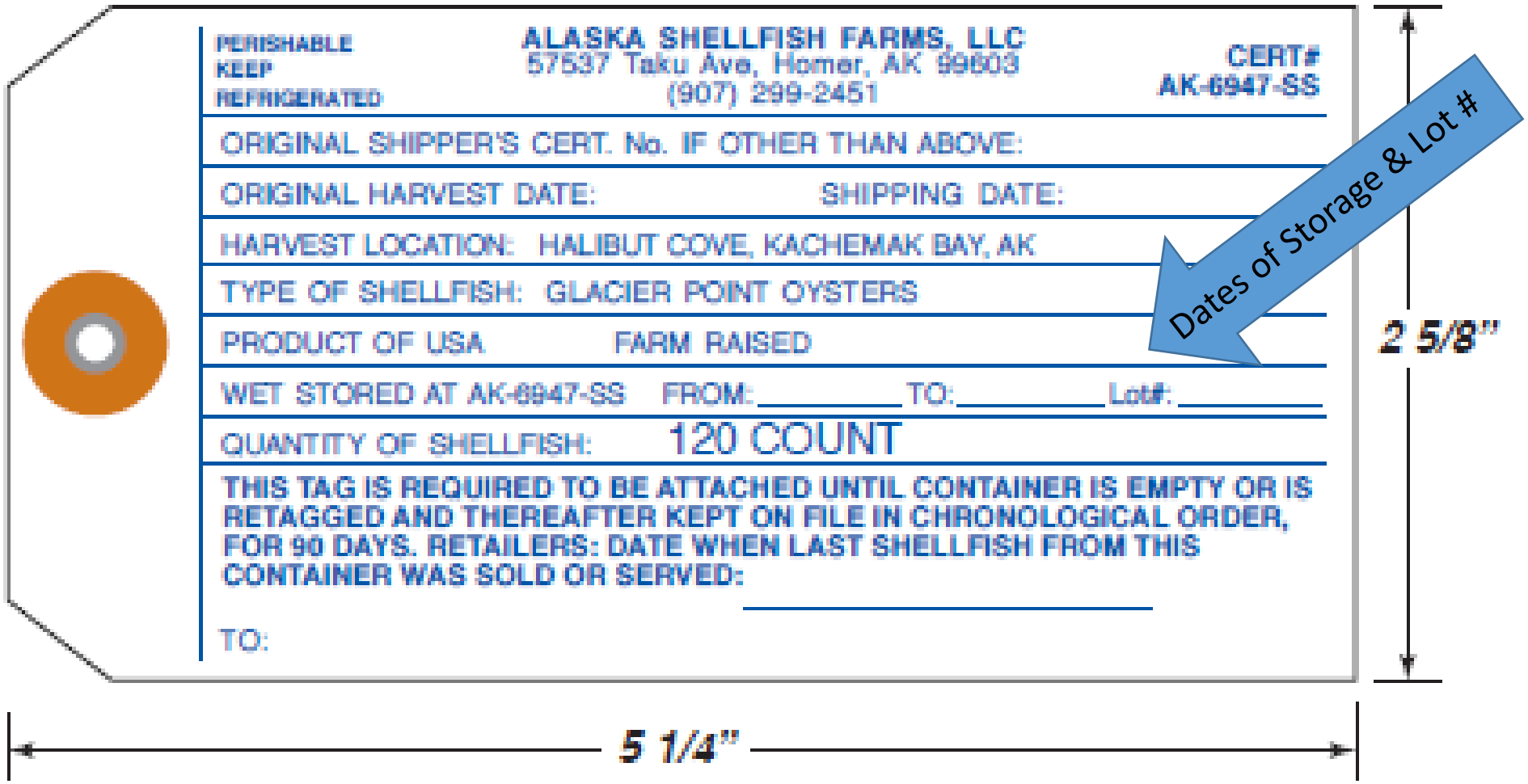
Harvester


COMPLETE ON-BOARD / TRADITIONAL
(Circle Option Used)
Harvester SPL# or AQ#
Date of Harvest
Time of Harvest
Time of Refrigeration, if applicable
Specific Harvest Area Name or # (Circle one)
1601 1612 1632 1621 1671
1611 1622 1642 OTHER:
Legal Harvest Location Name or # (Circle one)
CATPOINT DRYBAR
EASTHOLE PLATFORM
OTHER:
Type of Shellfish
CLAM / OTHER:
Quantity of Shellfish
OTHER:
THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY
OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS

Wet Storage Dealer

Harvested in State

TAG FACE



Wet Storage Dealer
Harvested in Another State

"Keep Refrigerated"

XYZ Shellfish Company
1195 Commercial Way, Metropolis, WA 98000
Cert. # WA-9999-SS

ORIGINAL SHIPPER'S CERT. NO. (if other than above): ***OR 123 SS***

HARVEST DATE: ***November 18, 2010***

HARVEST LOCATION: ***Capitol Bay, OR***

TYPE OF SHELLFISH: ***Manila Clams***

THIS IS A PRODUCT OF **Oregon**

AND WAS WET STORED AT **WA-9999-SS** FROM: **11/18/10** TO: **11/25/10**

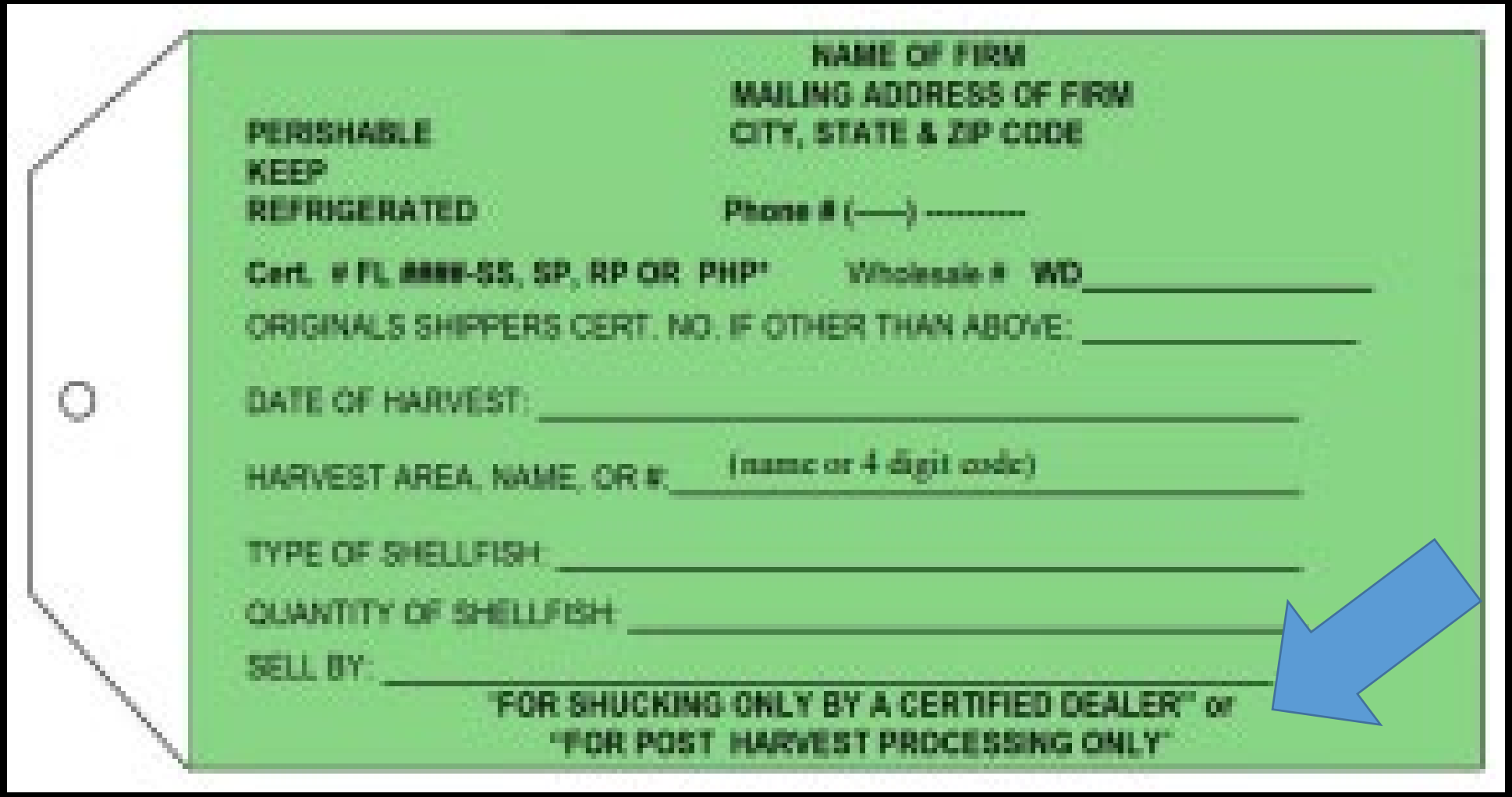
QUANTITY OF SHELLFISH: _____ dozen _____ pounds

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL THE CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS

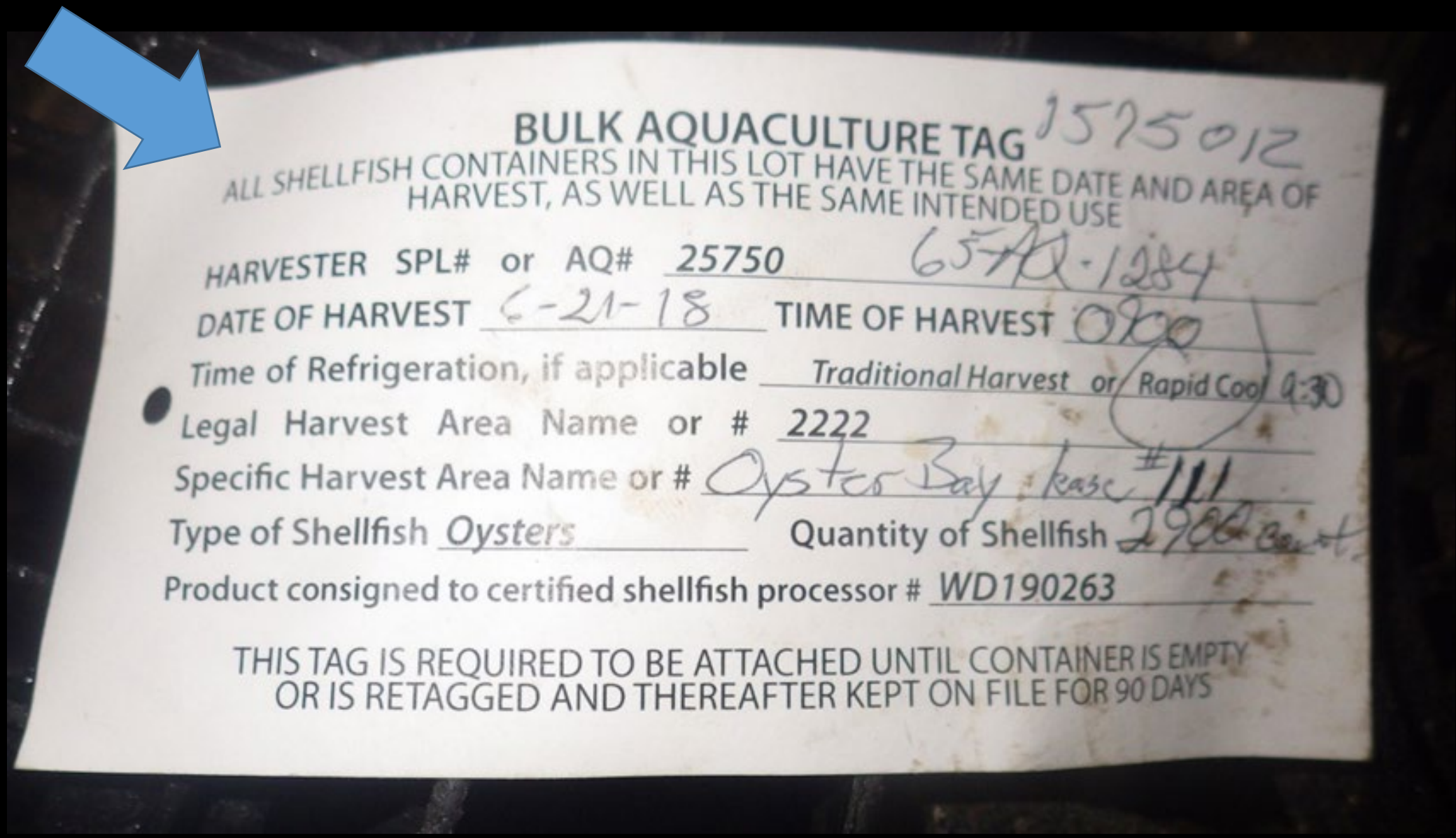
TO:	RESHIPPER'S CERT. No.	DATE RESHIPPED

https://www.doh.wa.gov/Portals/1/Documents/4400/332-128-Dealer-Tag-Example.pdf

Restricted Use



Bulk



BULK AQUACULTURE TAG 1525012

ALL SHELLFISH CONTAINERS IN THIS LOT HAVE THE SAME DATE AND AREA OF HARVEST, AS WELL AS THE SAME INTENDED USE

HARVESTER SPL# or AQ# 25750 65AQ-1284

DATE OF HARVEST 6-21-18 TIME OF HARVEST 0900

Time of Refrigeration, if applicable Traditional Harvest or Rapid Cool 0:30

Legal Harvest Area Name or # 2222

Specific Harvest Area Name or # Oyster Bay Lease #111

Type of Shellfish Oysters Quantity of Shellfish 2900 Count

Product consigned to certified shellfish processor # WD190263

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS

Section II, Chapter VIII.02(F)(7) and (8) - Chapter X.05(C)

5 1/4”

2 5/8”

TAG BACK

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE IN CHRONOLOGICAL ORDER, FOR 90 DAYS. RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER WAS SOLD OR SERVED:

_____

PERISHABLE KEEP REFRIGERATED

“RETAILERS, INFORM YOUR CUSTOMERS”

“Thoroughly cooking foods of animal origin such as shellfish reduces the risk of foodborne illness. Individuals with certain health conditions such as liver disease, chronic alcohol abuse, diabetes, cancer, stomach, blood or immune disorders may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information.”

Lot During Intermediate Processing

- If shellstock removed from original container
  - Harvester tag for 90 days
  - Keep track of growing area and date of harvest
  - Maintain lot identity during all stages of processing
- Intermediate processing plan to keep each lot separate, identified, prevent commingling/misidentification
  - Must be approved by Authority
- Dealer tags each lot of shellstock in accordance with plan

Transaction & Shipping Records

- Needed for authority to conduct outbreak investigations
- Must keep one year, two years if frozen product, or shelf life of product

Section II, Chapter X.08 Shipping Documents & Records
Section II, Chapter II.@.01 Outbreaks of Shellfish-Related Illness

Shipping Documents

- What is a shipping document?
  - Invoice
  - Bill of lading
  - Manifest
- Elements
  1. Shipping dealer's name, address, certification number
  2. Major consignee's name, address
  3. Kind, quantity of product
- Each receiving dealer must maintain copy to trace portion to original shipment
- Dealer must have business address at which records are maintained

Shipper Name
Shipper Address

INVOICE

Retail Name
Retail Address

INVOICE # 79027
DATE 08/21/2018
DUE DATE 09/04/2018
TERMS Net 14

ACTIVITY	QTY	PRICE EACH	AMOUNT
FIN FISH:CUT FISH:HALIBUT LB, HALIBUT FILLET	37.10	16.95	628.85
FIN FISH:CUT FISH:#1TunaLoins lb, #1 SUSHI TUNA LOIN	18.40	17.95	330.28
FIN FISH:4/5#salmon lb 4/5 salmon faroe island natural	7.60	9.50	72.20
Shellfish:Oyster. oyster per piece	250	0.89	222.50

BALANCE DUE $1,253.83

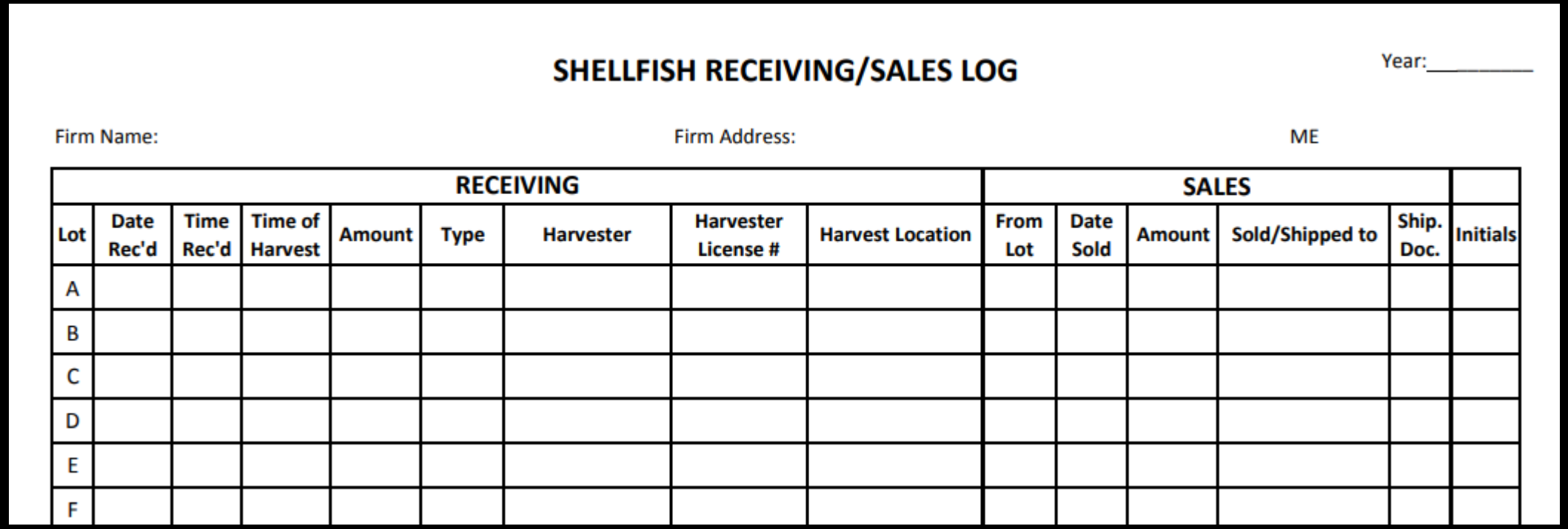
Section II, Chapter X.08(A)

Transaction & Shipping Records Sufficiency

1. Document that shellfish are from approved source
2. Allow container of shellfish to be traced back to specific incoming lot of shucked shellfish from which taken
3. Allow a lot of shucked shellfish or shellstock to be traced back to
   - growing area(s)
   - date(s) of harvest
   - date and locations of wet storage
   - harvester or group of harvesters
4. Trace wet storage history of the shellstock to
   - original harvest site
   - original harvest date
   - wet storage site(s) & dates

Transaction Records

- **F**orm(s) used to document each purchase or sale of shellfish at the wholesale level
- Shellfish harvest and sales records, ledgers, purchase records
- Computer records' format and use must be approved by Authority
- Entries must be made within 72 hours of purchase or sale



SHELLFISH RECEIVING/SALES LOG

Year:_____

Firm Name: Firm Address: ME

RECEIVING									SALES					
Lot	Date Rec'd	Time Rec'd	Time of Harvest	Amount	Type	Harvester	Harvester License #	Harvest Location	From Lot	Date Sold	Amount	Sold/Shipped to	Ship. Doc.	Initials
A														
B														
C														
D														
E														
F														

https://www.maine.gov/dmr/shellfish-sanitation-management/programs/haccpmanual/documents/ReceivinglogwithharvestandreceivedtimesOct2016.pdf

Shucker/Packer Lot Records

Sales Disposition Record

Lot #	Date Sold or Processed	Sold To Dealer Certificate Number (N/A if Processed)	Quantity Sold Unprocessed	Quantity Processed

Requirements for Shellfish at Retail

Raw shucked shellfish must be obtained in nonreturnable packages that bear a legible label identifying the name, address, and certification number of the shucker-packer. The label must include a "sell by" or "best if used by" date for packages of less than a half-gallon or the date shuck for packages larger than a half-gallon.

Shellfish must be obtained from an approved source. Reference the Interstate Certified Shellfish Shippers List | FDA to determine if the shipper is certified.

Requirement for the Identification of Shellstock

Each container of shellstock must have the certified shellfish dealer's tag with required harvest information. The tag or label must have the following information in order:

- Dealer's name, address, and certification number
- Original shipper's certificate number
- Date of harvest
- Harvest location, including water body and specific site
- Type and quantity of shellfish
- *The following statement in bold, capitalized font:* "**THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS.**"

Definitions

Commingle

To combine shellstock harvested on different days, packed on different days, or harvested from different growing areas.

Dealer

A person certified as a shellstock shipper, shucker-packer, repacker, shipper, or depuration processor.

Shellstock

Raw, in-shell molluscan shellfish, such as an oyster or mollusk. This does not include shrimp, lobster, or scallop muscle.

Shucked Shellfish

Molluscan shellfish that have one or both shells removed.

Shucker-packer

A person certified to shuck and pack shellfish.

Removal From the Original Container for Display

For dispensing to the consumer, shucked shellfish or shellstock may be removed from the original container and displayed on drained ice or held in a display container if:

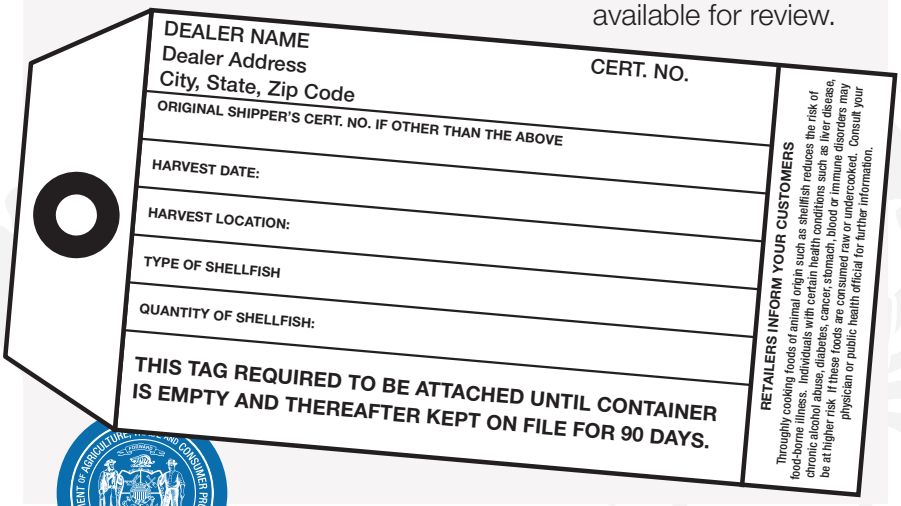
- The required label or tag information is retained and correlated to the dates when the shellfish is sold or served.
- The date that the last shellstock from the labeled container is sold must be recorded in a log or on the label itself.
- Products are protected from contamination.

Commingling

Commingling of shellstock is prohibited. Only containers of shellstock harvested on the same day and from the same growing area may be combined.

Recordkeeping Requirements

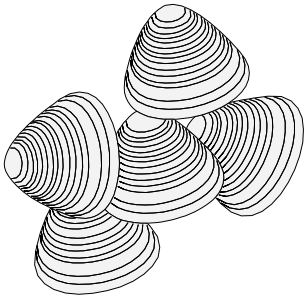
Tags must remain on the **SHELLSTOCK** container until the container is empty. The tags must then be retained for 90 calendar days, kept chronologically and available for review by the regulatory authority. If the label is printed on the container itself, the establishment may take a picture of the container with all relevant data in lieu of removing it and must be available for review.



Wisconsin Department of Agriculture,Trade and Consumer Protection | Division of Food and Recreational Licensing
2811 Agriculture Drive, PO Box 8911, Madison, WI 53708 datcp.wi.gov

P-DFRS0180.indd 05/2021

A Massachusetts Guide for
SAFE HANDLING OF SHELLFISH AT RETAIL



Molluscan shellfish include fresh and frozen oysters, clams, mussels and scallops. They grow in water that may become contaminated. Therefore, the Massachusetts Division of Marine Fisheries (DMF) and the Massachusetts Department of Public Health (DPH) work together to protect consumers by regulating the harvesting, distribution and handling of shellfish. Because molluscan shellfish are often eaten raw or undercooked, they require special handling except when the scallop product consists only of the shucked adductor muscle. To reduce the risk of foodborne illness caused by eating unsafe molluscan shellfish, follow these food safety practices for shellfish and shellstock (raw, in-shell shellfish). These practices are consistent with Massachusetts Department of Public Health, Food Protection Program regulations 105 CMR 590.000.

PREVENT CROSS CONTAMINATION and PRACTICE GOOD PERSONAL HYGIENE *When handling any food, always*	**CMR 590 REFERENCE**
• Report to the Person-in-Charge if you are feeling ill with symptoms of diarrhea, vomiting, fever, jaundice, sore throat with fever, lesions containing pus on hand, wrist or any exposed body part or if diagnosed with a medical disease that is transmissible through food.	**2-201.11** **590.003 (C)**
• Wash your hands before and after preparing raw seafood products.	**2-301.12 & 2-301.14 (G)**
• Do not handle ready-to-eat shellfish (shucked, raw ready-to-eat or cooked) with your bare hands.	**3-301.11**
• Use proper cleaning and sanitizing procedures.	**4-6 and 4-7**

AT RECEIVING *Check that the*	**CMR 590 REFERENCE**
• Shellstock and shucked shellfish are received under refrigeration and sanitary conditions.	**3-202.11 (B)**
• Shipment is from a certified interstate shipper or an approved in-state dealer.	**3-201.15**
• Containers of live shellstock are properly tagged and include the following information: 1. Dealer's name and address and certification number 2. Date of harvesting 3. Identification of the harvest location with the abbreviation of the name of the state or country 4. Type and quantity of shellfish (clams, oysters, mussels and scallops) 5. Statement requiring the tag to be attached to the container until emptied and then retained for 90 days	**3-202.18 [A(1 & 2)]**
• Containers of shucked shellfish are labeled to show the: 1. Name, address and certification number of shucker packer 2. Common name of product, i.e. clams, oysters, mussels and scallops 3. "Sell by" date on containers less than 1.89 L. (one-half gallon) 4. "Shucked" date on containers of 1.89 L. (one-half gallon) or more	**3-202.17 (A)**

XYZ Shellfish Co.
23 Seaweed Lane
Chowderville, MA 01003 CERTIFICATION # MA-6543-SS
Original Shipper's Cert. #, if different from Above:
Harvest Date: 1/24/07 Shipping Date: 1/25/07
Harvest Location: Wellspring, MA
Type of Shellfish: Oysters
Quantity of Shellfish: 5 pounds
THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS.

TO:
Sam's Clam Shack
123 Shoreline Road
Milford, CT 07931

Reshipper's Cert. No.	Dates Reshipped

These practices are consistent with Massachusetts regulations 105CMR 590.000 which adopts by reference the federal 1999 Food Code. 3/1/07. This fact sheet was developed by the MA Partnership for Food Safety Education with support from the Massachusetts Environmental Health Association and Massachusetts Health Officers Association in cooperation with the University of Massachusetts Extension Nutrition Education Program. UMass Extension is an equal opportunity provider and employer, United States Department of Agriculture cooperating. Contact your local Extension office for information on disability accommodations or the UMass Extension Director if you have complaints related to discrimination, 413-545-4800.

AT RECEIVING ***Accept the product when the***	**CMR 590 REFERENCE**
• Temperature of shellstock is 7°C (45°F) or less.	**3-202.11 (B)**
• Temperature of shucked shellfish is 7°C (45°F) or less.	**3-202.11 (B)**
• Shellstock is reasonably free of mud. Discard dead shellstock and shellstock with badly broken shells.	**3-202.19**

FOR STORAGE AND DISPLAY ***To store and display shellfish***	**CMR 590 REFERENCE**
• Refrigerate the shellfish immediately after receipt and cool to 5°C (41°F) or less within 4 hours.	**3-501.14 (C)**
• Hold shellfish during storage and display units at 5°C (41°F) or less.	**3-501.16 (B)**
• Store shellfish off the floor and stack the containers to allow for good air circulation.	**3-305.11**
• Separate different species of raw ready-to-eat shellstock during storage and while on display.	**3-302.11 (A)(2)(b)**
• Separate raw animal foods from cooked ready-to-eat and raw ready-to-eat shellfish during storage and while on display.	**3-302.11 (A)(1)(a&b)**
• Do not store shellstock below foods that may drip or leak onto the shellstock containers.	**3-302.11(A)(2)(b)**
• If displayed on ice, it must be drained ice.	**3-303.12 (B)**

FOR STORAGE AND DISPLAY ***About original containers and records***	**CMR 590 REFERENCE**
• Keep shellstock tags on or with the original container until empty. Once the containers are empty, remove the tags and keep them on file in chronological order for 90 days.	**3-203.12**
• Keep shucked shellfish in the original container until prepared for service or sold.	**3-203.11**
• Do not commingle (mix) shellfish from different containers or different species.	**3-203.11/12**

MONITORING SHELLFISH	**CMR 590 REFERENCE**
• Periodically check to make sure that the:	
✓ temperature of the shellfish is 5°C (41°F) or less.	**3-501.16 (B)**
✓ dead shellstock or shellstock with badly broken shells are discarded.	**3-202.19**
• Rotate shellfish from storage to display using the FIFO (First In, First Out) system based on date of receipt.	**recommended**

SALES AND SERVICE	**CMR 590 REFERENCE**
• A "Consumer Advisory" is required at the point of selection in food establishments that sell or serve raw or partially cooked shellfish.	**3-603.11**
• Make sure that shellstock on display can be identified and that the tags are filed once the containers are emptied.	**3-203.12**
• Observe proper procedures to prevent contamination of the shellfish.	**3-301 through 3-307**
• Do not commingle (mix) shellfish from different containers or different species of shellfish.	**3-203.11/12**

***Special Requirement for Molluscan Shellfish Tanks (For Person-In-Charge)** A life-support system display tank may be used for storage and/or display of shellstock intended for sale to the consumer if it is a spray-type system, not an immersion-type system, and it is operated and maintained in accordance with a variance and HACCP plan that is approved by the Department of Public Health and the local Board of Health. The immersion-type system is considered to be wet storage which is not allowed at the retail level in Massachusetts and if done at the wholesale level requires a wet storage permit approved by the Department of Public Health. [MA Food Code 4-204.110; and the National Shellfish Sanitation Program's (NSSP) Model Ordinance].

SHELLSTOCK TAG PROCEDURES
(Oysters, Scallops, Mussels, & Clams)

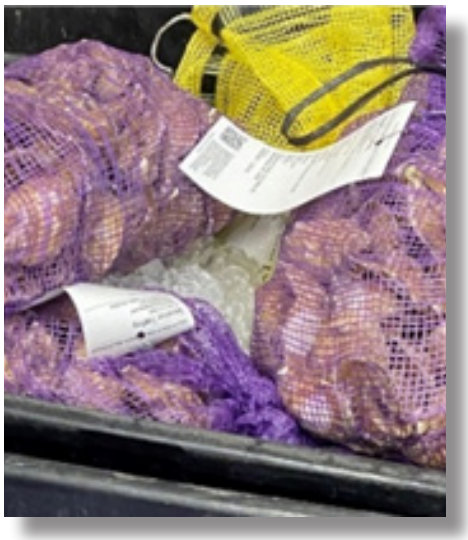
Retail Staff – It is a part of your job when selling shellstock to protect your customer. Failure to **keep, record and file** tags makes it impossible for inspectors to identify where the shellstock came from in the event of a foodborne illness, notify other retailers of safety issues, and protect the public from further foodborne illnesses.

Here are three easy steps needed to protect the health and safety of your customers:

KEEP

- The original tag must always remain with the shellstock container
- When splitting the container between storage and display a second tag / label must be used at the display. Options must be acceptable by your local regulator and could include:
  - o Make a photocopy of the tag to keep with the display
  - o Mark the display using a permanent marker, sticker, or similar identifier (example letter, date, number, color code)
  - o Use a second identical tag from the supplier to put with the display

****Never mix shellstock from different containers****



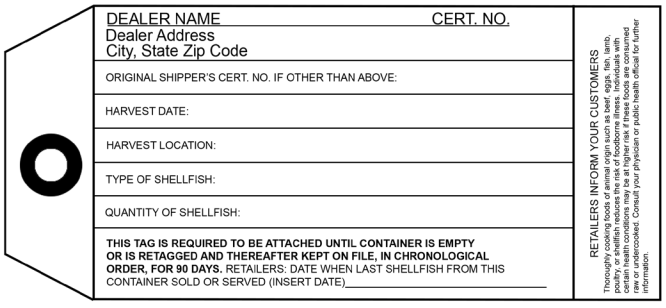
RECORD

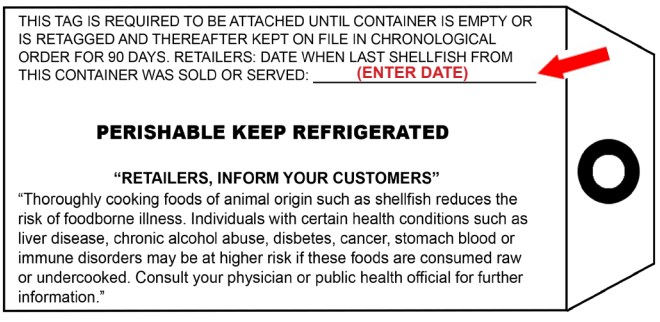
When the last shellstock from the bag / box has been sold, served, or discarded, **record the date** on the blank line / space on the tag with a permanent marker. If no line / space is provided, place the date anywhere on the tag.

FILE

- File the ***original*** tag in order by the date recorded on the tag when the last shellstock was **sold, served, or discarded.**
  - o Use a record keeping system such as a file box, binder, spreadsheet, notebook, or digital/electronic system to organize tags
- Keep the tags for **90 days**
- An inspector can ask to see tags during a routine inspection, and will ask to see tags in the event of a foodborne illness.

****If a foodborne illness occurs**, the properly completed tags provide critical information that can minimize further illnesses and protect your customers and your business**





Procedimientos de etiquetado de mariscos
(Ostras, Vieiras, Mejillones y Almejas)

Personal minorista – Parte de su trabajo cuando vende mariscos es proteger a su cliente. Si no se **mantienen, registran y archivan** las etiquetas, es imposible que los inspectores identifiquen de dónde provienen los mariscos en caso de una enfermedad transmitida por los alimentos, notifiquen a otros minoristas sobre problemas de seguridad y protejan al público de otras enfermedades alimentarias.

Aquí hay **3 pasos** fáciles que usted necesita saber para proteger la salud y la seguridad de sus clientes:

MANTENER

- La etiqueta original siempre debe permanecer con el contenedor de mariscos
- Al dividir el contenedor entre el almacenamiento y la exhibición, se debe usar una segunda etiqueta con los mariscos que están en exhibición. Las opciones deben ser **aceptables por su regulador** local y podrían incluir:
  - **Hacer una fotocopia** de la etiqueta para guardarla con los mariscos que se exhiben
  - **Marque los mariscos** que se exhiben con un marcador permanente, una etiqueta adhesiva o un identificador similar (por ejemplo, carta, fecha, número, código de color).
  - **Use una segunda** etiqueta idéntica del proveedor para colocarla con los mariscos que se exhiben

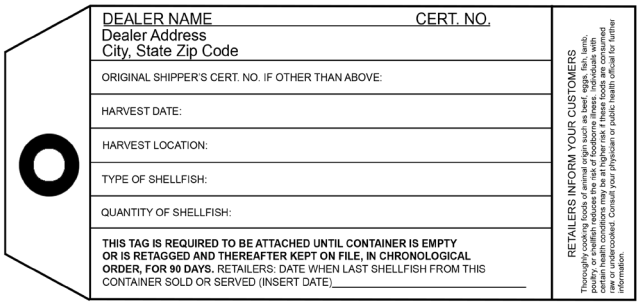
****Nunca combine los mariscos de diferentes contenedores****

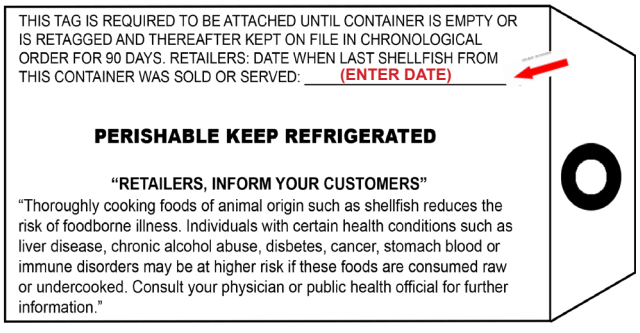
REGISTRAR

Cuando se haya vendido, servido o desechado el último marisco de la bolsa/caja, **registre la fecha** en la línea/espacio en blanco de la etiqueta con un marcador permanente. si no se proporciona una línea o espacio, coloque la fecha en cualquier lugar de la etiqueta.

ARCHIVAR

- Archive la **etiqueta original** en orden según la fecha registrada en la etiqueta cuando se vendió, sirvió o descartó el último marisco.
  - Use un sistema de mantenimiento de registros, como una caja de archivos, una carpeta, una hoja de cálculo, un cuaderno o un sistema digital/electrónico para organizar las etiquetas
- Guarde las etiquetas durante **90 días**
- Un inspector puede solicitar ver las etiquetas durante una inspección de rutina y solicitará ver las etiquetas en caso de una enfermedad transmitida por los alimentos.


DEALER NAME CERT. NO.
Dealer Address
City, State Zip Code
ORIGINAL SHIPPER'S CERT. NO. IF OTHER THAN ABOVE:
HARVEST DATE:
HARVEST LOCATION:
TYPE OF SHELLFISH:
QUANTITY OF SHELLFISH:
THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS. RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE)_____
RETAILERS INFORM YOUR CUSTOMERS
Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, pork, shellfish or poultry reduces the risk of foodborne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information.


THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE IN CHRONOLOGICAL ORDER FOR 90 DAYS. RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER WAS SOLD OR SERVED: (ENTER DATE)
PERISHABLE KEEP REFRIGERATED
"RETAILERS, INFORM YOUR CUSTOMERS"
"Thoroughly cooking foods of animal origin such as shellfish reduces the risk of foodborne illness. Individuals with certain health conditions such as liver disease, chronic alcohol abuse, disbetes, cancer, stomach blood or immune disorders may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information."

****Si se produce una enfermedad transmitida por los alimentos**, las etiquetas que se completaron correctamente brindan información crítica que puede minimizar futuras enfermedades y proteger a sus clientes y su negocio.**

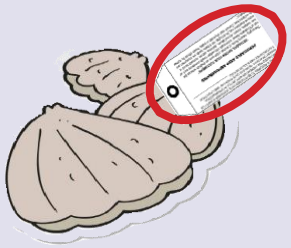
SHELLSTOCK TAG PROCEDURES

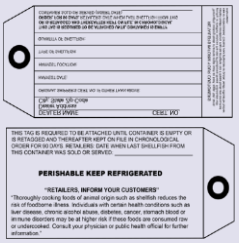
Procedimientos de etiquetado de mariscos

(Oysters, Scallops, Mussels, & Clams)

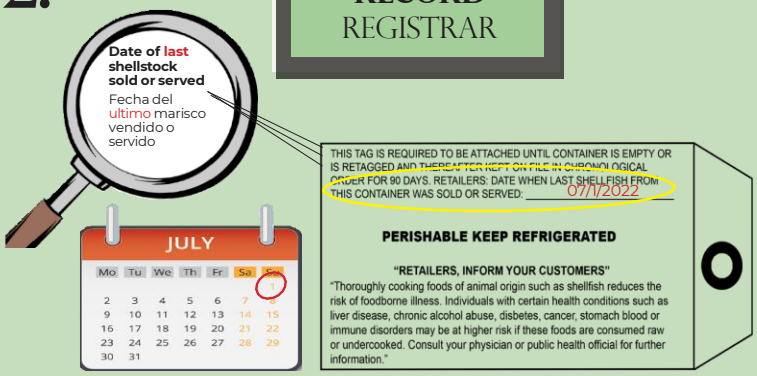
(Ostras, Vieiras, Mejillones y Almejas)

1. KEEP
MANTENER

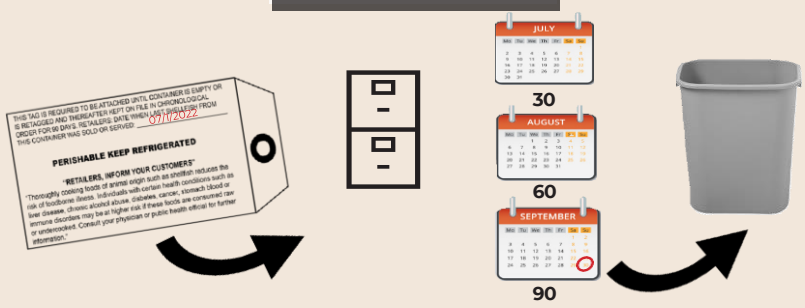




2. RECORD
REGISTRAR



3. FILE
ARCHIVAR



SHELLSTOCK TAGS
(Oysters, Scallops, Mussels, & Clams)

Shellstock tags (tags) provide a record of where the shellstock came from. If you do not **KEEP, RECORD, and FILE** tags the right way, this can make it hard for a food inspector to find out where the shellstock came from, alert the harvester and tell other businesses of food safety issues.

Here are three steps needed to protect your customers:

KEEP the tag with the shellstock in storage and on display
RECORD the date on the tag when the last of the shellstock from the bag / box is sold, served, or thrown away
FILE the original tag in order by the date you wrote on the tag

KEEP

- **Keep** the original shellstock tag with the shellstock
- When splitting the container between storage and display a second tag / label must be used at the display. Options **must be acceptable by your local regulator** and could include:
  - **Make** a photocopy of the tag to keep with the display
  - **Mark** the display using a permanent marker, sticker or similar identifier to trace to the original bag / box
  - **Put** a second identical tag from the supplier with the display

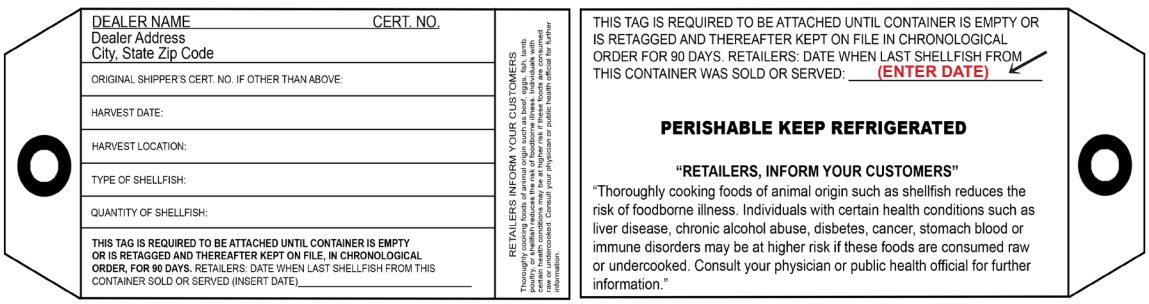
RECORD

- **Write** the date on the blank line / space on the tag when the last shellstock from the bag / box has been sold, served, or thrown away
  - **Use** a permanent marker to record the date
  - **Record** the date anywhere on the tag if there is no line / space

FILE

- **File** the original tag in order by date written on the tag when the last shellstock was **sold, served, or thrown away**
  - **Organize** tags with a file box, binder, spreadsheet, note book, or digital / electronic system
  - **Keep** the tags for **90 days**
- An inspector can ask to see tags during their inspection and will ask to see tags in the event someone gets sick

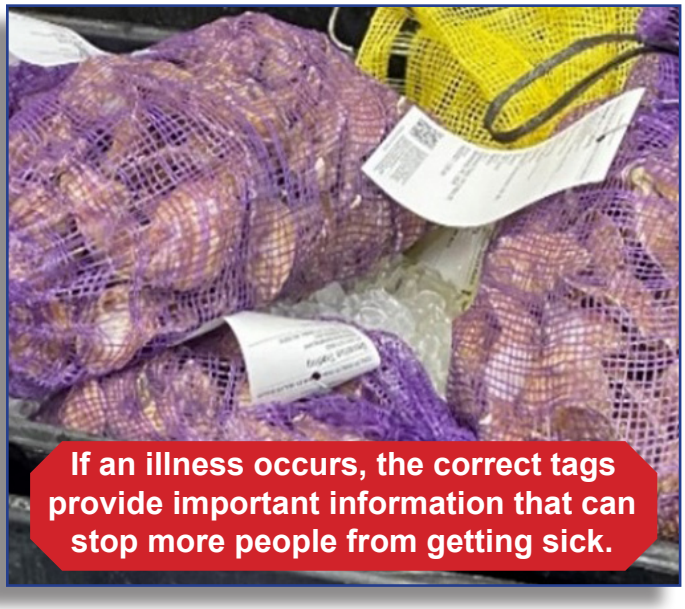
DO NOT MIX SHELLSTOCK!
Commingling, or mixing shellstock collected on different days, packed on different days, or collected from different growing areas is not allowed.



Definitions:

- **Shellstock -** live molluscan shellfish (raw oysters, clams, mussels and scallops) in the closed shell
- **Shellstock tags –** a record proving the shellstock was legally harvested and when, where and by whom they were harvested

SHELLSTOCK TAGS
(Oysters, Scallops, Mussels, & Clams)



DID YOU KNOW???

Hepatitis A is a serious virus that can hurt your liver. Sometimes, shellstock can have Hepatitis A in it, especially if the shellstock is from polluted water. It can take **56 days** for someone to start feeling sick from eating shellstock. Keep the tags on file for **90 days** due to the amount of time it could take to know someone is sick from eating shellstock and investigate the illness.

WHY following tag procedures is important?

- ✓ **Protect** your customers and your business
- ✓ **Provide** important information during a shellfish related illness investigation
- ✓ **Can help prevent** more people from getting sick
- ✓ **An inspector can ask** to see tags to make sure you are in compliance

All shellstock must be from an approved source

How do you know your shellstock provider is approved?

By checking the Interstate Certified Shellfish Shippers List, that's how.

Simply **Scan this QR code** to find out if your vendor is on the monthly approved provider list?

Etiquetado De Mariscos
(Ostras, Vieiras, Mejillones, & Almejas)

Etiquetado de Mariscos (Etiquetas) Proporcione un registro de la procedencia de los mariscos. Si no se MANTIENEN, REGISTRAN Y ARCHIVAN las etiquetas de una manera correcta esto puede dificultar que los inspectores de alimentos identifiquen de donde provienen los mariscos, no puedan alertar al cosechador y que no puedan informar a otras empresas sobre problemas de salud alimentaria.

Aquí hay tres pasos que deben seguir para proteger a los clientes:

MANTENER la etiqueta con los mariscos en almacenamiento y en exhibición.
REGISTRE la fecha en la etiqueta cuando se vendió, sirvió o desecho los mariscos
ARCHIVAR la etiqueta original en el orden según la fecha que usted escribió en la etiqueta.

MANTENER

- **Mantenga** la etiqueta original del marisco con el marisco
- Al dividir el contenedor entre el almacenamiento y la exhibición, se debe usar una segunda etiqueta en la exhibición. Las opciones **deben ser aceptables por su regulador local** y podrían incluir las siguientes:
  - **Hacer** una fotocopia de la etiqueta para guardarla con los mariscos que se exhiben
  - **Marque** los mariscos que se exhiben con un marcador permanente, una etiqueta adhesiva o un identificador similar para rastrear la bolsa/caja original
  - **Ponga** una segunda etiqueta idéntica del proveedor con los mariscos que se exhiben

REGISTRAR

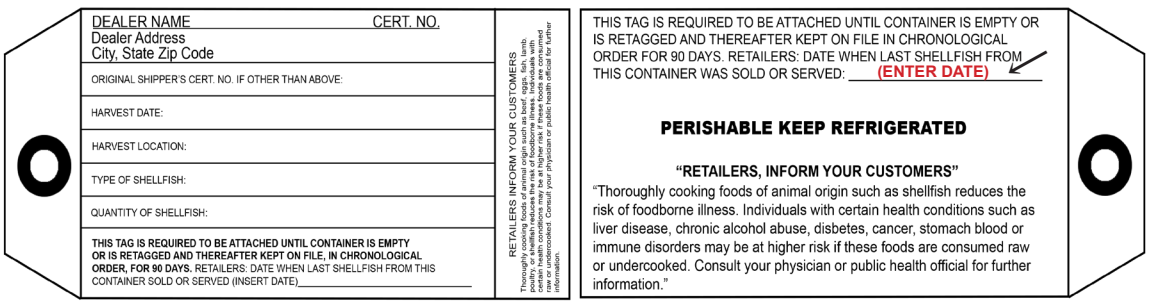
- **Escriba** la fecha en la línea/ espacio en blanco de la etiqueta cuando se vendió, sirvió o se desecho el ultimo marisco de la bolsa/caja
  - **Use** un marcador permanente para poner la fecha
  - **Escriba** la fecha en cualquier lugar de la etiqueta si no hay línea o espacio en blanco

ARCHIVAR

- **Archivar** la etiqueta original en orden según la fecha registrada en la etiqueta cuando se vendió, sirvió o se descartó el ultimo marisco
  - **Organizar** la etiqueta en una caja de archivos, una carpeta una hoja de cálculo, un cuaderno o un sistema digital/electrónico para organizar las etiquetas
  - **Guarde** las etiquetas durante 90 días
- **Un inspector** puede solicitar ver las etiquetas durante la inspección de rutina y solicitar ver las etiquetas en caso de que alguien se enferme

NO MEZCLE LOS MARISCOS!

No se permite mezclar o combinar los mariscos recolectados en diferentes días, empacados en diferentes días o recolectados de diferentes áreas de cultivo



DEALER NAME _____ CERT. NO.
Dealer Address
City, State Zip Code

ORIGINAL SHIPPER'S CERT. NO. IF OTHER THAN ABOVE:

HARVEST DATE:

HARVEST LOCATION:

TYPE OF SHELLFISH:

QUANTITY OF SHELLFISH:

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS. RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE)_____

RETAILERS INFORM YOUR CUSTOMERS
Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, pork, poultry or shellfish reduces the risk of foodborne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information.

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE IN CHRONOLOGICAL ORDER FOR 90 DAYS. RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER WAS SOLD OR SERVED: _____ (ENTER DATE)

PERISHABLE KEEP REFRIGERATED

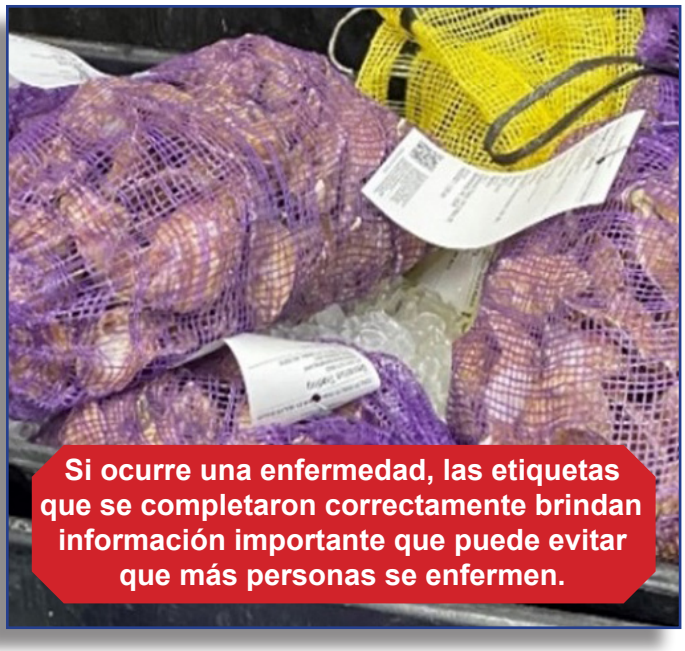
"RETAILERS, INFORM YOUR CUSTOMERS"

"Thoroughly cooking foods of animal origin such as shellfish reduces the risk of foodborne illness. Individuals with certain health conditions such as liver disease, chronic alcohol abuse, disbetes, cancer, stomach blood or immune disorders may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information."

Definiciones:

- **Mariscos –** moluscos vivos (ostras crudas, almejas, mejillones y vieiras) en la concha cerrada
- **Etiquetas de mariscos –** Un registro que prueba en donde, cuando y quien cosecho los mariscos legalmente

Etiquetado De Mariscos
(Ostras, Vieiras, Mejillones, & Almejas)



¿Sabías qué?

La Hepatitis A es un virus grave que puede dañar el hígado. A veces los mariscos pueden tener Hepatitis A, especialmente si el marisco proviene de agua contaminada. Puede tomar hasta 56 días para que alguien comience a sentirse enfermo por comer mariscos. Mantenga las etiquetas de los mariscos archivados durante 90 días debido a la cantidad de tiempo que podría pasar para saber si alguien está enfermo e investigar la enfermedad.

¿Porque es tan importante seguir los procedimientos de etiquetado?

- ✓ **Protege** a sus clientes y su negocio
- ✓ **Proporciona** información importante durante una investigación de enfermedades relacionadas con maricos
- ✓ **Puede ayudar a evitar** que más personas se enfermen
- ✓ **Un inspector puede solicitar** ver las etiquetas para asegurarse que usted esta en cumplimiento con la ley

Todos los mariscos deben provenir de una fuente aprobada

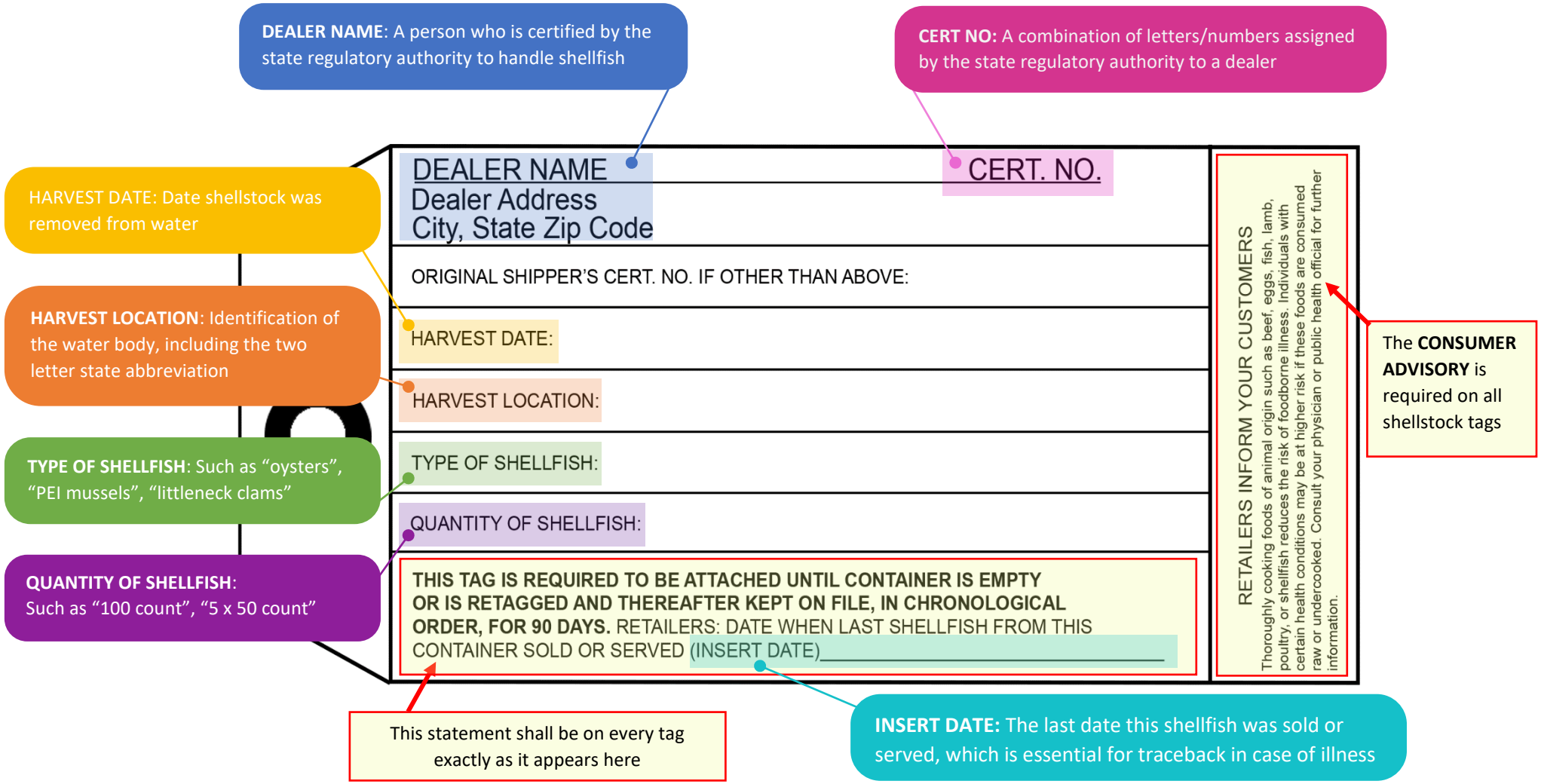
¿Como saber que su proveedor está aprobado?

Consultando la lista de transportistas de mariscos interestatales certificados.

Simplemente **escanee este código QR** para saber si su proveedor está en la lista mensual de proveedores aprobados.

ANATOMY OF SHELLSTOCK TAGS

Shellstock must be received from businesses listed on the ICSSL* and accompanied by tags



*Interstate Certified Shellfish Shippers List (ICSSL): https://www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list

Molluscan Shellfish—The Basics

What is molluscan shellfish?

An aquatic animal that lives in a shell. They are bivalve filter feeders that can contain pathogens in the surrounding water.

By which names are molluscan shellfish known?

Oyster, Clam, Mussel, or Scallop.

What is shellstock?

Raw, in-shell molluscan shellfish. For more information, see the bivalve shellfish identification resource: www.doh.wa.gov/community-and-environment/shellfish/recreational-shellfish/illness-prevention/identification

How might they be found in a restaurant, grocery store, truck, or roadside stand?

Fresh or frozen, removed from both their shells (shucked), one shell removed (shucked/half-shell), or contained in both shells (shellstock).

What is not molluscan shellfish?

Finfish (salmon, tilapia, tuna), crustaceans (lobster, crab, shrimp), snails, conch, octopus, sea urchin.

Why so much emphasis on molluscan shellfish?

Oysters, clams, and mussels grow in water that naturally contains pathogenic bacteria, such as *Vibrio* species. Many molluscan shellfish are consumed without a cooking step to kill those pathogens. In addition, some molluscan shellfish may contain toxins from algae in the growing water.

For more information, see *The Bad Bug Book* available for download: www.fda.gov/food/foodborne-pathogens/bad-bug-book-second-edition.

Other quick facts:

- Molluscan shellfish are time/temperature control for safety foods
- Date marking DOES NOT apply to shellstock
- Molluscan shellfish are often consumed raw, especially oysters
- Tag requirements do not apply to commercially packaged frozen or shucked shellfish, such as shucked scallops
- Molluscan shellfish are not included in the major food allergens because they are not crustacean

SHELLFISH CODE LANGUAGE TABLE

		SPECIFIC STANDARDS	
	2022 Food Code Reference	**SHELLSTOCK – Raw In-Shell Molluscan Shellfish**	**SHUCKED – Molluscan Shellfish with One/Both Shells Removed**
Receiving	**Approved Source** 3-201.15 Molluscan Shellfish	▪ ICSSL Interstate Certified Shellfish Shippers List ▪ 3-202.18 Shellstock Identification • Tag, Label, Invoice	▪ ICSSL Interstate Certified Shellfish Shippers List ▪ 3-202.18 Shucked Shellfish, Packing ID • Label, Invoice
	Temperature 3-202.11 Temperature	Per NSSP, adequately iced or ≤45˚F ambient air temp ***or*** as specified in LAW governing its distribution	Per NSSP, adequately iced or ≤45˚F ambient air temp ***or*** as specified in LAW governing its distribution
	Condition	Alive; reasonably free of mud, dead shellfish/broken shells. 3-202.17 Shellstock	Packages in good condition and protect the integrity of the shellfish. 3-202.15 Package Integrity
Storage	**Original Containers and Records** 3-203.11 Molluscan Shellfish, Original Container	▪ May not be removed from original container ▪ For display purposes, may be removed from the container	▪ May not be removed from original container except • For display purposes • When repacked in consumer self-service containers
	No Commingling 3-203.11 Shellstock, Maintaining ID	No commingling from one tagged/labeled container with ones from different harvest dates, growing areas	No commingling from one tagged/labeled container with ones from different harvest dates, growing areas
	Temperature 3-501.16 Time/Temp Control	41˚F or below	41˚F or below
Prep	**Food Employee** 2-2 Employee Health 2-3 Personal Cleanliness 3-301.11 Preventing BHC 3-302.11 Preventing contamination	▪ Employee health policy ▪ Hand washing ▪ Avoiding bare hand contact ▪ Cross contamination	▪ Employee health policy ▪ Hand washing ▪ Avoiding bare hand contact ▪ Cross contamination
Service	**Tag** 3-203.12 Shellstock, Maintaining ID 3-203.11 Molluscan Shellfish, Original Container (shucked ID)	▪ Tags/label remain attached to container until empty ▪ Record date on tag when last shellstock sold ▪ Tags retained for 90 days	▪ May be removed from the container in which they were received and repacked in Consumer self-service containers • Labeling information for the shellfish is on each Consumer self- service container • Labeling is retained and correlated with the date when, or dates during which, the shellfish are sold or served • Labels kept for 90 days
	Consumer Advisory 3-603.11 Consumer Advisory	▪ Served raw or undercooked • Disclosure • Reminder	▪ Served raw or undercooked • Disclosure • Reminder

Molluscan Shellfish Environmental Investigation Field Worksheet

Facility Name	Investigation Date(s)
Facility Contact Name	**Field Investigator Name**
Contact Information	

Type of Facility

☐ Oyster Bar or Restaurant ☐ Truck or Roadside Vendor ☐ Food Store ☐ Seafood Market ☐ Unknown

☐ Other:

Complaint Information

Consumption Date	Consumption Time	Amount Consumed
Suspect Shellfish Species		

Preparation & Service

Preparation Method (Product Form) for Suspect Shellfish at Service:

☐ Raw ☐ Baked ☐ Boiled ☐ Broiled ☐ Fried ☐ Steamed ☐ Unknown

☐ Other:

Service:

☐ Table Service ☐ Buffet ☐ Self- Service

☐ with Utensils Provided ☐ Serving Tongs ☐ Sneeze Guards

☐ On Half Shell with Ice

Documentation Checklist

(If collected, check and provide)

☐ **Suspect Meal Menu** (type list of fresh available, photo for days in question)

☐ **Other Parties/Special Events** (title, contact name, phone)

☐ **Shellfish Tags**

☐ **Receipts, Shopper Card Information** (to contact customers – name, phone number)

☐ **Reservation Lists** (name, phone, party size, occasion)

☐ **Production Sheets/Logs** (where different shellfish are available – to Identify types/origins of all oysters available with different meal services)

☐ **Delivery Invoices** (showing date of delivery, company, type of shellfish, lot, quantity)

Supplier Information

Supplier(s) Name(s)

Date(s) Suspect Lot Received

Imported From Another Country

☐ No ☐ Yes ***If Yes***, write import country:

Processor Treatment

☐ None ☐ Pasteurization ☐ Unknown

☐ High pressure processing ☐ Irradiation ☐ Other:

Product Form at Receipt by Retail/Food Service

☐ **In Shell** (non-living, processed shellfish with one or more shells present)

☐ **Shellstock** (raw, in-shell molluscan shellfish)

☐ **Shucked Meat**

☐ Other:

Flow Chart of Suspect Items

Receiving

Storage

Prep (including shucking)

Handling after shucking

Service

Shellfish Temperatures & Cold-Holding Method

	Mechanical	Ice	Ambient & Internal Temps & Notes
During Shipping			
At Receiving			
Storage			
Cold-Holding			

Questions

1. **Does facility display shellfish? (*If Yes*, answer 2.)**	☐ Yes ☐ No
2. **how facility prevents cross-contamination:**	***If Yes*, explain**
3. Does facility offer a variety of sources at one time (mixed plate of shellfish from variety of sources)?	☐ Yes ☐ No
4. Does facility offer a variety of oysters for order?	☐ Yes ☐ No
5. How do servers prevent commingling?	
6.	If facility shucks: ☐ N/A
a. Are cut-resistant gloves used? (*If Yes¸ answer 6b. If No, continue to 6c.)*	☐ Yes ☐ No
b. *If Yes*, are gloves smooth, durable, and nonabsorbent or covered by a glove that is smooth, durable, and nonabsorbent or single-use?	☐ Yes ☐ No
c. Is a towel used? (*If Yes¸ answer 6d. If No, continue to 6e.)*	☐ Yes ☐ No
d. *If Yes*, explain use:	
e. Do food workers handle shellfish with bare hands?	☐ Yes ☐ No
f. Does facility utilize separate sanitizer bucket for shucking?	☐ Yes ☐ No
g. Are shells used for other entrees?	☐ Yes ☐ No
h. Do the number of tags in the records match the number of animals delivered as per invoice records (are all received animals accounted for with tags)?	☐ Yes ☐ No

MOLLUSCAN SHELLFISH RETAIL & FOOD SERVICE INVESTIGATION FIELD CHECKLIST

SUSPECT AGENT/PATHOGEN OF CONCERN & CORRESPONDING FIELD FOCUS		RISK FACTORS & INTERVENTIONS FIELD FOCUS	METHODS, REMEDIATION & CONTROL MEASURES
TOXINS	**FIELD FOCUS**	**SOURCE (S)**	*Consider items and check each used.*
☐ Paralytic shellfish poisoning	S	☐ Copies of delivery receipts/invoices	**INVESTIGATION METHODS**
☐ Diarrhetic shellfish poisoning		☐ Shellfish tags, ICSSL (Interstate Certified Shellfish Shippers List)	☐ Food, Environmental Samples
☐ Neurotoxic shellfish poisoning		**ILL FOOD WORKERS (ILL FW)**	☐ Stool Samples
☐ Amnesic shellfish poisoning		☐ Exclusion policy	☐ Photographs
		☐ Check work schedules (employee list)	☐ Suspect Meal Menu
BACTERIAL INFECTIONS	**FIELD FOCUS**	☐ Determine employee health status	☐ Reservation Lists, Receipts
☐ *Vibrio cholerae O1*	S	☐ Determine roles of food workers for suspected meals and ingredients	☐ Special Events, Parties
☐ *Vibrio cholerae non-O1*	Ill FW	**BARE HAND CONTACT (BHC)**	☐ Invoices, Inventory, Traceback
	BHC	☐ Gloves/utensils available & indications of usage	☐ Multiple Establishments Investigated
	HW	☐ History of BHC control in facility	☐ Additional Case Finding
	CH	**HANDWASHING (HW)**	**CONTROL MEASURES**
	XC	☐ Handwash sinks available & have soap/towels	☐ Behavior Change
	CA	☐ Observe proper HW	☐ Procedure Change
BACTERIAL INFECTIONS*	**FIELD FOCUS**	**COLD HOLDING (CH)**	☐ Exclude Ill FW
☐ *Vibrio parahaemolyticus*	S	☐ Proper CH	☐ Food Destruction
☐ *Vibrio vulnificus*	CH	☐ History of proper temperature control practices	☐ Detention Order
	XC	☐ Discussion of food prep steps	☐ Cleaning & Sanitizing
*Not typically transmitted person to person	CA	☐ Advanced preparation	☐ Suspension/Closure
		CROSS-CONTAMINATION (XC)	**MOVING FORWARD**
		☐ Proper storage during cold-holding, display	☐ Follow-up Visit Scheduled
		☐ Separation of utensils used for raw product	☐ Follow-up Visit with Interpreter
		☐ Cleaning/sanitizing of equipment/utensils	☐ Increased Inspections
		☐ Shells used for other entrees	☐ Menu Reduction
		☐ Shucking gloves, towels, sanitizer buckets	☐ Required Education/Training
		CONSUMER ADVISORY (CA)	☐ Office Conference
		☐ Menu disclosure and reminder	**COMMUNICATION**
			☐ State Shellfish Authority

SAFE HANDLING OF SHELLFISH AT RETAIL

Alaska molluscan shellfish, specifically live fresh oysters, are often eaten raw or undercooked. To reduce the risk of foodborne illness in molluscan shellfish, follow the Alaska Food Safety & Sanitation Program's practices for safe handling. For more information on seafood safety at retail in Alaska, please visit the State of Alaska website at https://dec.alaska.gov/eh/fss/food/food-service-markets.

RECEIVING

1 APPROVED SOURCE

- Check ICSSL list for certified supplier*

2 LIVE SHELLSTOCK

- No open shells
- Mist or tap to check if shell closes

3 SAFE TEMPERATURES & GOOD CONDITIONS

- Receiving temps should be below 45F°
- No off odor smells
- Shells are not starting to open and no broken shells

4 PROPER TAGGING

- Dealer's name, address, and certification number
- Data/location of harvest
- Type and quantity of shellfish
- Statement that tag needs to stay attached to the container until emptied and then retained for 90 days

DISPLAY & STORING

1 MONITOR FOR SAFE DISPLAY

- Temperature is at 41F° or less
- Discard any dead shellstock
- Rotate on display—First in First out
- Make sure displayed shellfish returns to the same container w/ original tag

2 SAFE STORAGE

- If stored on ice, use a drip pan system
- Never place in air tight container or fresh water
- Don't store near foods that can leak or that could be contaminated
- Keep shellstock tags on original container until empty

SHELLFISH SALE

1 SAFE RECORDKEEPING

- Fill out tag once container is empty
- File tag in chronological order
- Keep tag for 90 days after container is emptied

2 COMMUNICATE SAFETY

- Display consumer advisory for raw or undercooked seafood.
- Advise on storing and handling practices

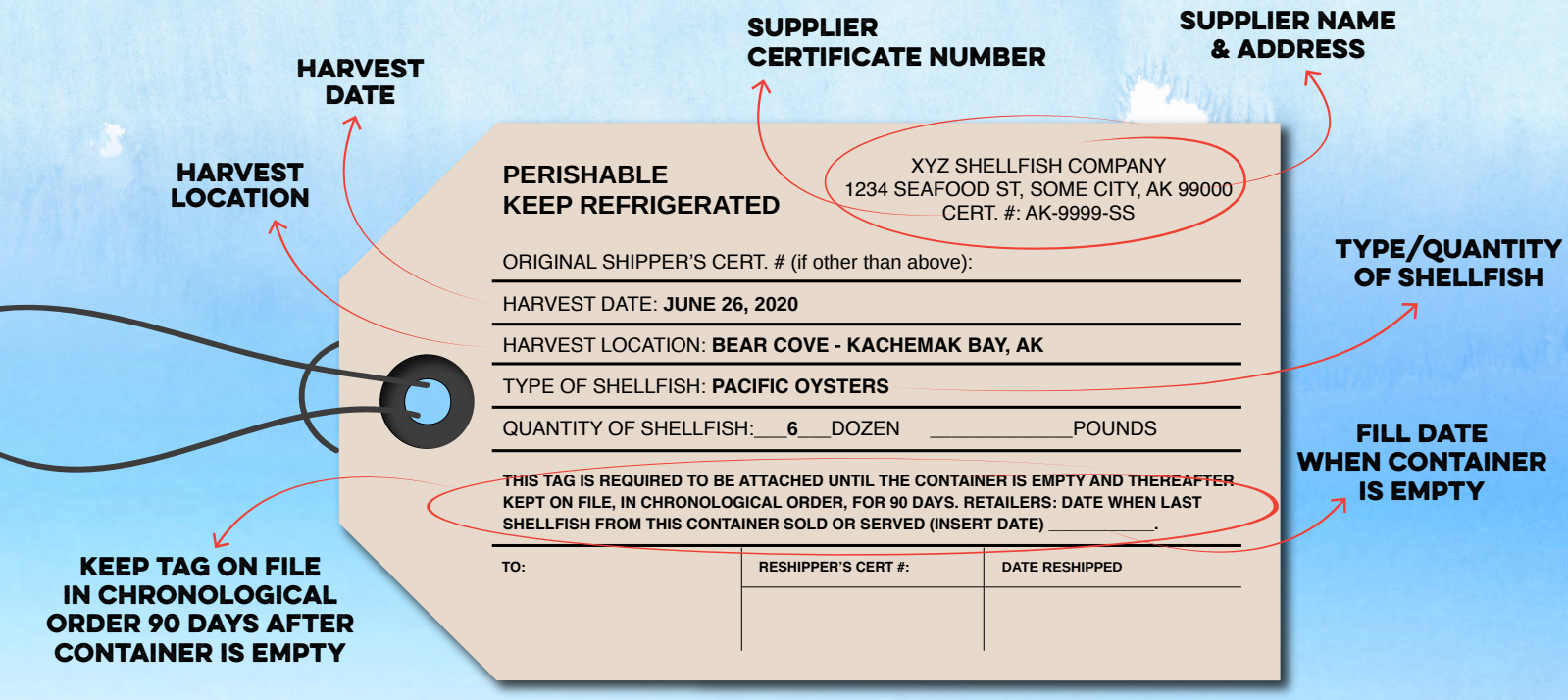
ADEC Food Safety & Sanitation Program

555 Cordova Street,
Anchorage, AK 99501

P: 907.269.7501
dec.alaska.gov/eh/fss.aspx

*https://www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list

SHELLSTOCK TAG INFORMATION



CONSUMER ADVISORY INFORMATION

Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions.

Refrigerate purchased shellfish as soon as possible to 41F° or less. Do not mix the raw seafood with other seafood or foods in storage.

QUICK FACTS

SHELLSTOCK

Live shellfish that remain in their shells

MOLLUSCAN SHELLFISH

Fresh or frozen oysters, clams, mussels, and scallops

SHELLFISH SAFETY CONCERN

Due to where molluscan shellfish live, how they feed, and how they're eaten, these shellfish can contain bacteria and viruses that can cause illness if not handled properly

SHELLFISH SAFETY ACTION

To minimize risk, the Alaska Food Safety and Sanitation Program works to implement FDA measures to ensure refrigeration controls are practiced to prevent foodborne illness, all shellfish are properly tagged, all shellfish are harvested from safe and permitted areas, and harvest facilities and operations meet appropriate sanitary standards

For more information on shellfish safety and handling, please visit the Alaska Food Safety and Sanitation Program website: https://dec.alaska.gov/eh/fss/shellfish

APPROVED SOURCE

1. Approved Source Critical Limits

APPROVED SOURCES & RECEIVING

- Delivery vehicle clean, free from insects / vermin; no evidence of cross contamination
- Time-Temperature Control for safety foods delivered under refrigeration are 41ºF or below
- Frozen foods do not show evidence of thawing or freezing
- Evaluations indicate no signs of spoilage; off odors; discoloration; thawing of frozen foods; ice crystals; etc.
- Product packaging is not damaged exposing food to contamination

SHELLSTOCK

- Shellstock obtained from source identified on the Interstate Certified Shellfish Shippers List (ICSSL) http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/default.htm
- Shellstock shall be obtained in container bearing legible source identification tags or labels:
  - ✓ Harvester's tag or label
    - Harvester's identification number that is assigned by the shellfish control authority
    - The date of harvesting
    - Most precise identification of harvest location including the abbreviation of the name of the state or country in which the shellfish are harvested
    - Type and quantity of shellfish
    - Statement in bold, capitalized type: *THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTIED OR RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS*
  - ✓ Dealer's tag or label
    - Dealer's name and address, and the certification number assigned by the shellfish control authority
    - The original shipper's certification number including the abbreviation of the name of the state or country in which the shellfish are harvested
    - The same information as specified for the harvester's tag or label (above)
    - Statement in bold, capitalized type: *THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTIED AND THEREAFTER KEPT ON FILE FOR 90 DAYS*
  - ✓ Shellfish tag maintenance:
    - Tags remain attached to container in which the shellstock are received until the container is empty;
    - The date when last shellstock from the container is sold/served must be recorded on the tag or label;
    - Tags must be retained in chronological order for 90 days from date recorded on the tag or label (the date when the last shellstock from the container is sold or served).
  - ✓ National Shellfish Sanitation Program also requires the following statement on tags: *RETAILER INFORM YOUR CUSTOMERS. Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, poultry or shellfish reduces the risk of foodborne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information.* http://www.issc.org
- Shucked Shellfish
  - ✓ Shipped in nonreturnable containers
  - ✓ May be removed from original containers for displaying/dispensing if the labeling information is retained and correlated to the date when, or dates during which, the shellfish are sold or served
  - ✓ Labeled with name, address and certification number of the shucker-packer or repacker; and
    - "sell by" date for < ½ gallon or
    - "date shucked" for ≥ ½ gallon

2. Questions to Assess AMC of Approved Source

- How do you verify that the food you receive is from an approved source?
- Do you have purchase specifications for specific food items?
- Do you any food products that require the suppler to sign a certificate of conformance with your operation?
- What method do you use to verify the source of your shellfish?
- How frequently do have food delivered to your facility?
- Have you established specific times of the days when food is to be delivered to your facility or do you work within the parameters of the supplier's schedule?
- Who is responsible for checking food delivered to the facility?
- What do you check when food is delivered to your establishment?
- How do you know if the food is at proper temperature when it is received?
- Do you maintain any receiving logs?

3. Tips to Assess AMC of Approved Source

- The time and day of the inspection is important when assessing whether foods are received from safe sources and in sound condition. Food may be received in the food establishment on set days. Ask questions to ascertain the day or days that deliveries are received and also the receiving procedures in place by the food establishment. Schedule inspections at times when it is known that product will be received by the food establishment.
- If food is being delivered during the inspection, you should:
  - ✓ Verify internal product temperatures
  - ✓ Examine package integrity upon delivery
  - ✓ Look for signs of temperature abuse (e.g., large ice crystals in the packages of frozen products)
  - ✓ Examine the delivery truck and products for potential for cross contamination
  - ✓ Observe the food employees behaviors and practices as they relate to the establishment's control of contamination and holding and cooling temperatures of received products
  - ✓ When evaluating approved sources for shellfish, such as clams, oysters, and mussels, you should ask whether shellfish are served at any time during the year. If so, review the tags or labels to verify that the supplier of the shellfish is certified and on the most current Interstate Certified Shellfish Shippers List
  - ✓ Note whether all required information is provided on the tags or labeled and that these records have been retained for 90 days and stored in chronological order.

IMPROPER HOLDING / TIME & TEMPERATURE CONTROL

CONTROL AREAS

A. Cold Holding of Temperature Control for Safety (TCS) Foods
B. Date Marking of Ready to Eat (RTE), TCS Foods
C. Time Used as a Microbial Growth Barrier

A. COLD HOLDING & DATE MARKING

1. Critical Limits of Cold Holding & Date Marking

A. COLD HOLDING OF TCS FOODS	
Process / Product	**Critical Limit**
Cold holding of TCS foods	41ºF (5ºC) or less

B. DATE MARKING OF RTE, TCS FOODS	
Process / Product	**Critical Limit**
Refrigerated RTE, TCS Foods: ✓ prepared in the establishment ✓ opened package from a commercial processing plant ✓ held for more than 24 hours	✓ 7 days at 41ºF (5ºC) or less ✓ Marked to indicate the date or day the food must be consumed on the premises, sold, or discarded ✓ Day of "preparation" or "opening is counted as "Day 1" ✓ Date mark not to exceed manufacturer's use by date
RTE, TCS Foods Subsequently Frozen:	✓ Marked at the time of freezing as to the days already held at refrigeration and upon removing from the freezer, the new "date" is 7 days minus the time held before freezing
**Date Marking is not required by Alaska Food Code*	

2. Questions to Assess AMC of Cold Holding & Date Marking

- How do you monitor your refrigeration units to ensure they are maintaining proper temperature?
- Are there any refrigeration/cold food storage units located outside of the kitchen area (salad bars, food transportation units, etc.)?
- Do you use methods, other than storing under refrigeration, to maintain foods cold (e.g. storage in ice)?
- What kind of monitoring procedures do you implement for ensuring food is at the proper cold holding temperature?
- What type of equipment is used to check the food product temperatures? How often is this done? How do you know the temperature measuring devices are accurate?
- Do you keep temperature logs? Do you record the temperature of the refrigeration units, product temperatures, or both? (not required per the Alaska Food Code)
- How do employees know what food is to be used first (first in, first out)?
- What is your date marking procedure for ready-to-eat, TCS Food? (not required in Alaska Food Code)
- How does the manager/food employees handle situations when they discover prepared food that has been stored in the walk-in cooler or other refrigeration unit without date marking or that has expired dates?

3. Tips to Assess AMC of Cold Holding & Date Marking

- Check cold holding temperatures with a thermocouple, thermistor, or other appropriate temperature measuring device. This includes the temperature of TCS food during transport (receiving trucks, cold holding carts being used to transport food to patient room in a hospital, satellite kitchens, or off-site catering events).
- DO NOT USE an infrared thermometer for verifying cold holding temperatures. Relying on surface temperatures may mask potential problems related to improper internal product temperatures and will not provide enough information to make an accurate assessment of cold holding procedures. In addition, inspectors should not stir cold soups and the like since it is important to know the temperature before the food is agitated.
- Open top refrigerated display cases and sandwich prep units may present significant cold holding challenges. When located across from cooking equipment or hot holding devices, these units may have a difficult time maintaining product temperatures. For refrigerated display cases, packaged food products may be stored directly on top of refrigerated air vents or placed in the case in a manner that blocks the flow of refrigerated air. Determine the system the establishment has in place for monitoring these units to ensure product temperatures are maintained at 41ºF or less. An alarm system (commonly used by large grocery store chains) may not be sufficient alone in ensuring product temperatures are maintained at 41ºF or less.
- Cold holding temperature control does not stop once the product leaves the kitchen. How does the facility ensure cold holding temperatures are maintained for products sent to satellite schools, patient rooms, or other food distribution points that may be off-site? Who is responsible for monitoring the temperature once it leaves the kitchen areas? Is it the kitchen foodservice personnel or is it the nursing staff in hospital facilities? Are satellite school facilities responsible for checking temperatures when the food arrives? How is this done and reported back to the main commissary kitchen?
- Date marking systems may use calendar dates, days of the week, color-coded marks, or another type of system. When the person in charge explains the system, is it clear to you what is expected and does it meet the Food Code requirements? Can food employees explain the system and is their version consistent with management's expectation?

C. TIME USED AS A MICROBIAL GROWTH BARRIER

1. Critical Limits for Time Used as Microbial Growth Barrier

C. TIME USED AS A MICROBIAL GROWTH BARRIER FOR TCS FOODS

Written procedure must be available on-site and:

- ✓ Identifies the foods to be held using time only as a public health control
- ✓ Describes the procedures for implementing time without temperature as a public health control (procedures, training, monitoring, documentation)

Time without temperature control is used as the public health control up to a MAXIMUM OF **4 HOURS**

- ✓ Food must have an initial temperature of:
  - ❖ 41ºF (5ºC) or less when removed from cold holding temperature control, OR
  - ❖ 135ºF (57ºC) or above when removed from hot holding temperature control
  - ❖ TCS Food marked or identified with the maximum 4 hour period when removed from temperature control
  - ❖ After 4 hours any remaining food product is discarded
  - ❖ Unmarked containers or packages or containers marked that exceed a 4 hour limit are to be discarded

Time without temperature control is used as the public health control up to a MAXIMUM OF **6 HOURS**

- ✓ Food must have an initial temperature of:
  - ❖ 41ºF (5ºC) or less when removed from cold holding temperature control
  - ❖ Food temperature may not exceed 70ºF (21ºC) during the 6 hour period
  - ❖ The food shall be monitored to ensure the warmest portion of the food does not exceed 70ºF (21º) during the 6-hour holding period
  - ❖ TCS Food marked to indicate time when the food is removed from 41ºF (5ºC) or less cold holding temperature control
  - ❖ TCS Food marked or identified with the maximum 6 hour period when removed from temperature control
  - ❖ TCS Food is discarded of the temperature of the food exceeds 70ºF (21ºC) OR
  - ❖ After 6 hours any remaining food product is discarded
  - ❖ Unmarked containers or packages or containers marked that exceed a 6 hour limit are to be discarded

2. Questions to Assess AMC

- How long is TCS Food being held out of temperature before or after cooking?
- How do you monitor how long products are out of temperature control?
- Do you have specific food products for which you use time instead of temperature as a food safety control?
- What type of system do you have in place to monitor the time?
- Who is responsible for ensuring that time frames for holding product out of temperature control are not exceeded?
- What happens to food that exceeds the time frames for holding?
- For the products that you hold using time rather than temperature, what action do you take after 2 hours if it appears that all the product will not be sold or served within the 4 or 6 hour time frames?

3. Tips to Assess AMC

- Each temperature scenario for using time only as a microbial growth barrier incurs different risks in regard to the type of foodborne pathogens able to grow and the rate of growth likely to occur. For both cooling and warming conditions, growth depends on the amount of time the food spends in an optimum growth temperature range and its equilibration with its surroundings.
- Several factors influence the rate of temperature changes in a food such as the type of food, thickness of food, and the temperature differential between the food and its surroundings. When evaluating the safety of a 4-hour limit for food with no temperature control, products and environmental parameters must be selected for a worst-case scenario for pathogen growth and possible toxin production.
- Consider the type of operation that is using time as a microbial growth barrier. Are the establishment's written procedures easy to implement? Monitoring the time period for the food may be a greater challenge if the product is displayed in an area of the store that is located outside of the food preparation area such as rotisserie chicken displayed in the aisle section outside the deli area in a retail food store.
- Determining how the operation maintains clear marking of the 4 hour period of time may be difficult if multiple batches are made during the course of the day and are stored, commingled, in a display case. In this scenario, each individual product would have to be clearly marked or a system that provides distinct separation of lots would have to be established within a display or holding case.
- Having written procedures and appropriate product marking will only be effective if the individuals responsible for the procedure are properly implementing them. The individuals responsible for monitoring (and when appropriate, discarding the product) must be clearly identified.
- Holding cold food without temperature control has some additional consideration. An assessment of the products start temperature must be made to ensure it was maintained at 41ºF or below prior to being removed from temperature control. Determine where these products are stored prior to using time as a public health control and evaluate the product temperature within these refrigeration units. The type of refrigeration unit and its capacity should also be considered when assessing these products.
- Holding cold food without temperature control must include a system for assuring the product temperature never exceeds 70ºF. The ideal scenario would be to have a product temperature measuring device constantly recording or displaying the warmest part of the food. In many cases, an establishment may want to use alternative monitoring such as the ambient air temperature of a refrigeration unit. What steps have they taken to validate that this type of procedure is effective, and how do they verify that the system is implemented at all times?
- Keep in mind that using time as a microbial growth barrier is an intentional use of time rather than temperature to control growth of pathogens. Corrective action of a cold holding problem may use the same principles as when time alone is used but it is different in that when time is used, the establishment needs to have a distinct system in place. The assessment should not only be on the written procedures in place, but the rotation of the product. Does the facility add product to a container under time control in busy periods or does the system incorporate procedures for completely changing out the containers? Are foods intended to be held cold without temperature control, stored or commingled with foods intended to be temperature-controlled?

PERSONAL HYGIENE

CONTROL AREAS

*Active Managerial Control for the Personal Hygiene risk factor must include **all three of the elements identified A-C below**. Concurrent use of each of these three control measures will help prevent the transmission of viruses, bacteria, and protozoan oocysts from food employees to customers through contaminated food*

A. Ill Food Workers (Ill FW)
B. Handwashing (HW)
C. Bare Hand Contact (BHC)

A. ILL FOOD WORKERS

1. Critical Limits for Ill Food Workers (Employee Health)

A. ILL FOOD WORKERS (

- **Employee Health Program must address:**
  - **5 pathogens** (due to low infectious dose, contamination of the gastrointestinal system after ingestion, and shed in feces):
    1. Norovirus
    2. *Salmonella* Typhi (typhoid-like fever)
    3. *E. coli* O157:H7, Enterohemorrhagic or Shiga toxin-producing *E. Coli*
    4. *Shigella* spp.
    5. Hepatitis A virus
  - **5 symptoms**
    1. Vomiting
    2. Diarrhea
    3. Jaundice (yellow skin or eyes)
    4. Sore throat with fever
    5. Infected cuts and burns with pus on hands and wrists
- The manager or Person-in-Charge (PIC) ensures that food employees **trained in 4 subjects**
  1. Cause of foodborne illness
  2. Relationship between the food employee's job task, personal hygiene, and foodborne illness
  3. Importance of and requirement for reporting
  4. Specific symptoms, diagnoses, and exposures that must be reported to the Person-in-Charge
- **Report to Management**:
  1. **5 symptoms**: Vomiting, diarrhea, jaundice, sore throat with fever, or any exposed boil or open, infected wounds or cuts on hands or arms
  2. **Diagnoses of 5 pathogens:** An illness diagnosed by a health practitioner that was caused by: *Salmonella* Typhi; *Shigella* spp.; Norovirus; Hepatitis A; or E coli O157:H7 or other Enterohemorrhagic or Shiga toxin producing *E. coli*
  3. **Past illness** with typhoid-like fever within the past 3 months unless treated with antibiotics
  4. **Exposure** to typhoid-like fever, shigellosis, Norovirus, Hepatitus A virus, *E. coli* O157:H7 or other Enterohemorrhagic or Shiga toxin-producing *E. coli*, by eating or serving food that was implicated in a foodborne illness outbreak or if residing with a diagnosed individual.

► Exclusion and restriction policies must adhered to those provided in the decision tree tables contained in the FDA Employee Health and Personal Hygiene Handbook

2. Questions to Assess AMC of Ill Food Workers (Employee Health)

- What kind of policy do you have in place for handling sick employees?
- Is there a written policy? (Note: a written policy is not required in the Food Code, but having a written policy may give an indication of the formality of the policy being discussed.)
- Describe how managers and food employees are made knowledgeable about their duties and responsibilities under the employee health policy.
- Are food employees asked if they are experiencing certain symptoms or illnesses upon conditional offer of employment? If so, what symptoms or illnesses are food employees asked about? Is there a written record of this inquiry?
- What are food employees instructed to do when they are sick?
- What conditions or symptoms are reported?
- What may some indicators be of someone who is working while ill?
- When are employees restricted from working with exposed food or food contact surfaces? When are they excluded from working in the food establishment?
- For employees that are sick and cannot come to work, what policy is in place for allowing them to return and for notifying the regulatory authority?

3. Tips to Assess AMC of Ill Food Workers (Employee Health)

- In general, most individuals do not like discussing subjects related to illnesses such as diarrhea and vomiting. It will be important to put the Person-in-Charge at ease. Explaining that the Centers for Disease Control and Prevention (CDC) has identified that employees coming to work when ill is a primary contributor of foodborne illness will provide rationale to establish a common ground for communication. Including a discussion of the difficult economy and the pressure on employees to work in order to have income often helps on operator relate to the business side of the issue.
- Establishing a dialogue with the operator requires more than asking questions. In fact, an operator may feel they are being interrogated if too many questions are asked in succession. Be cognizant of the types of questions you are asking the operator. Not all the questions included in the previous Employee Health questions section need to be asked to assess the extent of an operation's employee health program or policies.
- Though it is important to look for visible signs of illnesses of wound infections at any time during the inspection, asking questions regarding an operation's employee health policy may be better addressed later in the inspection rather than the beginning. Often times this is a gap area for an operator because they haven't really thought about it in the past and regulatory agencies did not make it a priority during their inspections. Stressing a gap area in an establishment's food safety management system early on in the inspection may make the operator defensive and guarded.
- Employee Health can be a complex and intimidating subject for most operators who are first and foremost business people. Do not be mistaken, it is a subject they care about and know it is important to prevent ill employees from working to protect their customers and business. Much of the information pertaining to employee health will not be retained by the operator if it is based merely on an open discussion at the end of the inspection. It is important to leave a simple reference sheet or other written materials that will assist them in developing a sound employee health program. Two useful tools in this endeavor are the FDA Employee Health and Personal Hygiene Handbook or CD. These tools contain comprehensive Standard Operating Procedures and include forms for documenting food employees training and responsibilities pertaining to foodborne illnesses and their symptoms.
- If an operator has concerns about employee privacy, ADA, or HIPPA, a good resource is

B. HANDWASHING

1. Critical Limits for Handwashing

B. HANDWASHING Critical Limits

- When food employees should wash their hands:
  - ✓ Immediately after engaging activities that contaminate hands
  - ✓ When entering a food preparation area
  - ✓ Before putting on clean, single-use gloves for working with food and between glove changes
  - ✓ Before engaging in food preparation
  - ✓ Before handling clean equipment and serving utensils
  - ✓ When changing tasks and switching between handling raw foods and working with ready-to-eat foods
  - ✓ After handling soiled dishes, equipment, or utensils
  - ✓ After touching bare human body parts, for example, parts other than clean hands and clean, exposed portions of arms
  - ✓ After using the toilet
  - ✓ After coughing, sneezing, blowing the nose, using tobacco, eating, or drinking
  - ✓ After caring for or handling service animals or aquatic animals such as molluscan shellfish or crustacean in display tanks

- Handwashing procedure
  - ✓ Clean hands and exposed portions of arms, including surrogate prosthetic devices for hands and arms, for at least 20 seconds using the following procedure:
    1. Rinse under clean, warm running water
    2. Apply soap and rub all surfaces of the hands and fingers together vigorously with friction for at least 10 to 15 seconds, giving particular attention to the area under the fingernails, between the fingers/fingertips, and surfaces of the hands, arms, and surrogate prosthetic devices
    3. Rinse thoroughly with clean, warm running water
    4. Thoroughly dry the hands and exposed portions of arms with single-use paper toweling, a heated-air hand-drying device, or a clean, unused towel system that supplies the user with a clean towel
    5. Avoid recontamination of hands and arms using a clean barrier, such as a paper towel, when turning off hand sink faucets or touching the handle of a restroom door

2. Questions to Assess AMC of Handwashing

- How do employees know when to wash their hands and what method to use?
- What type of system do you have in place to ensure employees wash their hands when you expect them to do so?
- Who is responsible for checking to see that employees practice good handwashing procedures?
- What action is taken when an employee is observed not washing their hands when you expect them to do so?
- What type of system do you have in place to ensure that handsinks are continually stocked with hand soap and paper towels (or hand drying devices)?
- Do you use any techniques or methods to encourage employees to wash their hands?
- Do you maintain any type of documentation that attempts to monitor employees' handwashing within the kitchen area?

3. Tips to Assess AMC of Handwashing

- Conducting an assessment of proper and adequate handwashing procedures in an establishment requires patience. A snap shot observation of a poor employee practice may not provide enough information to gain an understanding of the root cause of the problem. The lack of handwashing and improper handwashing methods are not always directly attributed to an employee failing to follow good practices. Observations of the entire food preparation procedure can uncover environmental antecedents to poor handwashing such as: the volume of foods being prepared, activity level in the establishment, location of handwashing facilities and an employee's ability to reach them, and lack of training or monitoring by food service management. In order to change employee behavior, it is essential to identify the root cause of the problem.
- It is important to know what the management's handwashing policy is. Not only can an assessment be made as to whether the establishment's policy adequately addresses all aspects of proper handwashing, but it can provide an indication as to whether the employees are following the procedure as described by management. This can provide an indication as to the level of awareness and training employees are receiving regarding the importance of handwashing.
- Having the foodservice manager or person-in-charge with you during the assessment of handwashing can help establish a common understanding of the root causes that might be contributing to poor practices. Management can observe first-hand the employee practices that have the potential to put their business at risk. The person-in-charge will begin to recognize that they need to reinforce the importance of proper handwashing procedures on a continual basis and have a method for providing feedback to all employees on how well they are doing.
- Having the person-in-charge/manager with you during the inspection provides an opportunity to assess what corrective actions are in place to address poor handwashing practices. If management observes poor handwashing, do they implement the type of corrective action they have described? If not, why not?

C. BARE HAND CONTACT (BHC)

1. Critical Limits for Bare Hand Contact

C. <u>NO BARE HAND CONTACT WITH READY-TO-EAT FOODS</u>

- Bare hand contact with a ready-to-eat food such as sandwiches and salads can result in contamination of food and contribute to foodborne illness outbreaks. Food employees should always use suitable utensils such as spatulas, tongs, single-use gloves, or dispensing equipment when handling ready-to-eat foods.
- Single-use gloves used along with handwashing can be an effective barrier to decrease the transfer of microorganisms from the hand to the food. Gloves are not total barriers to microbial transmission and will not be an effective barrier alone for food workers without education on proper glove use and handwashing requirements.
- Procedures for the use of single-use gloves include:
  - ✓ Always wash hands before donning gloves
  - ✓ Change disposable gloves between handling raw products and ready-to-eat products
  - ✓ Do not wash or reuse disposable gloves
  - ✓ Discard torn or damaged disposable gloves
  - ✓ Cover an infected lesion with pus (e.g. cut, burn, or boil) with a waterproof covering and disposable glove
  - ✓ Wear disposable gloves over artificial nails, nail polish, or uncleanable orthopedic support devices
    - The Food Code only allows bare hand contact with ready-to-eat food when the regulatory authority has granted prior approval for alternative procedure. The alternative procedure must address the management of food employees and related food handling activities to prevent food contamination, including the enforcement of thorough handwashing practices after toilet use.
    - The 2011 Supplement to the 2009 Food Code allows bare hand contact with ready-to-eat foods that are being added as an ingredient to a food that:
      - ✓ contains a raw animal food and is to be cooked in the establishment to required minimum temperatures, OR
      - ✓ does not contain raw animal food but is to be cooked in the food establishment to heat all parts of the food to 165ºF (74ºC)

2. Questions to Assess AMC of Bare Hand Contact

- Where do you prepare your shellfish?
- At what times of day do you prepare shellfish?
- What procedures are employees expected to follow when working with ready-to-eat foods?
- Can you describe the system you have in place to ensure employees that work with ready-to-eat foods follow your operational procedures?
- What action would be taken if you observed one of your food employees handling ready-to-eat foods with their bare hands?
- Do you conduct any ready-to-eat food processes for which an alternative procedure is in place to no bare hand contact? Is this alternative procedure in written form? Can you describe the alternative procedure? Have you submitted it to the health department for review?
- How do you know which foods can be touched with bare hands?

3. Tips to Assess AMC of Bare Hand Contact

- Identifying the location where ready-to-eat foods are prepared will provide an opportunity to observe food preparation procedures. Much like handwashing, it is important to observe the entire procedure/process in order to identify potential root causes for the occurrence of bare hand contact with ready-to-eat foods.
- It is also important to know what methods management has established in their procedures to ensure no bare hand contact with ready-to-eat foods. In many foodservice operations, multiple methods such as the use of single-use gloves, utensils, paper wraps, etc. are employed to prevent bare hand contact with ready-to-eat foods. Often, these are task-specific. Some operations may provide options for the employee (single-use gloves or utensils). Understanding the expected methods to prevent bare hand contact with ready-to-eat foods will provide a foundation for assessing how well employees have been trained and give an indication as to whether a system is in place to ensure operational procedures are being followed.
- Keep in mind that no bare hand contact with ready to eat foods is only one component of active managerial control of poor personal hygiene. An assessment of handwashing and employee health must always be conducted in conjunction with no bare hand contact.

CROSS CONTAMINATION (XC)

CONTROL AREAS

A. Separation of Raw Animal Foods from RTE Foods
B. Separation of Raw Animal Foods of Different Species
C. Cleaning Frequency
D. Cleaning & Sanitation of Food-contact Surfaces

A. SEPARATION OF RAW ANIMAL FOODS FROM RTE FOODS
B. SEPARATION OF RAW ANIMAL FOODS OF DIFFERENT SPECIES

1. Critical Limits for Preventing Contamination of Food

A. <u>SEPARATION OF RAW ANIMAL FOODS FROM READY-TO-EAT FOODS</u>

- Food shall be protection from cross contamination by separating raw animal foods during storage, preparation, holding, and display from:
  - ✓ Ready-to-eat foods, including other raw animal food (such as fish for sushi or **molluscan shellfish)** or other ra ready-to-eat food (such as fruits and vegetables)
  - ✓ Cooked, ready-to-eat food

NOTE: *Frozen commercially processed and packaged raw animal food may be stored or displayed with or above frozen, commercially processed and packaged, ready to eat food*

B. <u>SEPARATION OF RAW ANIMAL FOODS OF DIFFERENT SPECIES</u>

- Food shall be protection from cross contamination by separating types of raw animal foods from each other such as beef, fish, lamb, pork, and during storage, preparation, holding, and display by:
  - ✓ Using separate equipment for each type, or
  - ✓ Arranging each type of food in equipment so that cross-contamination of one type with another is prevented, and
  - ✓ Preparing each type of food at different times or separate areas
  - ✓ Not storing and displaying comminuted or otherwise non-intact meats above whole-muscle intact cuts of meat unless they are packages in a manner that precludes the potential for cross contamination

2. Questions to Assess AMC of Preventing Contamination of Food

- Describe your system for storing raw animal foods in the walk-in cooler?
- Where are ready-to-eat foods that require refrigeration stored before service?
- How do food employees know which food products go on what shelves in the walk-in cooler?
- What steps do you use to prevent cross-contamination in the food preparation area?
- How do you verify that foods are being stored, prepared, held, and displayed to prevent cross-contamination? How often is this verification done?

3. Tips to Assess AMC of Preventing Contamination of Food

- Ask questions about the locations for the preparation of ready-to-eat foods and raw foods of animal origin. Gaining an understanding of the flow of food as it is prepared in the food establishment may uncover potential opportunities for cross-contamination. Most establishments have a system or production schedule for preparing different products during the course of the day.
- One of the preparation focus points should be the food preparation sink. Most foodservice operations have only one designated food preparation sink that is often used to wash ready-to-eat vegetables/fruits AND thaw raw animal food items, such as fish or other seafood items. What system does the facility have in place to prevent cross-contamination for the multiple varieties of foods that are processed using the food preparation sink?
- High volume areas like grill lines sometimes require food employees to work with both ready-to-eat and raw animal foods. What system or procedures does the operation have in place to prevent cross-contamination from utensils such as tongs and spatulas? How are work responsibilities delegated between employees? Has the management of the operation given any thought to segregating out work responsibilities based on preventing cross-contamination (Example: one employee only works with ready-to-eat foods and another with raw animal food products)?
- Observing the entire preparation procedure can provide a more complete picture of the establishment's active managerial control for preventing cross-contamination. What happens to the containers and utensils that have been used to transport and dispense raw animal food products to preparation areas? Are the same utensils or containers used to remove and store the cooked product?
- Observe whether practices are in place to eliminate the potential for contamination of food, utensils, equipment, or single-service items from environmental contamination. For example, handwashing sinks and fixtures may be located where splash may contaminate food contact surfaces or food. Splash guards may need to be installed or food contact surface relocated to prevent contamination.
- Raw animal foods stored on shelves in refrigeration units should be separated by cooking temperatures such that food requiring a higher cooking temperature like chicken is stored below or away from foods requiring a lower cooking temperature like pork and beef. If foods are not being cooled, they should be covered or packaged while in storage.

C. CLEANING FREQUENCY
D. CLEANING & SANITATION OF FOOD-CONTACT SURFACES

1. Critical Limits for Preventing Contamination of Equipment

C. CLEANING & SANITIZING OF FOOD CONTACT SURFACES

Food contact surfaces and utensils must be cleaned and sanitized each time:

- ✓ There is a change from working with raw animal foods to ready-to-eat foods
- ✓ Between uses with raw fruits and vegetables and with time-temperature control for safety foods
- ✓ Before using or storing food temperature measuring devices
- ✓ Contamination may have occurred, such as dropping a utensil on the floor
- ✓ Before each use of raw animal food (except in contact with a succession of different raw animal foods each requiring a higher cooking temperature than the previous food, such as raw fish followed by cutting / preparation or raw poultry

Cleaning Frequency, Based on Ambient Temperature of a Refrigerated Room or Area

Preparation Room Temperature	Cleaning Frequency	
41ºF (5ºC) or less	24 hours	Refrigerated room temperatures and cleaning frequency to be documented
> 41ºF (5ºC) to 45ºF (7.2ºC)	20 hours	
> 45ºF (7.2ºC) to 50ºF (10.0ºC)	16 hours	
> 50ºF (10.0ºC) to 55ºF (12.8ºC)	10 hours	
> 55ºF (12.8ºC) unrefrigerated rooms	4 hours	

- ✓ Cleaning frequency **time-temperature control for safety foods** – food contact surfaces:
  - In storage, containers of time-temperature control for safety foods (maintained at proper refrigeration temperatures and date marked) are cleaned when emptied.
  - Containers in serving situations such as salad bars that maintained and refilled with time-temperature control for safety foods, are cleaned at least every 24 hours.
  - In-use utensils intermittently stored in a container of hot water at ≥ 135ºF are cleaned every 24 hours or more frequently to preclude accumulation of soil residues.

- ✓ Cleaning frequency **non-time temperature control for safety foods** – food contact surfaces:
  - Utensils and equipment – at any time when contamination may have occurred
  - At least every 24 hours for ice tea dispensers and consumer self service utensils
  - Before restocking consumer self-service equipment and utensils
  - In or enclosed components of equipment such as ice bins, ice makers, beverage nozzles and syrup dispensing lines/tubes, cooking oil storage tanks and distribution lines, coffee bean grinders, and water vending equipment; as specified by the manufacturer or as necessary to preclude accumulation of soil residues.

D. CLEANING AND SANITIZING OF FOOD CONTACT SURFACES

Warewashing: Chemical
Sanitation: Concentration, pH, Temperature, Hardness and Contact Time

Minimum Concentration (ppm or mg/L	**pH ≤ 10.0 and Minimum Temperature**	**pH ≤ 8.0 and Minimum Temperature**	**Contact Time**
Chlorine 25	120ºF (49ºC)	120ºF (49ºC)	≥ 10 seconds
Chlorine 50	100ºF (38ºC)	75ºF (24ºC)	≥ 7 seconds
Chlorine 100	55ºF (13ºC)	55ºF (13ºC)	≥ 10 seconds
Iodine ≥ 12.5 to 25	pH ≤ 5.0 or per label; 75ºF (24ºC)		≥ 30 seconds
Quaternary Ammonium (per label)	water hardness ≤ 500 ppm or mg/L or per label; ≥ 75ºF (24ºC)		
Hot Water Sanitize 3 compartment sink w/ Integral heating device	≥ 171ºF (77ºC) immersed in rack or basket		

NOTE: *All chemical sanitizers shall be listed in 21 CFR 178.1010 Sanitizing Solutions and used in accordance with EPA-approves manufacturer's label use instructions*

Warewashing: Mechanical and Manual			
		Minimum Wash Temperature	**Minimum Sanitizing Temperature**
SPRAY TYPE WAREWASHERS Single Tank, Hot Water Sanitize	Stationary rack, single temperature	165ºF (74ºC)	165ºF (74ºC)
	Stationary rack dual temperature	150ºF (66ºC)	180ºF (82ºC)
	Conveyor, dual temperature	160ºF (71ºC)	
Multi-tank, Hot Water Sanitize	Conveyor, multi temperature	150ºF (66ºC)	
Chemical Sanitize	Any warewashing machine	120ºF (49ºC)	Sanitization levels as stated in the above table, or per labeled manufacturer's instructions on the container
3 Compartment Sink	Cleaning agent labeling may allow for lower washing temperatures	110ºF (43ºC)	

2. Questions to Assess AMC of Equipment

- Can you demonstrate how the 3-compartment sink is set-up when equipment and utensils are soiled and need to be cleaned?
- How do you know that the sanitizer concentration is correct?
- What procedures do you have in place to ensure that the dishmachine is operating properly?
- Describe the method you use to clean the meat slicer?
- Who is responsible for cleaning the food preparation sink? What procedure is used?
- How does an employee know that the food preparation sink was previous cleaned and sanitized before they use it to prepare food?
- Do you have a cleaning schedule for food equipment that cannot be sent thorough the dishmachine or cleaned in the three compartment sink?

3. Tips to Assess AMC of Preventing Contamination of Equipment

- Special attention needs to be given to the cleaning and sanitizing procedure for work stations where both raw animal food products and ready-to-eat foods are processed during the course of the day. Is there a planned system or schedule for what types of foods are prepared during the course of the day? For example, are ready-to-eat food processed before raw animal foods OR is preparation done on an as-needed basis. While this assessment is important for all operations, it is especially critical for smaller establishments that may have limited space for food preparation.
- In addition to the schedule and flow of food preparation, it is important to obtain an understanding of who is responsible for ensuring that a food preparation surfaces has been cleaned and sanitized. Is it the responsibility of the person who completed preparing food on the work surface/sink or is it the responsibility of the person who will be using the surface to clean and sanitize it before placing foods on a work table or in a preparation sink? Understanding these types of systems will provide insights as to how well the cleaning and sanitizing procedure is monitored throughout the facility.
- An assessment of wiping cloths used for food contact surfaces requires more than just checking the sanitizer concentration of the solution in the wiping cloth buckets. Observe how, when, and on what surfaces food employees use the wiping cloth. Is it being used to clean surfaces that have accumulated heavy amounts of organic material or may have been used to process raw animal foods? Keep in mind that sanitizers will only be effective if the surface has been cleaned /rinsed first. High volume work areas like grill lines may create challenges for employees to effectively clean and sanitize food contact surfaces.

Suggested Immediate Corrective Actions and Intervention Strategies for Achieving Long-Term Compliance of Out-of-Control Procedures

Out-of-Control Procedure	Associated Hazards	Immediate Correction Action(s)	Intervention Strategies for Achieving Long-term Compliance
Approved Source	Bacteria, Viruses	Reject or Discard.	Change Buyer Specifications, Train Employees
Receiving Temperatures	Bacteria	Reject or Discard.	Change Buyer Specifications, Train Employees, Develop SOP/ HACCP/ Recipe
Cold Holding	Vegetative Bacteria, Toxin-forming and Spore-forming Bacteria	Conduct Hazard Analysis.	Change Equipment, RCP, Train Employees, Develop SOP/ HACCP/ Recipe
Bare Hand Contact with RTE Food	Bacteria, Viruses	Conduct Hazard Analysis.	RCP, Train Employees, SOP/HACCP Development
Ill Food Worker	Bacteria, Viruses	Exclude Ill Workers, Conduct Hazard Analysis	Train Employees, Develop SOP
Handwashing	Bacteria, Viruses	Wash Hands Immediately; Conduct Hazard Analysis.	Change Equipment Layout, Train Employees, RCP, Develop SOP/ HACCP
Contaminated Food	Bacteria, Parasites, and Possibly Viruses	Discard or Reheat RTE Food.	Change Equipment Layout, RCP, Train Employees, Develop SOP/ HACCP/Recipe
Contaminated Equipment	Bacteria, Parasites, and Viruses	Clean and Sanitize Equipment; Discard or Reheat RTE Food.	Train Employees, Change Equipment or Layout, Develop SOP

Retail Shellfish Requirements

Hawaii Administrative Rules (HAR) Chapter 11-50 Food Safety Code

DEFINITIONS:

Commingle

To combine shellstock harvested on different days or from different growing areas.

Dealer

A person certified by DOH as a shellstock shipper, shucker-packer, re-packer, shipper or depuration proccesor.

Shellstock

Raw, in-shell molluscan shellfish.

Shucked shellfish

Molluscan shellfish that have one or both shells removed.

Shucker-packer

A person certified by DOH to shuck and pack shellfish.

REQUIREMENT FOR IDENTIFICATION OF SHUCKED SHELLFISH

Raw shucked shellfish must be obtained in nonreturnable packages which bear a legible label that identifies the name, address, and certification number of the SHUCKER-PACKER. The label must include "sell by" or "best if used by" date for packages of less than one-half gallon or the date shuck for packages larger than one-half gallon.

REQUIREMENT FOR IDENTIFICATION OF SHELLSTOCK

Each container of SHELLSTOCK must have the certified shellfish DEALER'S tag with required harvest information. The tag or label must have the following information in order:

1. Dealer's name, address and certification number
2. Original shipper's certificate number
3. Date of harvest
4. Harvest location, including water body and specific site designation
5. Type and quantity of shellfish
6. The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days"

REMOVAL FROM THE ORIGINAL CONTAINER FOR DISPLAY

For dispensing to the consumer, SHUCKED SHELLFISH or SHELLSTOCK may be removed from the original container and displayed on drained ice or held in a display container if:

- The required label or tag information is retained and correlated to the dates when the shellfish is sold or served; and
- Products are protected from contamination

COMMINGLING

COMMINGLING of SHELLSTOCK is prohibited, except containers of SHELLSTOCK harvested on the same day and from the same growing area may be combined.

RECORD KEEPING REQUIREMENTS

Tags must remain on the SHELLSTOCK container until the container is empty and must be retained for 90 calendar days. Tags must be kept in an orderly, chronological system and available to the Department of Health (DOH) regulatory authority for review.

food code facts

Alaska Food Code Guidance
Food Safety & Sanitation Program
Alaska Department of Environmental Conservation

Molluscan Shellfish at Retail

"Because shellfish is often consumed raw, it must be sourced from clean water under sanitary conditions."

Food Code References:
18 AAC 31.200(c)(6)
18 AAC 31.200(d)
18 AAC 31.990

Definitions:

Commingle
To combine shellstock harvested on different days or from different growing areas; or to combine shucked shellfish from containers with different container codes or shucking dates.

Dealer
A person certified by FSS or certified by another regulatory authority as a shellstock shipper, shucker-packer, re-packer, re- shipper, or depuration processor.

Molluscan Shellfish
An edible species of fresh or frozen oysters, clams, mussels, or scallops (except a scallop that consists only of the shucked adductor muscle.

Shellstock
Raw, in-shell molluscan shellfish.

Shucked Shellfish
Molluscan shellfish that have one or both shells removed.

Shucker-Packer
A person certified by FSS to shuck and pack shellfish

IDENTIFICATION OF SHUCKED SHELLFISH
Raw SHUCKED SHELLFISH must be obtained in containers which bear a legible label that identifies the name, address, and certification number of the SHUCKER-PACKER. The label must also include the "sell by" date for packages of less than one-half gallon or the date shucked for packages larger than one-half gallon.

IDENTIFICATION OF SHELLSTOCK
Each container of SHELLSTOCK must have the certified shellfish DEALER'S tag with required harvest information. The tags must have the following information in order:

1. DEALER name, address, and certification number
2. Original shipper's certification number
3. The date of harvest
4. The harvest location, including water body and specific site designation
5. The type and quantity of shellfish
6. The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days"

REPACKAGING OF PRODUCT AT FOOD ESTABLISHMENTS
SHELLSTOCK may be repackaged in consumer self-service containers if each self-service container is plainly marked with the type and quantity of shellfish, harvest location, date of harvest, and DEALER certification number, or otherwise marked with a code that links the product with the tag or label information. SHUCKED SHELLFISH may ***not*** be removed from the original container and repacked by the food establishment into consumer self-service containers.

REMOVAL FROM THE ORIGINAL CONTAINER FOR DISPLAY
For dispensing to the consumer, SHUCKED SHELLFISH or SHELLSTOCK may be removed from the original container and displayed on drained ice or held in a display container if:

- the required label or tag information is retained and correlated to the dates when the shellfish is sold or served; and
- the products are protected from contamination.

COMMINGLING
COMMINGLING of SHELLSTOCK is prohibited, except containers of SHELLSTOCK harvested on the same day and from the same growing area may be combined.

RECORD KEEPING REQUIREMENTS
A SHELLSTOCK tag must remain on the SHELLSTOCK container until the container is empty and must be retained for 90 calendar days. The record keeping system for maintaining SHELLSTOCK tags must be an orderly, chronological system that correlates with the dates of product sale or service and is acceptable to the regulatory authority.

NOTE: This fact sheet is a compilation of major food safety rules regarding the given topic and is not designed to replace reading the Alaska Food Code.
Rev 5/16

food code facts

Alaska Food Code Guidance
Food Safety & Sanitation Program
Alaska Department of Environmental Conservation

Molluscan Shellfish at Retail

"Because molluscan shellfish is often consumed raw, it requires special handling to reduce risk of illness."

Food Code References:
18 AAC 31.060
18 AAC 31.215
18 AAC 31.220
18 AAC 31.222
18 AAC 31.226
18 AAC 31.300
18 AAC 31.310
18 AAC 31.990

Definitions:

Highly Susceptible Population
A group of persons more likely than another group to experience foodborne illness because they are immunocompromised, preschool aged, or older adults AND are obtaining food at a facility that provides services, such as custodial care, assisted living, or health care.

Disclosure
A written statement identifying shellfish that is or can be ordered raw, undercooked, or otherwise processed to eliminate pathogens.

Reminder
A written statement concerning risk of consuming raw or undercooked shellfish.

Diseases Communicable by Food
1. Salmonella
2. Shigella
3. E coli
4. Hepatitis A
5. Norovirus

RAW MOLLUSCAN SHELLFISH AT CERTAIN FACILITIES
Unless prepared in response to a specific adult consumer's request, raw molluscan shellfish may not be served or offered in a ready-to-eat form in a facility that serves a HIGHLY SUSCEPTIBLE POPULATION.

PRACTICE GOOD PERSONAL HYGIENE
- Do not handle ready-to-eat MOLLUSCAN SHELLFISH with bare hands.
- Report symptoms of illness (diarrhea, vomiting, fever, jaundice, sore throat with fever) or diagnosis of a disease communicable by food to the person-in-charge and do not handle food.
- Wash hands before and after handling raw MOLLUSCAN SHELLFISH.

PREVENTING CONTAMINATION DURING STORAGE AND DISPLAY
- Store SHUCKED SHELLFISH or SHELLSTOCK off the floor.
- Separate different species of raw, ready-to-eat during storage and display.
- Separate raw animal foods from cooked, ready-to-eat food and raw, ready-to-eat SHUCKED SHELLFISH or SHELLSTOCK during storage and display.
- Do not store SHELLSTOCK below foods that may drip or leak.
- If displayed on ice, the ice must be drained.
- Rotate from storage to display using the FIFO (First In, First Out) system based on the date of receipt.

CONSUMER SELF-SERVICE
Except when offered at a buffet or salad bar, or individual portions for immediate cooking, raw, unpackaged MOLLUSCAN SHELLFISH may not be offered for consumer self-service.

TEMPERATURE AND TIME CONTROL
SHUCKED SHELLFISH or SHELLSTOCK must be received and held at 41˚ F

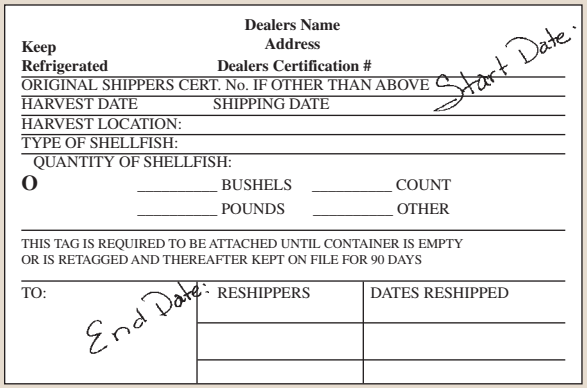
SALE AND SERVICE
A brochure, deli case or menu advisory, label statement, table tent, placard, or other effective means must contain a consumer advisory. The two parts of this consumer advisory are:

1. disclosure by either a description of the food, such as "oysters on the half shell (raw oysters), or identification of the food using an asterisk by the name of the food that refers to a footnote that states the item is raw or undercooked; and
2. a reminder that refers to the description or asterisk that states:
   - o "Regarding the safety of these foods, written information is available upon request."
   - o Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness." OR
   - o "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

NOTE: This fact sheet is a compilation of major food safety rules regarding the given topic and is not designed to replace reading the Alaska Food Code.
Rev 5/16

Recordkeeping

- Keep shellfish tags or labels with the product until the containers are empty.
- Keep shellfish tags or labels on file for 90 days after the container has been emptied.
- Keep shellfish tags and labels in chronological order of dates sold or consumed.
- For easy traceability keep a log of tags and labels and record the date the container is emptied on the tag (example below)



Dealers Name
Address
Keep Refrigerated — Dealers Certification #
Start Date
ORIGINAL SHIPPERS CERT. No. IF OTHER THAN ABOVE
HARVEST DATE — SHIPPING DATE
HARVEST LOCATION:
TYPE OF SHELLFISH:
QUANTITY OF SHELLFISH:
O _____ BUSHELS _____ COUNT
_____ POUNDS _____ OTHER
THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS
TO: End Date — RESHIPPERS — DATES RESHIPPED

Resources:

For a current listing of shellfish shippers that have been certified by regulatory authorities in the United States and abroad, visit Interstate Certified Shellfish Shippers List:

http://www.cfsan.fda.gov/~ear/shellfis.html

For more information about safe food handling practices at retail and foodservice, visit FDA Food Code:

http://www.cfsan.fda.gov/~dms/fc05-toc.html

For more information contact:

HANDLING FRESH AND FROZEN RAW

U.S. Food and Drug Administration

MOLLUSCAN SHELLFISH HANDLING

Receiving

- Verify shellfish shipments are from sources listed on the Interstate Certified Shellfish Shippers List at *http://www.cfsan.fda.gov/~ear/shellfis.html*.
- Check product temperature upon receiving. Verify that:
  - Live shellfish are at 50°F (10°C) or below.
  - Air temperature in delivery vehicle or shipping container is 45°F (7.2°C) or below.
  - Frozen product is received frozen.
- Verify that the quality and quantity in your product order is correct. Place shellfish under temperature control immediately.
- Accept only shellfish that are clean, alive and with whole unbroken shells.
- Keep tags and labels with the containers of live product.

Storage and Display

- Keep storage and display refrigerators cold enough to maintain product at 41°F (5°C) or less.
- Do not co-mingle (mix) different lots or species of shellfish.

Scallops

Mussels

Clams

Oysters

- Store shellfish above or away from other raw animal foods that could drip or leak onto the shellfish.
- Protect shellfish from contamination, such as refrigerate condensation, that could drip onto the product.
- Store raw shellfish away from and below ready-to-eat foods.
- Monitor product daily. Remove any dead shellfish and badly broken shellfish.
- Clean and sanitize equipment and food contact surfaces regularly.

Personal Hygiene

- Wash your hands before handling or preparing food.
- Wash your hands during food preparation to prevent cross contamination.
- Wash your hands when switching between working with raw food and ready-to-eat food.
- Wash your hands after engaging in other activities that contaminate the hands.
- Use utensils or gloves to handle ready-to eat shellfish. Never use your bare hands.

Record Keeping

Vital for Illness Outbreak Trace Back

2019 Pacific Rim Shellfish Sanitation Association Regional Meeting

What We'll Cover

- Records as Foundation of Shellfish Traceability
- Traceback and Traceforward
- Retail Food & Food Service Requirements
- Dealer Requirements
  - Tagging
  - Shipping and Transaction Records

Identification is Key to Traceback

Retail / Food Service

Dealer(s)

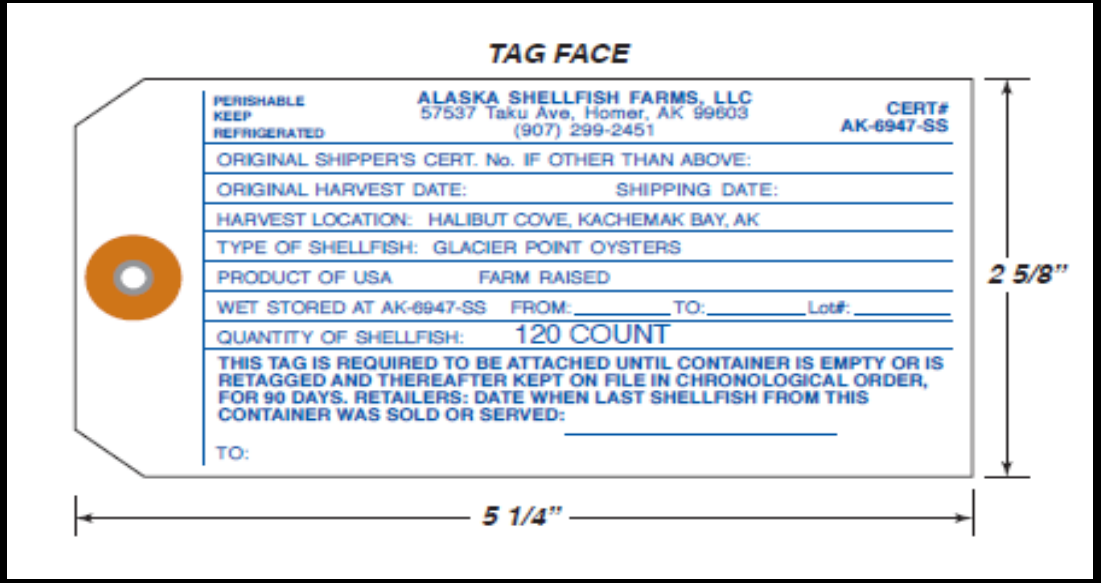
Harvester

Core principle of NSSP

- Harvest by licensed harvesters * Shipped & processed by licensed dealers
  * Trace product at each step * Lot-by-lot traceability
  * Correlate lot to growing area

Records as Evidence

- Accurate records are principal mechanism for tracing shellfish to source
- Provide evidence to support public health and regulatory decisions and support closure
- Support removal of product from distribution



Traceback vs. Traceforward

Response

- Starts with the consumer or the point-of-service and traces the distribution of the product **back** to the source.

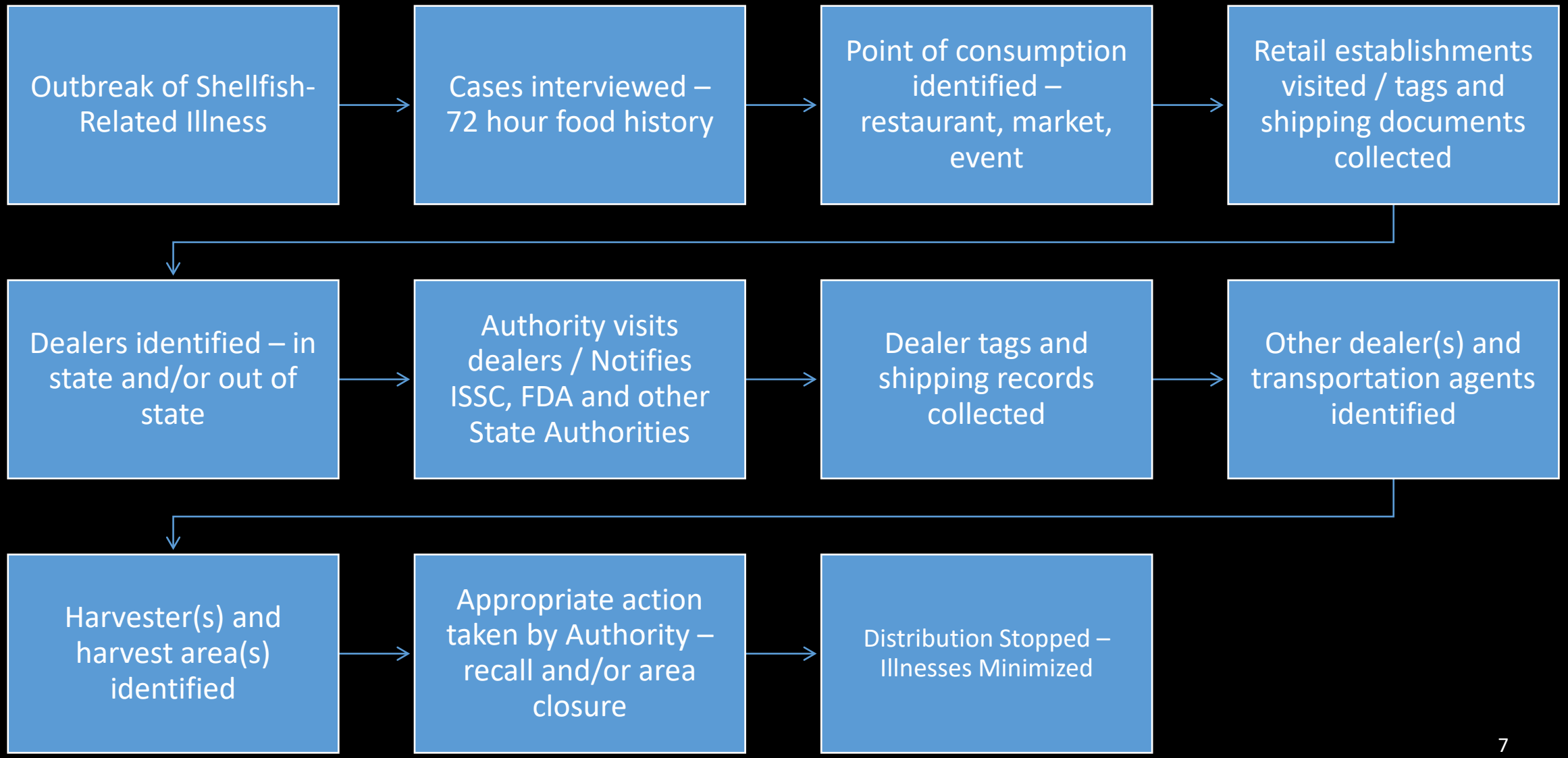
Recall

- Begins with source and traces **forward** to consumer

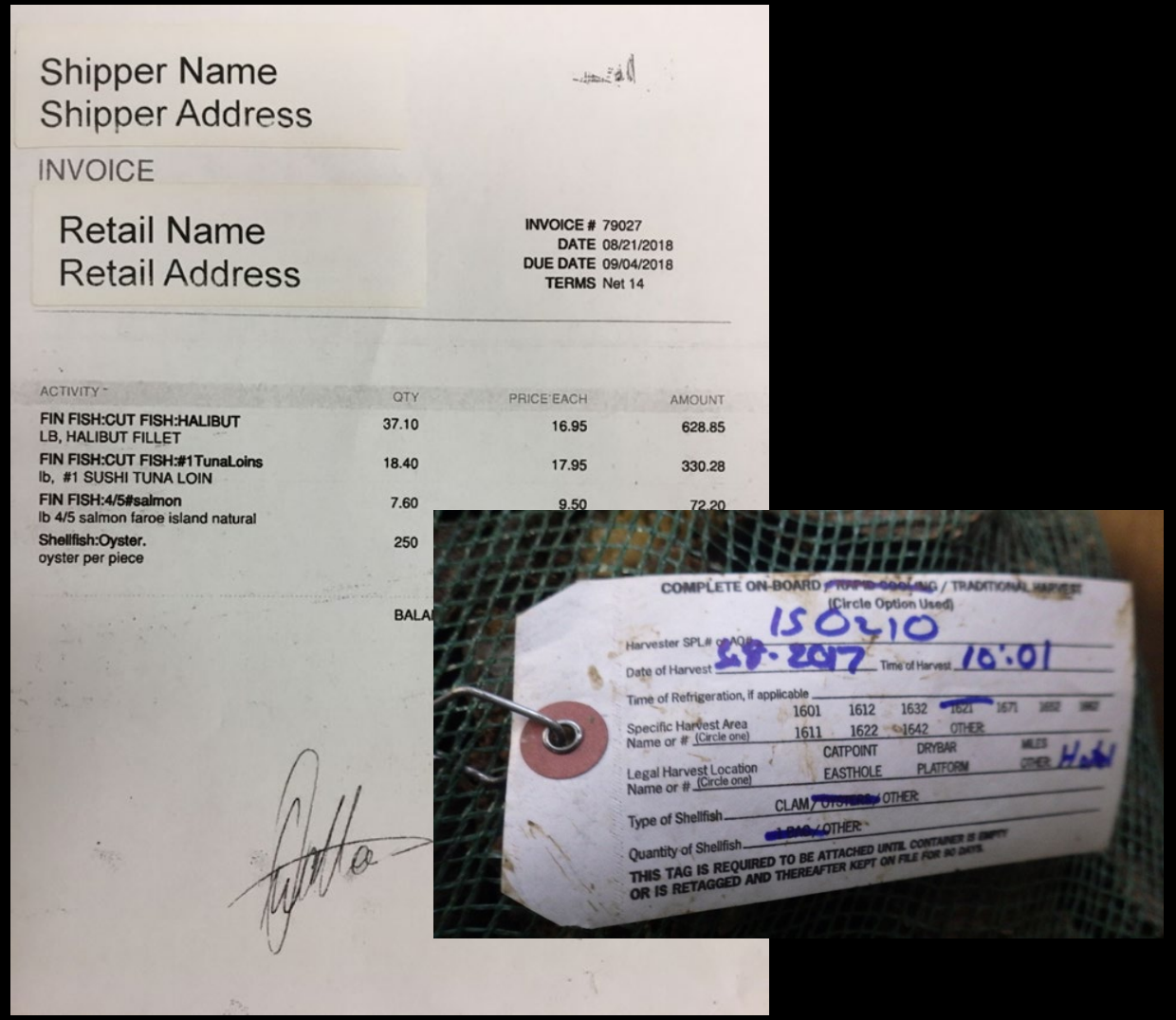
Traceback Objectives

1. Identify Source
2. Immediately Close Area
3. Remove Product from Marketplace
4. Prevent Further Illness

Investigation Flow Chart



Regulatory Traceback


Shipper Name
Shipper Address

INVOICE

Retail Name
Retail Address

INVOICE # 79027
DATE 08/21/2018
DUE DATE 09/04/2018
TERMS Net 14

ACTIVITY	QTY	PRICE EACH	AMOUNT
FIN FISH:CUT FISH:HALIBUT LB, HALIBUT FILLET	37.10	16.95	628.85
FIN FISH:CUT FISH:#1TunaLoins lb, #1 SUSHI TUNA LOIN	18.40	17.95	330.28
FIN FISH:4/5#salmon lb 4/5 salmon faroe island natural	7.60	9.50	72.20
Shellfish:Oyster. oyster per piece	250		

BALA

Documents the distribution through the supply chain, and the source(s) of a product that has been implicated in illness investigation.

Traceback Process

Retail / Food Service

- Collect Tags, Invoices Based on Exposure Dates
- Determine Shipments & Dealer(s)

Dealer(s)

Determine Source

- Tags
- Shipping Documents
- Transaction Documents

Growing Area

Take Action

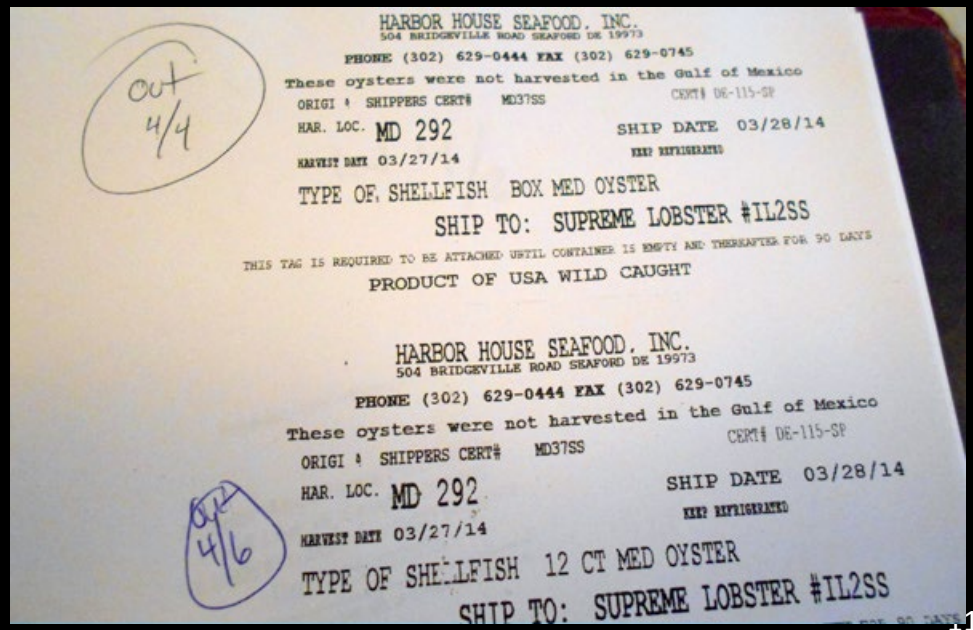
Retail

Retail Requirements

Every package has required tag

When last shellstock sold, date, and keep 90 days

No commingling during display


HARBOR HOUSE SEAFOOD, INC.
504 BRIDGEVILLE ROAD SEAFORD DE 19973
PHONE (302) 629-0444 FAX (302) 629-0745
These oysters were not harvested in the Gulf of Mexico
ORIGI ♦ SHIPPERS CERT# MD37SS
CERT# DE-115-SP
HAR. LOC. MD 292
SHIP DATE 03/28/14
HARVEST DATE 03/27/14
KEEP REFRIGERATED
TYPE OF SHELLFISH BOX MED OYSTER
SHIP TO: SUPREME LOBSTER #IL2SS
THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER FOR 90 DAYS
PRODUCT OF USA WILD CAUGHT

out 4/4

HARBOR HOUSE SEAFOOD, INC.
504 BRIDGEVILLE ROAD SEAFORD DE 19973
PHONE (302) 629-0444 FAX (302) 629-0745
These oysters were not harvested in the Gulf of Mexico
ORIGI ♦ SHIPPERS CERT# MD37SS
CERT# DE-115-SP
HAR. LOC. MD 292
SHIP DATE 03/28/14
HARVEST DATE 03/27/14
KEEP REFRIGERATED
TYPE OF SHELLFISH 12 CT MED OYSTER
SHIP TO: SUPREME LOBSTER #IL2SS

OK 4/6

FDA Food Code 3-203.11, 3-203.12

Dealers

Tag Basics

- Harvester's tag must remain with each container of shellstock until shipped or container emptied
- Durable
- Waterproof
- Approved by Authority
- 13.8 square inches in size
- Indelible ink, legible
- Keep Refrigerated
- Consumer Advisory (if raw)

- Restricted use tags should not include retailer language
- When both dealer & harvester tags on container, dealer not required to duplicate
- If retail containers of 5 lbs or less shipped in master carton, each container need not be tagged
- "For shucking by certified dealer" statement – shellstock must be sold to or processed by certified shucker-packer for shucking only

Dealer

"Keep Refrigerated"

XYZ Shellfish Company
1195 Commercial Way, Metropolis, WA 98000
Cert. # WA-9999-SS

ORIGINAL SHIPPER'S CERT. NO. (if other than above):

HARVEST DATE: *November 17, 2010*

HARVEST LOCATION: *WA-Totten Inlet* Harvest Site ID: *Bed/BIDN/Parcel#*

TYPE OF SHELLFISH: *Manila Clams*

QUANTITY OF SHELLFISH: _____ dozen _____ pounds

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL THE CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS

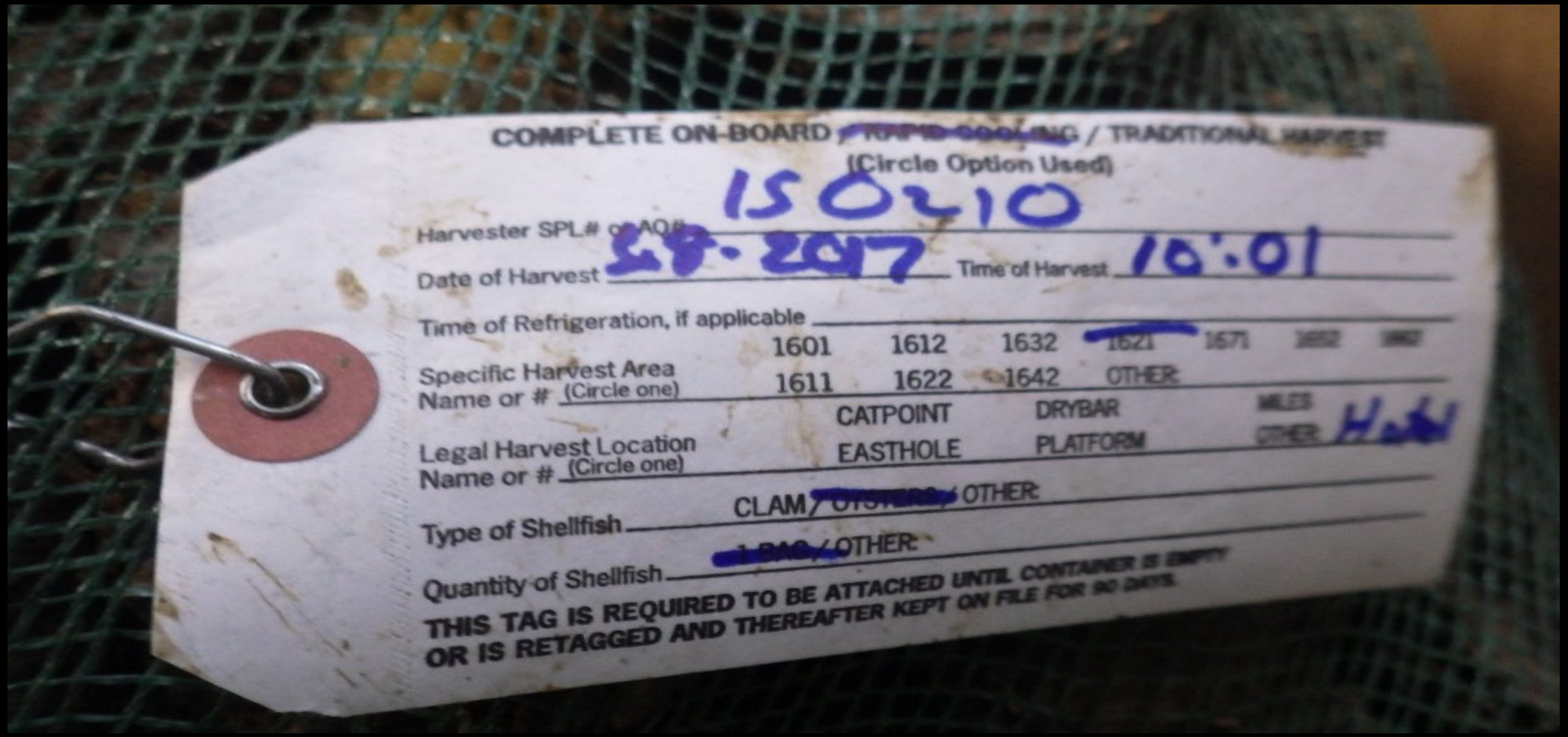
TO:	RESHIPPER'S CERT. No.	DATE RESHIPPED

Not required if depurated

If depurated, date of depuration and cycle or lot number

https://www.doh.wa.gov/Portals/1/Documents/4400/332-128-Dealer-Tag-Example.pdf

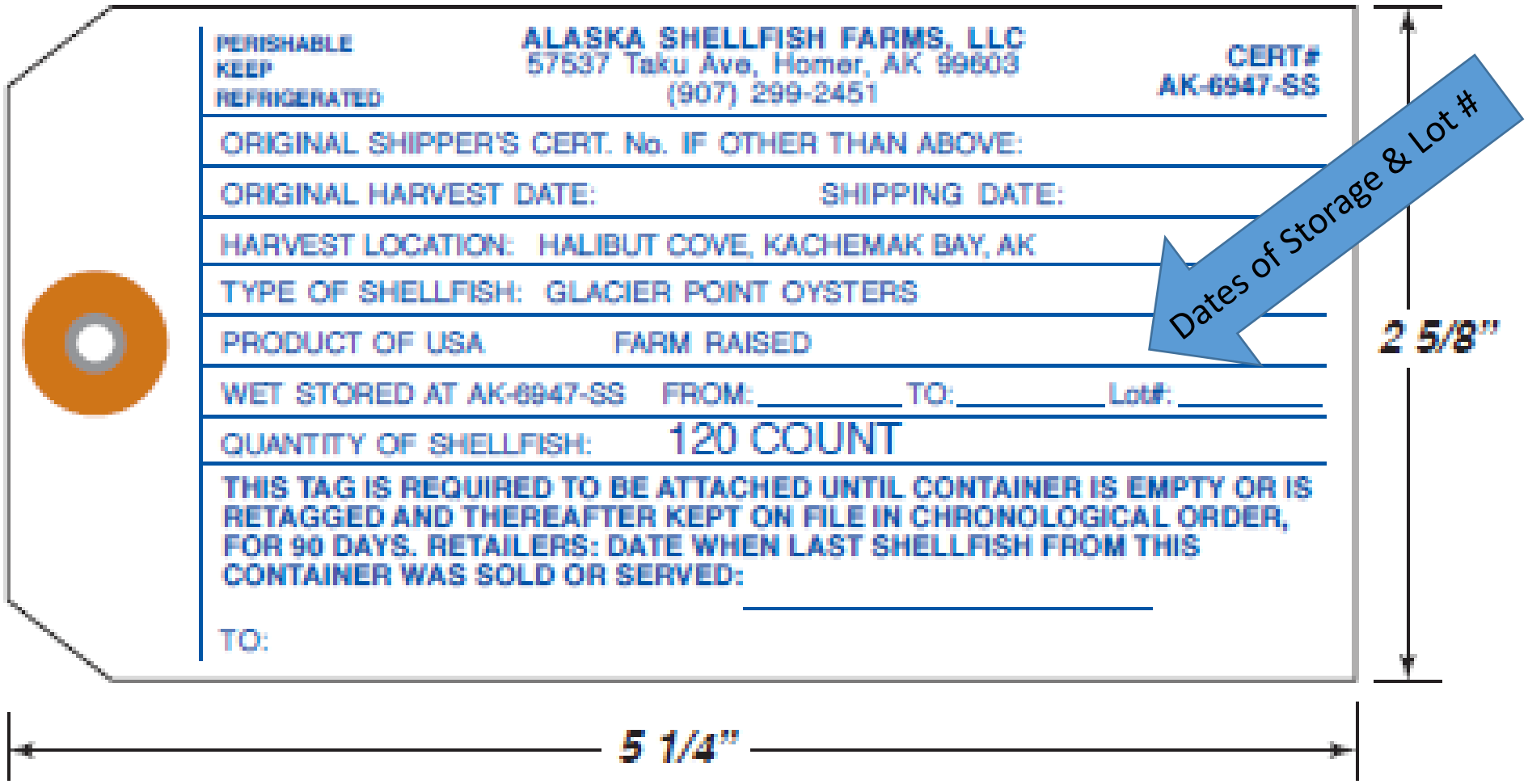
Harvester


COMPLETE ON-BOARD / TRADITIONAL
(Circle Option Used)
Harvester SPL# or AQ#
Date of Harvest
Time of Harvest
Time of Refrigeration, if applicable
Specific Harvest Area Name or # (Circle one)
1601 1612 1632 1621 1671
1611 1622 1642 OTHER:
Legal Harvest Location Name or # (Circle one)
CATPOINT DRYBAR
EASTHOLE PLATFORM
OTHER:
Type of Shellfish
CLAM / OTHER:
Quantity of Shellfish
OTHER:
THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY
OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS

Wet Storage Dealer

Harvested in State

TAG FACE



Wet Storage Dealer
Harvested in Another State

"Keep Refrigerated"

XYZ Shellfish Company
1195 Commercial Way, Metropolis, WA 98000
Cert. # WA-9999-SS

ORIGINAL SHIPPER'S CERT. NO. (if other than above): ***OR 123 SS***

HARVEST DATE: ***November 18, 2010***

HARVEST LOCATION: ***Capitol Bay, OR***

TYPE OF SHELLFISH: ***Manila Clams***

THIS IS A PRODUCT OF **Oregon**

AND WAS WET STORED AT **WA-9999-SS** FROM: **11/18/10** TO: **11/25/10**

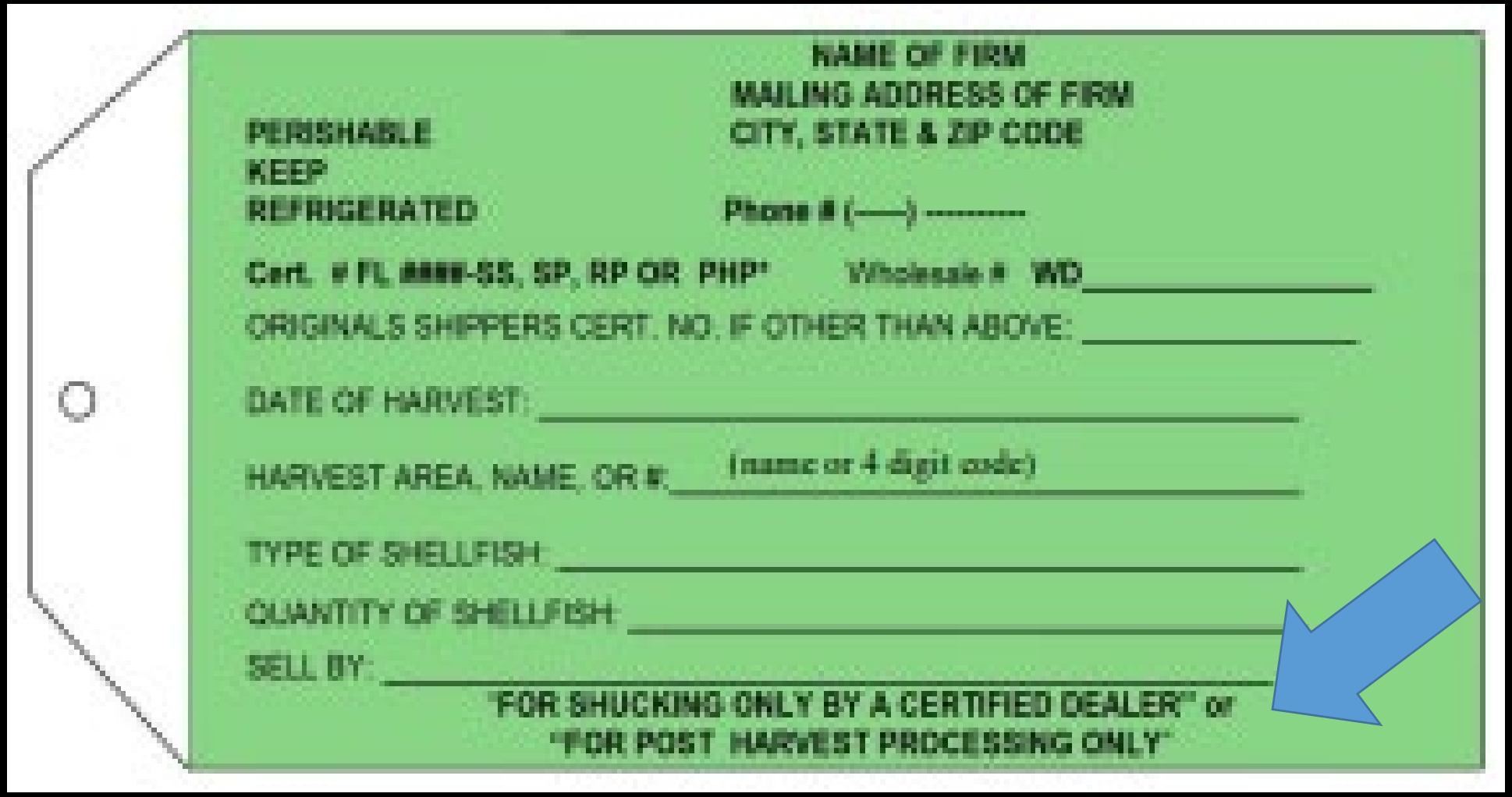
QUANTITY OF SHELLFISH: _____ dozen _____ pounds

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL THE CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS

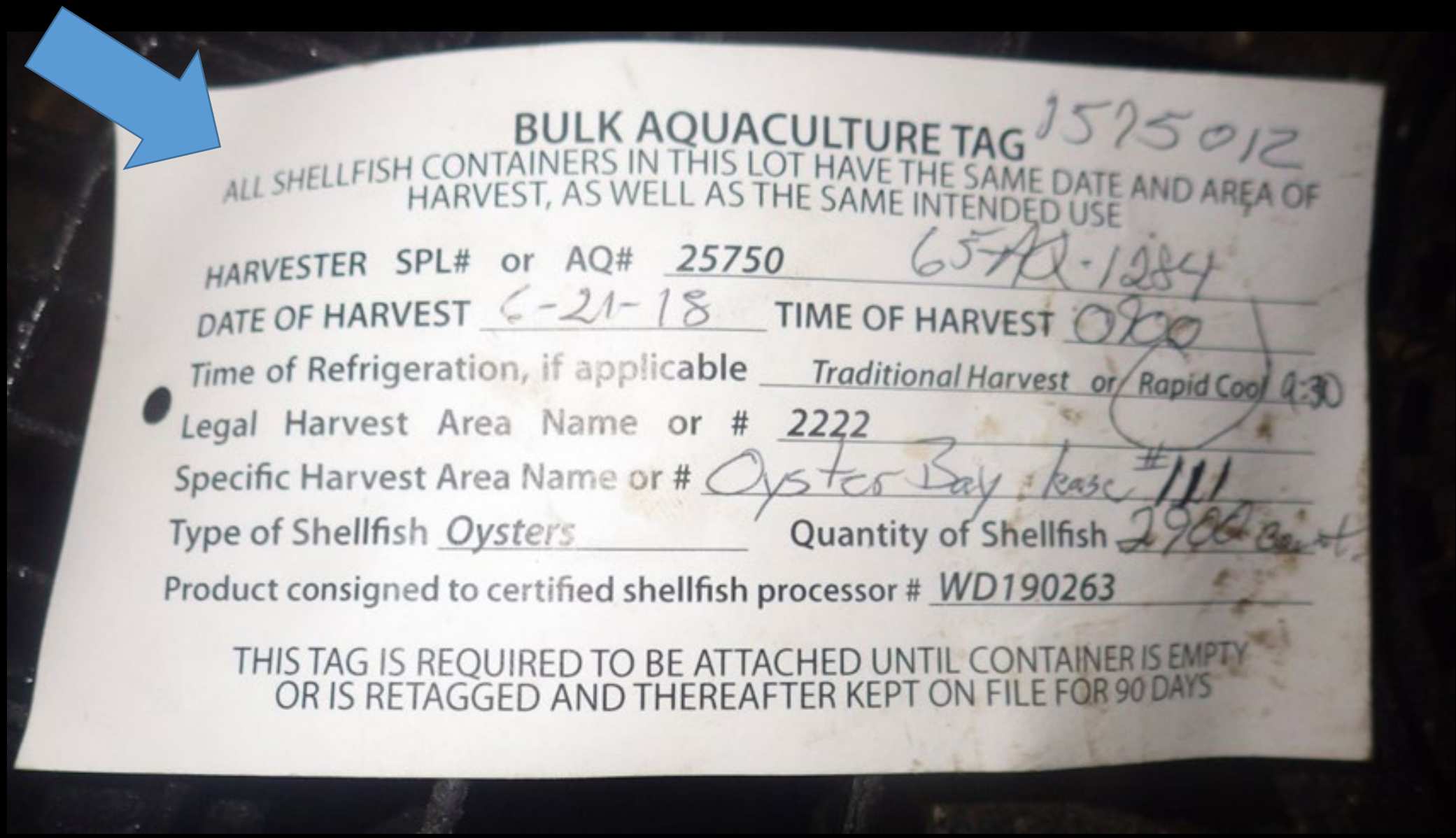
TO:	RESHIPPER'S CERT. No.	DATE RESHIPPED

https://www.doh.wa.gov/Portals/1/Documents/4400/332-128-Dealer-Tag-Example.pdf

Restricted Use



Bulk



BULK AQUACULTURE TAG 1525012

ALL SHELLFISH CONTAINERS IN THIS LOT HAVE THE SAME DATE AND AREA OF HARVEST, AS WELL AS THE SAME INTENDED USE

HARVESTER SPL# or AQ# 25750 65AQ-1284

DATE OF HARVEST 6-21-18 TIME OF HARVEST 0900

Time of Refrigeration, if applicable Traditional Harvest or Rapid Cool 0:30

Legal Harvest Area Name or # 2222

Specific Harvest Area Name or # Oyster Bay Lease #111

Type of Shellfish Oysters Quantity of Shellfish 2900 Count

Product consigned to certified shellfish processor # WD190263

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS

Section II, Chapter VIII.02(F)(7) and (8) - Chapter X.05(C)

5 1/4”

2 5/8”

TAG BACK

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE IN CHRONOLOGICAL ORDER, FOR 90 DAYS. RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER WAS SOLD OR SERVED:

_____

PERISHABLE KEEP REFRIGERATED

“RETAILERS, INFORM YOUR CUSTOMERS”

“Thoroughly cooking foods of animal origin such as shellfish reduces the risk of foodborne illness. Individuals with certain health conditions such as liver disease, chronic alcohol abuse, diabetes, cancer, stomach, blood or immune disorders may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information.”

Lot During Intermediate Processing

- If shellstock removed from original container
  - Harvester tag for 90 days
  - Keep track of growing area and date of harvest
  - Maintain lot identity during all stages of processing
- Intermediate processing plan to keep each lot separate, identified, prevent commingling/misidentification
  - Must be approved by Authority
- Dealer tags each lot of shellstock in accordance with plan

Transaction & Shipping Records

- Needed for authority to conduct outbreak investigations
- Must keep one year, two years if frozen product, or shelf life of product

Section II, Chapter X.08 Shipping Documents & Records
Section II, Chapter II.@.01 Outbreaks of Shellfish-Related Illness

Shipping Documents

- What is a shipping document?
  - Invoice
  - Bill of lading
  - Manifest
- Elements
  1. Shipping dealer's name, address, certification number
  2. Major consignee's name, address
  3. Kind, quantity of product
- Each receiving dealer must maintain copy to trace portion to original shipment
- Dealer must have business address at which records are maintained

Shipper Name
Shipper Address

INVOICE

Retail Name
Retail Address

INVOICE # 79027
DATE 08/21/2018
DUE DATE 09/04/2018
TERMS Net 14

ACTIVITY	QTY	PRICE EACH	AMOUNT
FIN FISH:CUT FISH:HALIBUT LB, HALIBUT FILLET	37.10	16.95	628.85
FIN FISH:CUT FISH:#1TunaLoins lb, #1 SUSHI TUNA LOIN	18.40	17.95	330.28
FIN FISH:4/5#salmon lb 4/5 salmon faroe island natural	7.60	9.50	72.20
Shellfish:Oyster. oyster per piece	250	0.89	222.50

BALANCE DUE $1,253.83

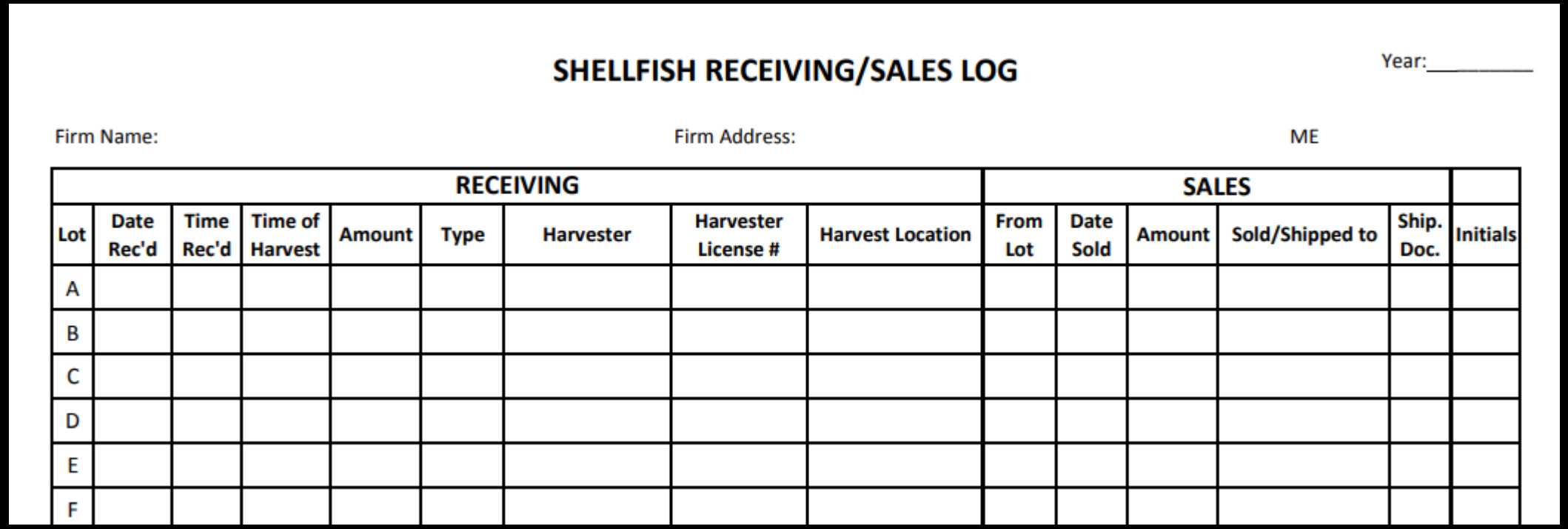
Section II, Chapter X.08(A)

Transaction & Shipping Records Sufficiency

1. Document that shellfish are from approved source
2. Allow container of shellfish to be traced back to specific incoming lot of shucked shellfish from which taken
3. Allow a lot of shucked shellfish or shellstock to be traced back to
   - growing area(s)
   - date(s) of harvest
   - date and locations of wet storage
   - harvester or group of harvesters
4. Trace wet storage history of the shellstock to
   - original harvest site
   - original harvest date
   - wet storage site(s) & dates

Transaction Records

- **F**orm(s) used to document each purchase or sale of shellfish at the wholesale level
- Shellfish harvest and sales records, ledgers, purchase records
- Computer records' format and use must be approved by Authority
- Entries must be made within 72 hours of purchase or sale



SHELLFISH RECEIVING/SALES LOG

Year:_____

Firm Name: Firm Address: ME

RECEIVING									SALES					
Lot	Date Rec'd	Time Rec'd	Time of Harvest	Amount	Type	Harvester	Harvester License #	Harvest Location	From Lot	Date Sold	Amount	Sold/Shipped to	Ship. Doc.	Initials
A														
B														
C														
D														
E														
F														

https://www.maine.gov/dmr/shellfish-sanitation-management/programs/haccpmanual/documents/ReceivinglogwithharvestandreceivedtimesOct2016.pdf

Shucker/Packer Lot Records

Sales Disposition Record

Lot #	Date Sold or Processed	Sold To Dealer Certificate Number (N/A if Processed)	Quantity Sold Unprocessed	Quantity Processed

Requirements for Shellfish at Retail

Raw shucked shellfish must be obtained in nonreturnable packages that bear a legible label identifying the name, address, and certification number of the shucker-packer. The label must include a "sell by" or "best if used by" date for packages of less than a half-gallon or the date shuck for packages larger than a half-gallon.

Shellfish must be obtained from an approved source. Reference the Interstate Certified Shellfish Shippers List | FDA to determine if the shipper is certified.

Requirement for the Identification of Shellstock

Each container of shellstock must have the certified shellfish dealer's tag with required harvest information. The tag or label must have the following information in order:

- Dealer's name, address, and certification number
- Original shipper's certificate number
- Date of harvest
- Harvest location, including water body and specific site
- Type and quantity of shellfish
- *The following statement in bold, capitalized font:* "**THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS.**"

Definitions

Commingle

To combine shellstock harvested on different days, packed on different days, or harvested from different growing areas.

Dealer

A person certified as a shellstock shipper, shucker-packer, repacker, shipper, or depuration processor.

Shellstock

Raw, in-shell molluscan shellfish, such as an oyster or mollusk. This does not include shrimp, lobster, or scallop muscle.

Shucked Shellfish

Molluscan shellfish that have one or both shells removed.

Shucker-packer

A person certified to shuck and pack shellfish.

Removal From the Original Container for Display

For dispensing to the consumer, shucked shellfish or shellstock may be removed from the original container and displayed on drained ice or held in a display container if:

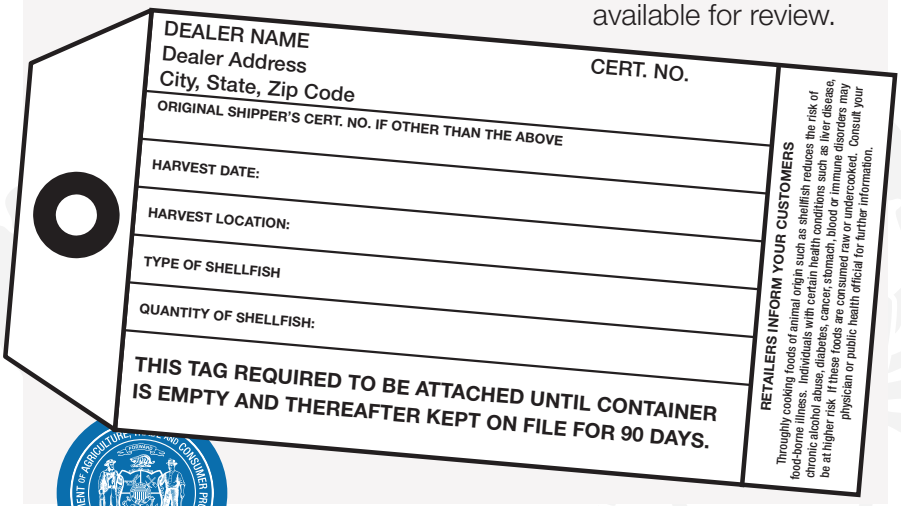
- The required label or tag information is retained and correlated to the dates when the shellfish is sold or served.
- The date that the last shellstock from the labeled container is sold must be recorded in a log or on the label itself.
- Products are protected from contamination.

Commingling

Commingling of shellstock is prohibited. Only containers of shellstock harvested on the same day and from the same growing area may be combined.

Recordkeeping Requirements

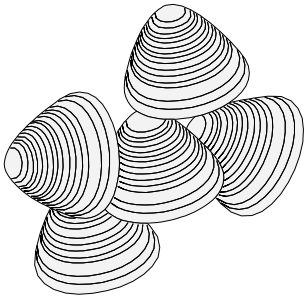
Tags must remain on the **SHELLSTOCK** container until the container is empty. The tags must then be retained for 90 calendar days, kept chronologically and available for review by the regulatory authority. If the label is printed on the container itself, the establishment may take a picture of the container with all relevant data in lieu of removing it and must be available for review.



Wisconsin Department of Agriculture,Trade and Consumer Protection | Division of Food and Recreational Licensing
2811 Agriculture Drive, PO Box 8911, Madison, WI 53708 datcp.wi.gov

P-DFRS0180.indd 05/2021

A Massachusetts Guide for
SAFE HANDLING OF SHELLFISH AT RETAIL



Molluscan shellfish include fresh and frozen oysters, clams, mussels and scallops. They grow in water that may become contaminated. Therefore, the Massachusetts Division of Marine Fisheries (DMF) and the Massachusetts Department of Public Health (DPH) work together to protect consumers by regulating the harvesting, distribution and handling of shellfish. Because molluscan shellfish are often eaten raw or undercooked, they require special handling except when the scallop product consists only of the shucked adductor muscle. To reduce the risk of foodborne illness caused by eating unsafe molluscan shellfish, follow these food safety practices for shellfish and shellstock (raw, in-shell shellfish). These practices are consistent with Massachusetts Department of Public Health, Food Protection Program regulations 105 CMR 590.000.

PREVENT CROSS CONTAMINATION and PRACTICE GOOD PERSONAL HYGIENE *When handling any food, always*	**CMR 590 REFERENCE**
• Report to the Person-in-Charge if you are feeling ill with symptoms of diarrhea, vomiting, fever, jaundice, sore throat with fever, lesions containing pus on hand, wrist or any exposed body part or if diagnosed with a medical disease that is transmissible through food.	**2-201.11** **590.003 (C)**
• Wash your hands before and after preparing raw seafood products.	**2-301.12 & 2-301.14 (G)**
• Do not handle ready-to-eat shellfish (shucked, raw ready-to-eat or cooked) with your bare hands.	**3-301.11**
• Use proper cleaning and sanitizing procedures.	**4-6 and 4-7**

AT RECEIVING *Check that the*	**CMR 590 REFERENCE**
• Shellstock and shucked shellfish are received under refrigeration and sanitary conditions.	**3-202.11 (B)**
• Shipment is from a certified interstate shipper or an approved in-state dealer.	**3-201.15**
• Containers of live shellstock are properly tagged and include the following information: 1. Dealer's name and address and certification number 2. Date of harvesting 3. Identification of the harvest location with the abbreviation of the name of the state or country 4. Type and quantity of shellfish (clams, oysters, mussels and scallops) 5. Statement requiring the tag to be attached to the container until emptied and then retained for 90 days	**3-202.18 [A(1 & 2)]**
• Containers of shucked shellfish are labeled to show the: 1. Name, address and certification number of shucker packer 2. Common name of product, i.e. clams, oysters, mussels and scallops 3. "Sell by" date on containers less than 1.89 L. (one-half gallon) 4. "Shucked" date on containers of 1.89 L. (one-half gallon) or more	**3-202.17 (A)**

XYZ Shellfish Co.
23 Seaweed Lane
Chowderville, MA 01003 CERTIFICATION # MA-6543-SS
Original Shipper's Cert. #, if different from Above:
Harvest Date: 1/24/07 Shipping Date: 1/25/07
Harvest Location: Wellspring, MA
Type of Shellfish: Oysters
Quantity of Shellfish: 5 pounds
THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS.

TO:
Sam's Clam Shack
123 Shoreline Road
Milford, CT 07931

Reshipper's Cert. No.	Dates Reshipped

These practices are consistent with Massachusetts regulations 105CMR 590.000 which adopts by reference the federal 1999 Food Code. 3/1/07. This fact sheet was developed by the MA Partnership for Food Safety Education with support from the Massachusetts Environmental Health Association and Massachusetts Health Officers Association in cooperation with the University of Massachusetts Extension Nutrition Education Program. UMass Extension is an equal opportunity provider and employer, United States Department of Agriculture cooperating. Contact your local Extension office for information on disability accommodations or the UMass Extension Director if you have complaints related to discrimination, 413-545-4800.

AT RECEIVING ***Accept the product when the***	**CMR 590 REFERENCE**
• Temperature of shellstock is 7°C (45°F) or less.	**3-202.11 (B)**
• Temperature of shucked shellfish is 7°C (45°F) or less.	**3-202.11 (B)**
• Shellstock is reasonably free of mud. Discard dead shellstock and shellstock with badly broken shells.	**3-202.19**

FOR STORAGE AND DISPLAY ***To store and display shellfish***	**CMR 590 REFERENCE**
• Refrigerate the shellfish immediately after receipt and cool to 5°C (41°F) or less within 4 hours.	**3-501.14 (C)**
• Hold shellfish during storage and display units at 5°C (41°F) or less.	**3-501.16 (B)**
• Store shellfish off the floor and stack the containers to allow for good air circulation.	**3-305.11**
• Separate different species of raw ready-to-eat shellstock during storage and while on display.	**3-302.11 (A)(2)(b)**
• Separate raw animal foods from cooked ready-to-eat and raw ready-to-eat shellfish during storage and while on display.	**3-302.11 (A)(1)(a&b)**
• Do not store shellstock below foods that may drip or leak onto the shellstock containers.	**3-302.11(A)(2)(b)**
• If displayed on ice, it must be drained ice.	**3-303.12 (B)**

FOR STORAGE AND DISPLAY ***About original containers and records***	**CMR 590 REFERENCE**
• Keep shellstock tags on or with the original container until empty. Once the containers are empty, remove the tags and keep them on file in chronological order for 90 days.	**3-203.12**
• Keep shucked shellfish in the original container until prepared for service or sold.	**3-203.11**
• Do not commingle (mix) shellfish from different containers or different species.	**3-203.11/12**

MONITORING SHELLFISH	**CMR 590 REFERENCE**
• Periodically check to make sure that the:	
✓ temperature of the shellfish is 5°C (41°F) or less.	**3-501.16 (B)**
✓ dead shellstock or shellstock with badly broken shells are discarded.	**3-202.19**
• Rotate shellfish from storage to display using the FIFO (First In, First Out) system based on date of receipt.	**recommended**

SALES AND SERVICE	**CMR 590 REFERENCE**
• A "Consumer Advisory" is required at the point of selection in food establishments that sell or serve raw or partially cooked shellfish.	**3-603.11**
• Make sure that shellstock on display can be identified and that the tags are filed once the containers are emptied.	**3-203.12**
• Observe proper procedures to prevent contamination of the shellfish.	**3-301 through 3-307**
• Do not commingle (mix) shellfish from different containers or different species of shellfish.	**3-203.11/12**

***Special Requirement for Molluscan Shellfish Tanks (For Person-In-Charge)** A life-support system display tank may be used for storage and/or display of shellstock intended for sale to the consumer if it is a spray-type system, not an immersion-type system, and it is operated and maintained in accordance with a variance and HACCP plan that is approved by the Department of Public Health and the local Board of Health. The immersion-type system is considered to be wet storage which is not allowed at the retail level in Massachusetts and if done at the wholesale level requires a wet storage permit approved by the Department of Public Health. [MA Food Code 4-204.110; and the National Shellfish Sanitation Program's (NSSP) Model Ordinance].

NOTE: Supporting documents are provided with the Issue for publications available publicly. Web Links are provided for those studies with limited open access.

Documents attached to the Issue (8):

1. **Attachment** 1 – Summary of FDA Allergen Cross Contact References
2. Bedford, B., Liggans, G; Williams, L., Jackson, L. (2020). Allergen Removal and Transfer with Wiping and Cleaning Methods Used in Retail and Food Service Establishments. J Food Prot (2020) 83 (7): 1248–1260. https://doi.org/10.4315/JFP-20-025
3. Boden, M., Dadswell, R., & Hattersley, S. (2005). Review of statutory and voluntary labelling of food allergens. Proc Nutr Soc, 64(4), 475-480. https://doi.org/10.1079/pns2005453
4. Boyd, Marie, Serving Up Allergy Labeling: Mitigating Food Allergen Risks in Restaurants (2018). Oregon Law Review, Vol. 97, No. 109, 2018, Available at SSRN: https://ssrn.com/abstract=3330372
5. Gendel SM, Zhu J. 2013. Analysis of U.S. Food and Drug Administration food allergen recalls after implementation of the Food Allergen Labeling and Consumer Protection Act. J. Food Prot 76(11):1933–1938. https://doi.org/10.4315/0362-028X.JFP-13-171
6. Gupta RS, Springston EE, Warrier MR, Smith B, Kumar R, Pongracic J, et al. The prevalence, severity, and distribution of childhood food allergy in the United States. Pediatrics 2011;128:e9-17. https://doi.org/10.1542/peds.2011-0204
7. Gupta RS, Warren CM, Smith BM, Jiang J, Blumenstock JA, Davis MM, et al. Prevalence and severity of food allergies among US adults. JAMA Netw Open 2019;2:e185630. doi:10.1001/jamanetworkopen.2018.5630
8. Sharma, G., Ma. Y. and Luccioli. (2022). P3-08 Food Allergen and Gluten Associated Recalls of FDA Regulated Foods from October 2012 to September 2019. In: International Association of Food Protection; July 31- August 3. Pittsburgh, PA. https://www.foodprotection.org/upl/downloads/meeting/archive/63052f3cd9f5354e6afef.pdf

Web Link Accessible Only Publications (2):

Fierstein JL, Brown D, Gupta R, Bilaver L. Understanding Food-Related Allergic Reactions Through a US National Patient Registry. J Allergy Clin Immunol Pract. 2021; 9(1): 206–215.e1. https://doi.org/10.1016/j.jaip.2020.08.011

Oriel. R. C., Waqar. O., Sharma, H.P., Casale. T. B., Wang, J. (2021). Characteristics of Food Allergic Reactions in United States Restaurants. The Journal of Allergy and Clinical Immunology: In Practice, 9 (4): 1675-1682. ISSN 2213-2198, https://doi.org/10.1016/j.jaip.2020.12.018.

Web Resources (5):

FARE (2021, January 15). FARE patient registry data. https://www.foodallergy.org/fare-blog/fare-patient-registry-data-sheds-light-prevention-and-management-food-allergy-reactions

https://www.foodallergy.org/resources/avoiding-cross-contact#:~:text=Cross%2Dcontact%20occurs%20when%20an,reaction%20to%20the%20food%20eaten

https://www.fmi.org/docs/default-source/food-safety/retail-allergen-resource-document.pdf?sfvrsn=6

https://www.mda.state.mn.us/food/safety/allergen-risks-retail

https://resources.centralrestaurant.com/food-safety-101-common-food-allergies-and-preventing-cross-contact/

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Research Paper

Allergen Removal and Transfer with Wiping and Cleaning Methods Used in Retail and Food Service Establishments

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ABSTRACT

Preventing the transfer of allergens from one food to another via food contact surfaces in retail food environments is an important aspect of retail food safety. Existing recommendations for wiping and cleaning food contact surfaces is mainly focused on preventing microorganisms, such as bacteria and viruses, from contaminating foods. The effectiveness of these wiping and cleaning recommendations for preventing the transfer of food allergens in retail and food service establishments remains unclear. This project investigated (i) allergen removal from surfaces by wiping with paper wipes, terry cloth, and alcohol quaternary ammonium chloride (quat) sanitizing wipes; (ii) cleaning of allergen-contaminated surfaces by using a wash–rinse–sanitize–air dry procedure; and (iii) allergen transfer from contaminated wipes to multiple surfaces. Food contact surfaces (stainless steel, textured plastic, and maple wood) were contaminated with peanut-, milk- and egg-containing foods and subjected to various wiping and cleaning procedures. For transfer experiments, dry paper wipes or wet cloths contaminated with allergenic foods were wiped on four surfaces of the same composition. Allergen-specific lateral flow devices were used to detect the presence of allergen residues on wiped or cleaned surfaces. Although dry wipes and cloths were not effective for removing allergenic foods, terry cloth presoaked in water or sanitizer solution, use of multiple quat wipes, and the wash–rinse–sanitize–air dry procedure were effective in allergen removal from surfaces. Allergens present on dry wipes were transferred to wiped surfaces. In contrast, minimal or no allergen transfer to surfaces was found when allergen-contaminated terry cloth was submerged in sanitizer solution prior to wiping surfaces. The full cleaning method (wash–rinse–sanitize–air dry) and soaking the terry cloth in sanitizer solution prior to wiping were effective at allergen removal and minimizing allergen transfer.

HIGHLIGHTS

- Wet cloths and wipes were more effective in allergen removal from surfaces than dry wipes.
- Prescraping food from surfaces prior to full cleaning aided allergen removal.
- Cloth storage in sanitizer solution minimized allergen transfer between surfaces.
- Allergens were difficult to remove from a textured plastic surface.

Key words: Allergen; Cross-contact; Food contact surface; Removal; Retail

The prevalence of food allergies among the U.S. population is estimated between 3 to 4%, with evidence of food allergies in children as high as 8% *(1, 5, 8, 17, 18)*. Allergic reactions to foods are the most common cause of anaphylaxis reported in the community *(5)*. With more than 54% of food expenditures in 2018 attributed to food purchases away from home, there is a need for evaluations of effective allergen control procedures in various food establishments to protect food-allergic consumers *(20)*.

Recommendations for ensuring the safety and protection of food prepared in retail and food service establishments are described in the U.S. Food and Drug Administration (FDA) Food Code *(23)*. Most state, local, tribal, and territorial regulatory agencies have adopted some edition of the FDA Food Code (hereafter "Food Code"), which is updated every 4 years by the FDA's Retail Food Protection Staff. Although many of the provisions in the Food Code were originally developed to reduce microbial risks associated with foods, the effectiveness of these practices for preventing allergen cross-contact remains unclear. The definition of major food allergens contained in the Food Allergen Labeling and Consumer Protection Act of 2004 *(22)* was added to the 2005 edition of the Food Code. The updated 2009 Food Code further specified that food allergy awareness must be part of the food safety training duties of the person in charge of the establishment. Additionally, the 2013 Food Code amended the cleaning

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and sanitizing frequency for food contact surfaces or utensils that are in contact with raw animal food that is a major food allergen, such as fish, followed by other types of raw animal foods. The 2015 supplement to the 2013 Food Code further specified that employees must be properly trained in food safety, including food allergy awareness, as it relates to assigned duties. Although recommendations are provided in Chapters 3 (Subpart 3-304) and 4 (Subparts 4-301, 4-501, 4-603, 4-703) of the 2017 edition of the Food Code *(23)* for manual warewashing or full cleaning and use limitations for wiping cloths, little information exists on whether they are effective at preventing allergen transfer, because these recommendations were originally developed to reduce microbial contamination risk *(19, 27)*.

Published information on the effectiveness of cleaning and wiping procedures used in retail and food service establishments for allergen control on food contact surfaces is scarce. Previous literature reports mostly focused on peanut distribution in different environments, such as the home, school, and hospitals or investigated peanut removal from hands or surfaces by using common cleaning agents or household or hospital wipes *(6, 14, 26)*. One of the few surveys on the occurrence of milk, egg, and gluten on food contact surfaces in school cafeterias was conducted by Ortiz et al. *(13)*. This research team determined the presence of milk, egg, and gluten on food contact surfaces and utensils used in school cafeterias in Spain and documented the percentage of positive results by allergen and general or exclusive use of surfaces and utensils.

Several publications on cleaning and other control strategies for preventing allergen cross-contact in a food manufacturing environment highlighted dry and wet cleaning methods along with indirect (visually clean) and direct (allergen-specific tests) validation and verification procedures when developing an effective allergen control program *(9, 15, 24)*. Additionally, the Food Code, which provides recommendations for ensuring the safety and protection of food prepared in retail and food service establishments *(23),* also provides some details about the cleaning of food contact surfaces, although these were originally focused to reduce microbial risks associated with foods. Although there are differences in the procedures used for allergen removal and cleaning in industrial food manufacturing operations compared with retail and food service operations, the factors influencing allergen removal are similar. Parameters that influence allergen removal include the nature of the allergenic food matrix (dry powder, wet, paste, or sticky, and high fat), allergen load applied to a surface, food contact material composition, surface characteristics (smooth, textured, or porous), and the type of wipe used in allergen removal *(16)*. The complex set of factors that influence allergen removal, combined with the reality that staff in a retail food setting often rely on speed and efficiency with regard to wiping and cleaning surfaces, can make allergen control in food establishments difficult.

The three primary objectives of this study were to investigate (i) the effectiveness of wiping on the removal of peanut, egg, and milk allergen from stainless steel (SS), textured polyethylene plastic, and maple hardwood surfaces; (ii) the impact of a manual wash–rinse–sanitize–air dry full cleaning method on allergen removal from allergen-contaminated surfaces; and (iii) the extent of allergen transfer to surfaces when using allergen-contaminated wipes or cloths. The materials and methods in this study were chosen with the main intent to mimic and study dry, wet, or sticky and paste food compositions of certain major food allergens that may be commonly found on food contact surfaces in various retail and food service establishments.

MATERIALS AND METHODS

Materials. Food-grade SS (304 alloy, 2B finish, Online Metal Supply, Houston, MO), textured polyethylene plastic cutting boards (15.24 by 25.4 cm; Food Service Warehouse, Greenwood, CO) and hard maple wood cutting boards (Carlisle-HLA800, 40.64 by 60.96 by 3.81 cm; Food Service Warehouse) were used for the study. The SS, plastic, and wood were cut to form coupons (~12 by 12 cm) prior to use. Coupons and surfaces were cleaned prior to each set of experiments by using the following procedure. All items were first rinsed individually under running warm tap water (~45°C), followed by applying a 2% solution of Micro-90 alkaline detergent (International Products Corporation, Burlington, NJ). Disposable paper towels (Scott C-Fold, Kimberly-Clark, Roswell, GA) were used to scrub the coupon surface, and warm tap water was used to remove the detergent solution. The cleaning procedure was repeated twice, and a final rinse step with deionized water was used before the coupons or items were placed on a dish rack to air dry.

Dry or powdered, wet, and sticky or paste forms of foods containing milk, egg, and peanut allergens were purchased at local grocery stores or online. The foods included Carnation nonfat dry milk powder (NFDMP; Nestlé, Solon, OH), Philadelphia cream cheese (Kraft, Northfield, IL), fluid whole milk (Dean Foods, Dallas, TX), whole egg crystals (Hoosier Hill Farm, Fort Wayne, IN), Hellmann's mayonnaise (Unilever, Englewood Cliffs, NJ), Jif Peanut Powder (The J.M. Smucker Company, Orrville, OH), and Skippy Creamy Peanut Butter (Hormel Foods Corporation, Austin, MN). The protein content (percentage) of each allergenic food was measured with the Kjeldahl test by a contract laboratory (Merieux NutriSciences, Crete, IL). Protein concentrations of nonfat dry milk, cream cheese, fluid whole milk, whole egg crystals, mayonnaise, peanut powder, and peanut butter were 35.3, 5.0, 3.2, 42.2, 1.0, 45.6, and 21.6% (on an as-is basis), respectively. The various protein concentrations are important to note because the different allergenic foods contained different amounts of protein, the analyte detected in the lateral flow device (LFD) assays.

WypAll X60 dry paper wipes (31 by 40 cm; Kimberly-Clark, Roswell, GA), dry terry dish cloths (86% cotton and 14% polyester blend; 30 by 30 cm; Central Restaurant Products, Indianapolis, IN), and sanitizing wipes saturated with 5.48% isopropyl alcohol and 175 ppm of quaternary ammonium chloride (quat; 20 by 26 cm; Table Turners Sani-Professional no-rinse hard, nonporous surface sanitizing wipes, PDI, Inc., Orangeburg, NY) were used in the wiping and transfer studies. Wet terry dish cloths soaked in warm tap water (~43°C) or in a 50 ppm of total chlorine bleach sanitizer solution (~43°C) for 5 min were also used in the experiments. Wet terry cloth was gently squeezed to remove excess water or sanitizer solution prior to use. Total chlorine levels in the tap water and sanitizer were measured by using the Hach thiosulfate drop test (product CN-21P; Hach, Loveland, CO) and test strips (product 2745050). The concentration of total chlorine used for sanitizing solution in this study (50 ppm total) is within

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the concentration range (25 to 100 ppm of total chlorine) specified in the Food Code (Subpart 4-501.114) *(23)*.

Allergen detection. Coupon surfaces were swabbed after conducting the wiping, cleaning, and transfer experiments by using the instructions provided with Neogen allergen LFD kits. The presence of milk, egg, and peanut from swabbed surfaces was determined with allergen-specific Reveal 3-D (Neogen, Lansing, MI) LFD tests for total milk (product 8479), egg (product 902082Q), and peanut (product 901041L).

A set of experiments evaluated the effects of sanitizer residue (chlorine or quat) on LFD results. Tap water or chlorine sanitizer solutions (0 or 1 mL; 50 ppm or 100 ppm of total chlorine) were applied to clean, allergen-free surfaces. The surfaces were then swabbed and tested for responses with the LFD tests. Similarly, clean SS, plastic, and wood surfaces were also wiped with the quat sanitizing wipe for 5 s and then tested with a premoistened swab to determine if residual quat affected the LFD responses with the milk, egg, and peanut LFD test kits.

Another study also investigated the possibility of false-negative LFD responses when allergens were in the presence of sanitizers. This series of experiments used the liquid sampling procedure described in the allergen-specific test kits and did not involve swabs or coupons. The protocol used for milk allergen involved mixing 0.1 to 5 mL whole liquid milk with 5 mL of 100 ppm of total chlorine sanitizer solution for 30 s. One milliliter of the mixture was then added to the extraction buffer provided and then tested for the presence of milk with the procedure described in the milk LFD test kit. In a similar manner, 0.1 g of peanut butter was mixed for 30 s with 0.5 to 5 mL of 100 ppm of total chlorine sanitizer for the peanut allergen interference tests, but 0.25 mL of the mixtures were added to the extraction buffer, followed by testing for peanut by LFD. Egg allergen sanitizer interference studies examined the addition of 0.1 to 0.5 g of mayonnaise to 0.5 to 5 mL of 100 ppm of total chlorine sanitizer for 30 s, and 0.25 mL of the mixture was added to the extraction buffer. Similarly, whole egg crystals (0.05 g) added to 5 mL of sanitizer solution was also evaluated with a 30-s contact time with the egg LFD liquid sampling procedure. Overall, various ratios of the allergenic food (each containing different amounts of protein) to 100 ppm of total chlorine sanitizer solution were explored and ranged from a 1:1 to 1:100 ratio of allergen to chlorine sanitizer solution to simulate conditions near the maximum use limit for sanitizer solution. The 30-s mixing time was selected on the basis of the time frame used in the full cleaning study.

Wiping study. Each allergenic food was applied individually to the SS, plastic, and wood coupons to cover a surface area (10 by 10 cm) and spread as evenly as possible with a disposable spatula. The amounts of foods used to contaminate the coupons were as follows: peanut powder (0.05 g); peanut butter (0.1 g); NFDMP (0.05 g); cream cheese (0.1 to 4.0 g); fluid whole milk (1 mL); whole egg crystals (0.05 g); and mayonnaise (0.5 to 2.0 g).

Immediately after foods were applied to the coupons, each surface was then manually wiped for 5 s with a single dry paper wipe, dry terry cloth, or wet terry cloth (soaked in water or 50 ppm of total chlorine sanitizing solution prepared with bleach). Experiments in this study used sanitizing solutions near the mid-concentration level of 50 ppm of total chlorine instead of the upper limit of 100 ppm of total chlorine. After wiping, the presence of the residual allergen was determined by visually inspecting the coupon under room lighting by the same individual (typical of a food establishment) and by swabbing the surface with a premoistened swab by using the procedure described in each allergen-specific LFD test kit. For experiments evaluating sanitizing quat wipes, multiple wipes per surface were used if the surface tested positive for allergens after one wipe was used. Wiping experiments for each experimental condition (food contact surface, type of wipe, allergenic food type, and amount) were completed in triplicate.

A wiping time of 5 s was selected because experiments with 0.1 g of peanut butter or 0.05 g of whole egg crystals on the SS, plastic, and wood surfaces were visually clean on most surfaces after using the dry paper wipe. Wiping for 1 s did not yield a visually clean surface, but a 5- and 10-s wipe time removed most of the food soil from the coupons on the basis of visual inspection. The only exception was a very faint, light yellow stain noted after wiping peanut butter on the textured plastic surface in all triplicate trials.

Full manual cleaning by using the wash–rinse–sanitize–air dry method. Three contaminated coupons for each allergenic food and coupon type (SS, plastic, and wood) were prepared for the full cleaning study. The amounts of food applied to each coupon were peanut powder (0.5 g), peanut butter (1 g), whole egg crystals (1 g), mayonnaise (4 g), cream cheese (4 g), fluid whole milk (5 mL), and NFDMP (0.1 g). The manual ware-washing method with a three-bay sink as outlined in the Food Code was simulated in the laboratory by using three pails. The first pail was designated as a wash pail and contained 10 L of warm tap water (~43°C) mixed with 5 mL of detergent (Dawn Ultra, Procter and Gamble, Cincinnati, OH). The second pail acted as the rinse pail with 10 L of warm tap water (~43°C). The third pail contained 50 ppm of total chlorine sanitizer solution, prepared by mixing 6.6 mL of bleach with 10 L of warm tap water (~43°C). The Hach thiosulfate drop test was used to measure the total chlorine level, as described in the test kit. The full cleaning procedure involved submerging one SS coupon in the wash pail and manually wiping the surface under water in the wash pail with a clean terry cloth for 30 s. The coupon was then immersed in the rinse pail for 30 s, followed by submerging it in the sanitizer pail for 30 s. The final step was to air dry the coupons on a drying rack for a minimum of 30 min. The full cleaning procedure was repeated until all three SS, plastic, and wood coupons, having the same allergen load per surface, were washed consecutively by using the same wash, rinse, and sanitizer pails. After air-drying coupons for a minimum of 30 min, each surface was sampled with one premoistened swab and analyzed for allergen residue with the appropriate LFD test. All full cleaning experiments were conducted without scraping the surfaces with a plastic spatula (prescrape step) prior to washing the coupons. An exception was made for coupons contaminated with peanut butter, which were evaluated with and without a prescrape step. The full cleaning experiment was repeated three times.

Allergen transfer experiments. For the dry wipe transfer study, allergenic food was applied to the center of a dry paper wipe (WypAll X60). The amount of dry foods used to soil the dry wipe were as follows: whole egg crystals (0.01 to 0.05 g); peanut powder (0.01 to 0.05 g); and NFDMP (0.05 g). Sticky, paste, and wet foods were also evaluated in the study and included mayonnaise (0.5 to 2.0 g), peanut butter (0.1 g), fluid whole milk (1 mL), and cream cheese (0.5 g). The contaminated wipe was then used to wipe four consecutive coupon surfaces of the same composition for 5 s of contact time between the wipe and each surface. The wiped surfaces (1 to 4) were then sampled with a premoistened swab and analyzed for presence of allergen by using the appropriate LFD test.

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A set of experiments evaluated the extent of transfer from terry cloth to wiped surfaces when the cloths were stored in sanitizer solution before use. The Food Code, Subparagraph 3-304.14 (B)(1), recommends that cloths in use for wiping counters and other equipment surfaces are held between uses in a chemical sanitizer solution. A sanitizer solution (50 ppm of total chlorine) was prepared by adding 2.5 mL of bleach to 3.78 L of warm tap water (~40 to 45°C), and residual chlorine level was measured. A clean terry cloth was soaked in sanitizer solution for 5 min and then gently squeezed to remove excess sanitizer solution. The center of the wet cloth was loaded with individual allergenic foods (0.05 g of whole egg crystals, 0.05 g of peanut powder, 0.05 g of NFDMP, 2.0 g of mayonnaise, 0.1 g of peanut butter, 1 mL of fluid whole milk, and 2.0 g of cream cheese), and the allergen-contaminated cloth was then wiped on the surface of one coupon type for 5 s. The same cloth was submerged in sanitizer solution for 15 s and then wiped on a second coupon of the same composition as the first. The same procedure was followed to wipe the remaining two other coupons. All four surfaces were sampled by using a premoistened swab (one swab per surface) and analyzed for the presence of peanut, milk, or egg residue with an LFD test. Transfer experiments were repeated in triplicate.

RESULTS AND DISCUSSION

Food service and retail food establishments often handle a wide variety of food allergens in various forms that routinely contact SS, as well as plastic or hardwood food contact surfaces, such as cutting boards, bowls, cookware, and utensils during food preparation. Allergenic food matrices selected for this study were chosen on the basis of an attempt to evaluate various forms of milk (NFDMP, whole liquid milk, and cream cheese), egg (whole egg crystals and mayonnaise), and peanut (peanut powder and peanut butter) allergens in a dry, wet, or sticky and paste composition, that may be commonly found in kitchens of food establishments in preparation of sandwiches or bakery items. Additionally, these foods were chosen because milk, eggs and peanuts are identified as "major food allergens" in the Food Allergen Labeling and Consumer Protection Act of 2004 and in the Food Code *(22, 23)*. The coupons or surfaces selected for use were chosen to reflect different finishes (smooth, textured, and porous) and materials of composition (SS, polyethylene plastic, and hard maple wood) of food contact surfaces used in food establishments. Similarly, the dry paper wipes, terry cloth, and disposable quat wipes chosen for the study reflect items described in Chapter 4 of the Food Code and are commonly used in food establishments for wiping surfaces with or without use of a bleach-based sanitizing solution *(23)*. The wiping and allergen transfer studies were designed to provide information on the effectiveness of some practices that may be used outside of the Food Code recommendations. The full cleaning method, as described in Chapter 4 of the Food Code, used the manual three-compartment warewashing method incorporating a detergent containing wash (compartment 1), clean water rinse (compartment 2), chlorine-based sanitizing step (compartment 3) and was followed by air drying the surfaces *(23)*. To simulate a practical use application of this cleaning method, three SS, three plastic, and three wood surfaces each having high allergen loads on the individual surfaces were manually cleaned and evaluated for allergen residue by using allergen-specific LFDs.

Use of LFDs to detect allergen residues. Allergen-specific LFD tests used in this study provided a rapid, qualitative assessment regarding the presence of allergen residue rather than quantitative results. Positive control experiments were conducted to ensure that the lowest amount of each allergenic food used in the experiments could be detected on the coupons prior to any wiping or cleaning. For all allergenic foods (0.01 g of peanut powder, 0.1 g of peanut butter, 0.05 g of NFDMP, 0.1 g of cream cheese, 1.0 mL of fluid whole milk, 0.05 g of whole egg crystals, and 0.1 g of mayonnaise), positive LFD responses (3 of 3) were recorded. The limit of detection (LOD) for the peanut, milk, and egg LFD tests were not determined for each of the allergenic foods evaluated in this study.

Negative control experiments were used to confirm that the presence of chlorine sanitizer did not result in positive LFD results or interfere with the immunochemical tests. For example, testing 100 ppm of total chlorine sanitizer directly, by mixing with the extraction buffer included in the milk, peanut, and egg LFD kits, tested negative and showed no interference with the LFD test response (Supplemental Table S1). "High-positive" LFD results reflect an overloaded sample having a high allergen concentration. Additional experiments were also conducted to determine if the ability to detect allergenic food was influenced by residual sanitizer solution. Varying ratios of whole liquid milk, peanut butter, mayonnaise, or whole egg crystals and 100 ppm of total chlorine sanitizer solution were mixed for 30 s and analyzed with the appropriate LFD, after dilution with extraction buffer included with each LFD kit. The results of the LFD tests are shown in Table S1. All triplicate responses were positive or high positive (as described in Table S1 and the test kit insert on reading LFD results) for the presence of the allergens that indicated that 100 ppm of total chlorine sanitizer solution did not interfere with the LFD tests under the tested conditions. Additionally, sanitizer residue (chlorine or quat) swabbed from clean surfaces tested negative with the peanut, milk, and egg LFD tests.

Wiping study. It is common practice within retail and food establishments to routinely wipe surfaces with disposable wipes or reusable cloths. The current (2017) edition of the Food Code *(23)* provides recommendations and use limitations of wiping cloths from a microbial control perspective. An important distinction for this study is to note that "wiping" for allergen removal is not equivalent to "cleaning" as described in the Food Code. Both Tebbutt *(19)* and Welker et al. *(27)* examined cleaning and wiping from a microbial control perspective and concluded that wiping surfaces having a food soil is different from cleaning a surface.

Information is currently lacking on the effectiveness of wiping methods on the removal of peanut, milk, and egg allergens from common food contact surfaces used in food establishments. This wiping study investigated removal of allergens in dry, wet, paste, and sticky forms and used five

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TABLE 1. *Frequency of detecting peanut residue after wiping peanut powder from coupons, as determined with a peanut-specific lateral flow device (LFD)*[a]

	No. of positive LFD results/total LFD tests with each type of wipe					
Coupon type	Dry wipe	Dry terry cloth	Wet terry cloth (tap water)	Wet terry cloth (sanitizer solution)[b]	Alcohol quat wipe (one wipe)	Alcohol quat wipe (multiple wipes)
SS	3/3[c]	3/3	0/3	0/3	(f+)[d] 4/4	0/3 (2 wipes)
Plastic	3/3	2/3	0/3	0/3	(f+) 4/4	(f+) 2/3 (2 wipes) 0/3 (3 wipes)
Wood	3/3	3/3	0/3	0/3	(f+) 2/4	0/3 (2 wipes)

[a] Peanut powder (0.05 g) wiped from coupons. A positive control test with 0.01 g of peanut flour on SS, plastic, and wood coupons resulted in 3 of 3 positive LFD results. All wiped surfaces appeared visually clean. LOD of Neogen Reveal 3-D peanut LFD: 2 μg of peanut per 100 cm^2.
[b] Sanitizer solution refers to a 50 ppm of total chlorine sanitizing solution prepared with bleach.
[c] Ratio describes the number of positive LFD responses/total LFDs used.
[d] (f+), faint positive LFD response.

different types of wipes: a dry wipe (WypAll X60), a dry terry cloth, a wet terry cloth soaked in tap water, a wet terry cloth soaked in 50 ppm of total chlorine sanitizer solution, and a sanitizing disposable quat alcohol wipe. In general, the dry wipe and dry terry cloth were not effective in completely removing the different forms of peanut-, milk-, or egg-containing foods from most of the surfaces under the conditions tested as shown in Tables 1 to 7. Use of the dry wipe or cloth on the dry forms of the allergenic foods (i.e., peanut powder, nonfat dry milk, and egg crystals) was generally not adequate in removing allergens, because positive LFD results were detected on many of the surfaces in the triplicate trials, although the surfaces appeared visually clean (Tables 1, 3, and 6). For instance, as shown in Table 1, when the dry wipe was used to wipe peanut powder (0.5 g) from the SS, plastic, and wood, peanut residue was detected by LFD on all surfaces in triplicate trials. The dry terry cloth was used in the same manner, and peanut residue was detected on the SS, wood, and plastic surfaces in all three trials, except for one replicate trial for the plastic surface that showed complete removal of peanut powder. Similar to the results observed with the dry and powdered form of allergens, use of the dry wipe and dry terry cloth was not effective at removing allergenic food pastes (i.e., peanut butter, cream cheese, and mayonnaise) from the SS, plastic, and wood coupons (Tables 2, 4, and 7), although in some cases, the surfaces appeared visually clean.

The effectiveness of the wet terry cloth soaked in either tap water or 50 ppm of total chlorine sanitizer solution at allergen removal depended on the amount and form of the food allergen (dry, wet, paste, or sticky) and the composition of the coupon. For example, as shown in Tables 1, 4, and 7, the use of a wet terry cloth (soaked in tap water or sanitizer solution) to remove 0.05 g of peanut powder, 0.5 g of cream cheese, or 0.5 g of mayonnaise from coupon surfaces resulted in no detectable peanut, milk, or egg residues, respectively, on SS, plastic, and wood surfaces in triplicate trials. However, when higher amounts of cream cheese (Table 4) and mayonnaise (Table 7) were loaded on the wood or plastic surfaces, the wet terry cloth was not

TABLE 2. *Frequency of detecting peanut residue after wiping peanut butter from coupons, as determined with a peanut-specific lateral flow device (LFD)*[a]

	No. of positive LFD results/total LFD tests with each type of wipe					
Coupon type	Dry wipe	Dry terry cloth	Wet terry cloth (tap water)	Wet terry cloth (sanitizer solution)[b]	Alcohol quat wipe (one wipe)	Alcohol quat wipe (multiple wipes)
SS	2/3[c]	(f+) 3/3	2/3	2/3	3/3[d]	2/3 (2 wipes) 0/3 (3 wipes)
Plastic	3/3[e]	3/3	3/3	3/3	3/3	3/3 (2 wipes) (f+) 2/3 (3 wipes) 0/3 (4 wipes)
Wood	3/3	(f+) 3/3	3/3	2/3	3/3	(f+) 2/3 (2 wipes) 0/3 (3 wipes)

[a] Peanut butter (0.1 g) wiped from coupons. A positive control test with 0.1 g of peanut butter on SS, plastic, and wood coupons resulted in 3 of 3 positive LFD results. (f+), faint positive LFD response. LOD of Neogen Reveal 3-D peanut LFD: 2 μg of peanut per 100 cm^2.
[b] Sanitizing solution refers to a 50 ppm of total chlorine sanitizing solution prepared with bleach.
[c] Ratio describes the number of positive LFD responses/total LFDs used.
[d] SS surface showed slight sheen when wiped with one quat wipe. Plastic and wood surfaces appeared visibly clean.
[e] Very faint yellow residue on plastic observed.

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TABLE 3. *Frequency of detecting milk after wiping nonfat dry milk powder (NFDMP) from coupons, as determined with a milk-specific lateral flow device (LFD)*[a]

	No. of positive LFD results/total LFD tests with each type of wipe					
Coupon type	Dry wipe	Dry terry cloth	Wet terry cloth (tap water)	Wet terry cloth (sanitizer solution)[b]	Alcohol quat wipe (one wipe)	Alcohol quat wipe (multiple wipes)
SS	(h+) 3/3[c]	3/3	(f+) 3/3	(f+) 3/3	3/3	0/3 (2 wipes)
Plastic	(h+) 3/3	3/3	(f+) 3/3	(f+) 2/3	3/3	0/3 (2 wipes)
Wood	(h+) 3/3	(f+) 3/3	(f+) 1/3	0/3	(f+) 2/3	0/3 (2 wipes)

[a] NFDMP (0.05 g) wiped from coupons. A positive control test with 0.05 g of NFDMP on SS, plastic, and wood surfaces resulted in high positive LFD response (h+) 3 of 3 positive LFD results. All wiped surfaces were visibly clean. (f+), faint positive LFD response. Neogen Reveal 3-D milk LOD: 20 μg milk per 100 cm^2.
[b] Sanitizing solution refers to a 50 ppm of total chlorine sanitizing solution prepared with bleach.
[c] Ratio describes the number of positive LFD responses/total LFDs used.

always effective at allergen removal. The coupons appeared to be visually clean, unless noted otherwise in the tables.

In general, disposable quat wipes were effective for allergen removal from the various surfaces, especially when multiple wipes were used (Tables 1 to 7). In most cases, two, three, or four wipes were needed to effectively remove allergens from surfaces and test negative (0 of 3) with the LFDs. The textured plastic surface was more difficult to wipe clean than the SS or wood surfaces when contaminated with sticky or paste forms of the allergenic foods, and additional wipes were often required to completely remove the allergen to levels below the LFD detection limit. As shown in Table 2, three wipes were required to remove 0.1 g of peanut butter from the SS and wood surfaces, but the textured plastic required four wipes to test negative for peanut by using the LFD tests. An early study by Tebbutt *(19)* and Welker et al. *(27)* also found that it was challenging to remove microbial contaminants from polypropylene plastic and wood surfaces. All quat-wiped surfaces were visually clean after using one wipe to remove 0.1 g of peanut butter, with the exception of a slightly oily sheen on the SS surface. Overall, these results are similar those reported by Watson et al. *(26)* who demonstrated the effectiveness of using one or more sanitizer wipes to remove peanut butter from a variety of different surfaces (a nonporous plastic table, a plastic toy, and plastic ball).

Although SS and plastic surfaces are commonly found in food establishments, the use of hardwood surfaces has been a subject of debate, mainly due to microbiological safety concerns. Research on the cleanability of different food contact surfaces showed that it is was more difficult to recover bacteria inoculated onto the surfaces of hardwood (maple, beech, oak, or walnut) coupons than from plastic (polyethylene or polyacrylic) surfaces *(2, 3, 7)*. The researchers attributed their findings to the porosity of hardwood coupons. Additionally, Gehrig et al. *(7)* found through scanning electron microscopy that surfaces of polyethylene cutting boards after heavy use, had rough "cavernous" surfaces that could retain and later release bacteria.

In contrast, a study by Lucke and Skowyrska *(11)* found no significant differences between the hardwood and polyethylene cutting boards, with respect to cleanability from a microbial control perspective. A recent review by Aviat and Gerhards *(4)* suggests that in addition to the porosity of hardwood surfaces, reduced recovery of bacteria inoculated onto hardwood food contact surfaces can be attributed to the presence of antimicrobial compounds in wood. On the basis of recent research, wood surfaces may

TABLE 4. *Frequency of detecting milk after wiping cream cheese from coupons, as determined with a milk-specific lateral flow device (LFD)*[a]

	No. of positive LFD results/total LFD test with each type of wipe											
	Dry wipe	Dry terry cloth		Wet terry cloth (tap water)			Wet terry cloth (sanitizer solution)[b]			Alcohol quat wipe (one wipe)		Alcohol quat wipe (multiple wipes)
Coupon type	0.1 g	0.1 g	0.5 g	0.5 g	2 g	4 g	0.5 g	2 g	4 g	0.1 g	0.5 g[c]	0.5 g
SS	3/3[d]	(f+) 3/3	3/3	0/3	0/3	2/3	0/3	0/3	0/3	0/3	3/4	0/3 (2 wipes)
Plastic	3/3	(f+) 2/3	2/3	0/3	3/3	3/3	0/3	2/3	(h+) 3/3	0/3	4/4	(f+) 1/3 (2 wipes)
Wood	3/3	(f+) 3/3	2/3	0/3	2/3	3/3	0/3	(f+) 1/3	(h+) 2/3	0/3	3/4	0/3 (2 wipes)

[a] Cream cheese (0.1 to 4 g) wiped from coupons. A positive control test with 0.1 g of cream cheese on SS, plastic, and wood surfaces resulted in 3 of 3 positive LFD results. (f+), faint positive LFD response. (h+), high positive LFD response. LOD of Neogen Reveal 3-D milk LFD: 20 μg milk per 100 cm^2.
[b] Sanitizer solution refers to a 50 ppm of total chlorine sanitizing solution prepared with bleach.
[c] SS surface showed slight sheen when wiped with one quat wipe. Plastic and wood surfaces appeared visibly clean.
[d] Ratio identifies the number of positive LFD responses/total LFDs used.

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TABLE 5. *Frequency of detecting milk after wiping fluid whole milk from coupons, as determined with a milk-specific lateral flow device (LFD)*[a]

	No. of positive LFD results/total LFD tests with each type of wipe					
Coupon type	Dry wipe	Dry terry cloth	Wet terry cloth (tap water)	Wet terry cloth (sanitizer solution)[b]	Alcohol quat wipe (one wipe)[c]	Alcohol quat wipe (multiple wipes)
SS	3/3[d]	3/3	3/3	3/3	(h+) 4/4	0/3 (2 wipes)
Plastic	3/3	(h+) 3/3	3/3	3/3	(h+) 4/4	(vf+) 3/3 (2 wipes) 0/3 (3 wipes)
Wood	3/3	3/3	(vf+) 3/3	(vf+) 2/3	3/4	0/3 (2 wipes)

[a] Fluid whole milk (1.0 mL) wiped from coupons. A positive control test with 1.0 mL of fluid milk on SS, plastic, and wood surfaces resulted in high positive LFD response (h+) 3 of 3 positive LFD results. (vf+), very faint positive LFD response. LOD of Neogen Reveal 3-D milk LFD: 20 μg milk per 100 cm^2.
[b] Sanitizer solution refers to a 50 ppm of total chlorine sanitizing solution prepared with bleach.
[c] SS surface showed slight sheen when wiped with one quat wipe. Plastic and wood surfaces appeared visibly clean.
[d] Ratio describes the number of positive LFD responses/total LFDs used.

TABLE 6. *Frequency of egg on surfaces after wiping whole egg crystals from coupons, as determined with an egg-specific lateral flow device (LFD)*[a]

	No. of positive LFD results/total LFD tests with each type of wipe					
Coupon type	Dry wipe	Dry terry cloth	Wet terry cloth (tap water)	Wet terry cloth (sanitizer solution)[b]	Alcohol quat wipe (one wipe)	Alcohol quat wipe (multiple wipes)
SS	(h+) 3/3[c]	(h+) 3/3	2/3	1/3	3/3	3/3 (2 wipes) 0/3 (3 wipes)
Plastic	(h+) 3/3	(h+) 3/3	3/3	2/3	3/3	3/3 (2 wipes) (f+) 1/3 (3 wipes)
Wood	(h+) 3/3	3/3	0/3	0/3	2/3	(f+) 2/3 (2 wipes) 0/3 (3 wipes)

[a] Whole egg crystals (0.05 g) wiped from coupons. A positive control test with 0.05 of whole egg crystals on SS, plastic, and wood surfaces resulted in high positive LFD response (h+) 3 of 3 positive LFD results. All wiped surfaces were visibly clean. (f+), faint positive LFD response. LOD of Neogen Reveal 3-D egg LFD: 20 μg egg per 100 cm^2 (older kit version with type 3 extraction buffer). LOD of Neogen Reveal 3-D egg LFD: 10 μg egg per 100 cm^2 (new version of kit with type 8 extraction buffer and wetting solution).
[b] Sanitizer solution refers to a 50 ppm of total chlorine sanitizing solution prepared with bleach.
[c] Ratio describes the number of positive LFD responses/total LFDs used.

TABLE 7. *Frequency of detecting egg after wiping mayonnaise from coupons, as determined with an egg-specific lateral flow device (LFD)*[a]

	No. of positive LFD results/total LFD tests with each type of wipe								
	Dry wipe	Dry terry cloth	Wet terry cloth (tap water)		Wet terry cloth (sanitizer solution)[b]		Alcohol quat sanitizing wipe (one wipe)		Alcohol quat sanitizing wipe (multiple wipes)
Coupon type	0.5 g	0.5 g	0.5 g	2 g	0.5 g	2 g	0.5 g	2 g[c]	2 g
SS	(f+) 3/3[d]	(f+) 3/3	0/3	0/3	0/3	0/3	0/3	(f+) 4/4	0/3 (2 wipes)
Plastic	(f+) 3/3	(f+) 2/3	0/3	0/3	0/3	0/3	0/3	(f+) 4/4	0/3 (2 wipes)
Wood	(f+) 1/3	(f+) 1/3	0/3	0/3	0/3	(f+) 2/3	0/3	(f+) 3/4	0/3 (2 wipes)

[a] Mayonnaise (0.5 to 2 g) wiped from coupons. A positive control test with 0.1 g of mayonnaise on SS, plastic, and wood surfaces resulted in 3 of 3 positive LFD results. (f+), faint positive LFD response. LOD of Neogen Reveal 3-D egg LFD: 20 μg egg per 100 cm^2 (older kit version with type 3 extraction buffer). LOD of Neogen Reveal 3-D egg LFD: 10 μg egg per 100 cm^2 (new version of kit with type 8 extraction buffer and wetting solution).
[b] Sanitizer solution refers to a 50 ppm of total chlorine sanitizing solution prepared with bleach.
[c] SS surface showed slight sheen or smear with 2 g of mayonnaise when wiped with one quat wipe. Wiped plastic and wood surfaces appeared visibly clean.
[d] Ratio identifies the number of positive LFD responses/total LFDs used.

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TABLE 8. *Effectiveness of a wash-rinse-sanitize cleaning method for removing allergic food from SS, plastic, and wood coupon surfaces*[a]

	Food soil on coupon:							
Coupon type	Peanut powder (0.5 g)	Peanut butter (1 g)	Peanut butter (1 g) with prescrape step	Whole egg crystals (1 g)	Mayonnaise (4 g)	Cream cheese (4 g)	Fluid whole milk (5 mL)	NFDMP (0.1 g)
SS (trials 1, 2, 3)	0/3, 0/3, 0/3[b]	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3
Plastic (trials 1, 2, 3)	0/3, 0/3, 0/3	3/3, 3/3, 3/3[c]	(f+) 2/3 (f+) 3/3 (f+) 3/3[c]	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3
Wood (trials 1, 2, 3)	0/3, 0/3, 0/3	(f+) 1/3 0/3 (f+) 1/3[d]	(f+) 1/3 (f+) 1/3 (f+) 1/3[d]	0/3, 0/3, 0/3	0/3, 0/3, 0/3[d]	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3

[a] NFDMP, nonfat dry milk powder. All surfaces were visibly clean unless noted otherwise. (f+), faint positive LFD response. Neogen Reveal 3-D peanut LOD: 2 μg peanut per 100 cm^2. Reveal 3-D total milk LOD: 20 μg milk per 100 cm^2. Reveal 3-D egg LOD: 20 μg egg per 100 cm^2 (old version). Reveal 3-D Egg LOD: 10 μg egg per 100 cm^2 (new version).
[b] Ratio identifies the number of positive LFD responses/total LFDs used. Results are shown for three independent trials.
[c] Very faint yellow residue on plastic visually observed for five of nine plastic surfaces after full cleaning to remove peanut butter.
[d] One wood coupon had a visible oil stain after washing.

pose a lesser relative risk from a microbiological point of view, and it appears from this study that the same may also be true for allergen transfer.

The success of cleaning procedures on removal of allergenic foods from food contact surfaces depends on several factors, including the types of surfaces and cleaning methods available, especially because both factors are interrelated *(11, 16)*. The effectiveness of wipes for allergen removal may also be impacted by the absorbency of the wipe, the solvent used for wet wipes, the state of the allergen matrix (wet, sticky or paste, or dry), and the amount of food or allergen loaded on the surface. For parameters evaluated in this study, use of a wet wipe, cloth, or quat wipe to remove a dry allergen from a surface appeared to be more effective than use of a dry wipe. The food contact surface condition (smooth versus textured) appeared to play a role in determining the degree of effectiveness when wiping allergens from surfaces, similar to the results of studies that evaluated removal of microbial contaminants from food contact surfaces *(19, 27)*.

To more closely simulate what would be done in retail and food service operations, visual inspection of wiped surfaces was conducted by the same individual who performed the wiping experiments. Although surfaces that were visually clean did not always correspond to negative LFD test results, visual inspection provided a first step for evaluating the effectiveness of wiping treatments. For example, as shown in Table 5, wiping 1 mL of liquid milk with one quat wipe resulted in positive LFD responses on all surfaces, although no visible residue was apparent on the plastic or wood, and only a very slight sheen was apparent from an angled view on the SS surface. Use of two quat wipes resulted in all surfaces appearing visually clean, but the textured plastic surface contaminated with 1 mL of whole liquid milk still resulted in 3 of 3 very faint positive LFD results, and three quat wipes were required to correspond to negative LFD results. Similarly, 0.5 g of mayonnaise was easily wiped from each surface with one quat wipe, and all surfaces were visually clean and had negative LFD results (0 of 3; Table 7). Increasing the amount of mayonnaise to 2 g and use of a quat wipe resulted in faint positive LFD responses on all surfaces, which indicated that the amount of egg residue was near the LOD of the egg-specific LFD kit. Although all plastic and wood surfaces were visually clean, a slightly oily smear was initially visible only on the SS coupons, which then appeared visually clean after the mayonnaise residue dried. Two quat wipes were required to remove 2 g of mayonnaise from each surface to obtain a visually clean and negative LFD (0 of 3) response on all SS, plastic, and wood surfaces, as noted in Table 7.

Limitations that exist with visual assessment of cleaning effectiveness include the type and adequacy of the lighting, the color and textural differences between the food contact surface and the allergen residue, and the visual acuity of the examiner. In this study, the use of white plastic coupons hindered visualization of light-colored foods, such as milk, cream cheese, mayonnaise, and NFDMP. In these circumstances, visual inspection may not provide adequate assessment of the presence of food residues. Also, we found instances in which the surfaces appeared visually clean but still tested positive for allergen residue on the basis of the LFD test results. The significance of these results is not clear because the allergen-specific LFD tests used in this study provide qualitative rather than quantitative results. Thus, it is difficult to determine the amount of hazardous allergenic residue. It was observed that most allergen LFD results on some visually clean surfaces were faintly positive, suggesting that the amount of allergen present was close to the LOD of the LFD test and thus likely to be quite low. However, more research is needed to understand the significance of these positive residue results.

Full cleaning study. A full cleaning method, also referred to as the "wash–rinse–sanitize–air dry" procedure simulated the process of using a three-bay sink and air-drying surfaces on a dish rack after cleaning. The entire wash–rinse–sanitize–air dry procedure was repeated for a

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total of three independent trials. In this experiment, the amounts of food allergen added to each coupon was substantially greater than those used in the wiping study. As shown in Table 8, results demonstrated that the full cleaning method was consistently effective in allergen removal in triplicate trials (0 of 3, 0 of 3, 0 of 3 positive LFD test results for each type of surface and all surfaces were visually clean) for all types of coupons and for all allergenic foods, with the exception of peanut butter. The textured plastic coupons retained peanut residue as detected by the peanut-specific LFD in all three trials (3 of 3, 3 of 3, and 3 of 3), but two faint positive residues and negative responses were found for wood surfaces in the triplicate trials (f+ 1 of 3, 0 of 3, f+ 1 of 3). Note that during washing, peanut butter from the contaminated coupons (1 g of peanut butter per coupon) was transferred into the wash water (10 L). Because nine coupons were consecutively washed, the wash water contained up to 900 ppm of peanut butter at the conclusion of each trial. Also, because wood coupons were washed last in this study, the faint positive LFD results in two of the independent trials may be attributed to peanut butter present in the wash water that may have redeposited on the wood surfaces. The wood surfaces appeared visually clean except for a slightly oily and wet stain, yet the wood surfaces tested negative or registered faint positive LFD results for peanut residue.

All the SS surfaces appeared visually clean and tested negative for peanut in the LFD tests, which is most likely attributed to the smooth SS surface finish and because the SS surfaces were washed first in all trials. The white, polyethylene plastic coupons on the other hand, tended to retain peanut butter within the grooves of the textured surface and displayed a faint yellow color stain in five of the nine plastic coupons. Thus, approximately 44% of the textured plastic surfaces appeared visually clean, but all of the LFDs were positive for peanut residue. Implementing a prescrape step to remove the bulk of the peanut butter residue prior to washing improved the effectiveness of the cleaning procedure for the textured plastic coupons, with faint positive (f+ 2 of 3, f+ 3 of 3, f+ 3 of 3) LFD responses recorded in the three trials.

Relatively few studies report the effectiveness of a full manual cleaning procedure on allergen removal. The presence of milk, egg, and gluten on utensils, cookware, and other food contact surfaces present in school cafeterias and kitchens in Spain was examined by Ortiz et al. *(13)*. In that study, where the food contact surfaces were either washed with an automatic dishwasher or manually washed, milk residue was not found on the surfaces with LFD tests, but 15% of egg and 45% of gluten LFD results were positive. Cleaning conditions (i.e., time and temperature of the cleaning procedures, detergent concentrations, and use of three basins for manual washing) were not described. In addition, it was also unclear whether the positive results were due to recontamination of the surfaces by use of allergens in daily operation and management of the cafeteria. Miller et al. *(12)* found food contact surfaces and food prepared in a commercial kitchen could become contaminated with gluten if controls were not in place to prevent dispersal of gluten-containing ingredients.

In general, manual warewashing appeared to be effective for allergen removal when practiced according to the procedures outlined in the Food Code. Using a prescrape step (Subpart 4-603.12 Precleaning) to remove the bulk of allergenic food residues and decreasing food load in the wash water improved overall effectiveness of the full cleaning procedure *(23)*. Although not studied here, changing the wash water frequently to maintain clean solutions is another factor that can improve cleaning effectiveness. Other factors that may impact cleaning effectiveness include the amount and type of allergenic food on the surface, time and temperature of the wash solution, type and concentration of detergent in the wash sink, composition and finish of food contact surface material, and the mechanical and manual force used during the washing step. Other strategies to clean and minimize cross-contact include washing the prescraped allergen surface more than once, increasing the submersion time in wash water, or simply maintaining dedicated cutting boards or surfaces when possible, especially if using textured plastic materials with peanut butter. The U.S. Department of Agriculture cutting boards and food safety fact sheet *(21)* also suggests using a dedicated cutting board for raw meat, poultry, and seafood and maintaining a separate food contact surface for fresh produce to prevent microbial cross-contamination, despite the ability to effectively clean cutting boards from a microbial control perspective. This concept can also be extended to sticky allergenic foods, such as peanut butter and other similar foods, which can be problematic for effective manual warewashing on select materials.

A limitation of the full cleaning study design involved the use of a single order to wash the coupons (SS, plastic, and wood). Future experiments should randomize the order of cleaning the different surfaces to allow for exposure to wash water having varying levels of food soils. Another limitation of this washing study was the absence of food soils that were dried, cooked, or heated on the surfaces. Cooked food soils tend to require more manual force and cleaning effort in removing denatured proteins, such as heated milk, which can adhere to equipment and surfaces *(16, 25)*.

Allergen transfer study. The focus of this series of experiments was to determine the extent of allergen transfer to surfaces from a contaminated wipe or cloth. Unlike previous studies in which coupon surfaces were directly contaminated with allergenic foods, the allergenic foods were placed on dry wipes or sanitizer-soaked terry cloth for transfer experiments. In the experiments that used dry wipes, one allergen-contaminated dry wipe was used to wipe four consecutive coupon surfaces of the same material composition, followed by testing all four surfaces for the presence of allergens with allergen-specific LFD tests.

Most dry or powdered allergens transferred from the dry wipe to all four wiped surfaces as shown in Table 9. Whole egg crystals (0.01 g) on the dry wipe showed a

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TABLE 9. *Transfer of dry or powdered allergenic foods to food contact surfaces with contaminated dry paper wipes*[a]

Allergen	Food contact surface	Surface 1	Surface 2	Surface 3	Surface 4
0.01 g of whole egg crystals[b]	SS	3/3[c,d]	3/3	3/3	3/3
	Plastic	3/3[d]	3/3	2/3	2/3
	Wood	3/3	3/3	3/3	1/3
0.05 g of whole egg crystals	SS	(h+) 3/3[d]	3/3	3/3	3/3
	Plastic	(h+) 3/3[d]	3/3	3/3	3/3
	Wood	(h+) 3/3	3/3	3/3	3/3
0.01 g of peanut powder	SS	(f+) 3/3	2/3	0/3[e]	0/3
	Plastic	3/3[d]	3/3	(f+) 3/3	3/3
	Wood	(f+) 3/3	0/3[e]	0/3	0/3
0.05 g of peanut powder	SS	3/3[d]	3/3	3/3	2/3[d]
	Plastic	3/3	3/3	3/3	3/3
	Wood	3/3	3/3	2/3	(f+) 2/3
0.05 g of NFDMP	SS	3/3[d]	3/3[d]	3/3	3/3
	Plastic	(h+) 3/3	3/3	3/3	3/3
	Wood	(h+) 3/3	3/3	3/3	3/3

[a] Surfaces 1 to 4 are visibly clean unless noted otherwise. (h+), high positive LFD response. (f+), faint positive LFD response. NFDMP, nonfat dry milk powder. Neogen Reveal 3-D Peanut LOD: 2 μg peanut per 100 cm^2. Reveal 3-D total milk LOD: 20 μg milk per 100 cm^2. Reveal 3-D egg LOD: 20 μg egg per 100 cm^2 (old version).
[b] Reveal 3-D egg LOD: 10 μg egg per 100 cm^2 (new enhanced version used in third replicate test with 0.01 g of whole egg crystals).
[c] Ratio identifies the number of positive LFD responses/total LFDs used.
[d] Very light powder observed.
[e] Denotes the first surface with no allergen residue transfer, as shown with a 0 of 3 LFD response.

mixed degree of egg transfer to surface 4, while a higher allergen load of 0.05 g of whole egg crystals on the dry wipe, consistently transferred egg to all surfaces with (3 of 3) positive LFD results. Peanut powder (0.01 g) resulted in no detectable transfer (0 of 3) on wood coupon 2 and SS coupon 3, respectively. However, peanut residue was present on all textured plastic surfaces in all three trials. The NFDMP (0.05 g) also transferred from the dry wipe to all SS, plastic, and wood coupon 4, with positive LFD responses in all three trials.

Wet, paste, and sticky forms of allergens also transferred from the dry wipe to many of the subsequently wiped surfaces, as shown in Table 10. Only mayonnaise (0.5 g) resulted in minimal egg allergen transfer to subsequent surfaces, with no egg detected on all SS, plastic, and wood surface 3 (0 of 3). Increasing the food load to 2 g of mayonnaise on the dry wipe led to extended allergen transfer to some surface 4 plastic and wood coupons, but egg LFD responses were only faintly positive. In general, allergen absorption by the dry wipe and the porous wood

TABLE 10. *Transfer of sticky, paste, and wet allergenic foods to food contact surfaces with contaminated dry paper wipes*[a]

Allergen	Food contact surface	Surface 1	Surface 2	Surface 3	Surface 4
0.5 g of mayonnaise	SS	3/3[b]	0/3[c]	0/3	0/3
	Plastic	3/3	(f+) 1/3	0/3[c]	0/3
	Wood	3/3	0/3[c]	0/3	0/3
2.0 g of mayonnaise	SS	3/3[d]	3/3	(f+) 3/3	0/3[c]
	Plastic	3/3	3/3	(f+) 3/3	(f+) 3/3
	Wood	3/3	3/3	(f+) 3/3	(f+) 1/3
0.1 g of peanut butter	SS	3/3	2/3	0/3[c]	1/3
	Plastic	3/3[d]	3/3	3/3	3/3
	Wood	3/3	(f+) 3/3	(f+) 3/3	(f+) 3/3
1 mL of whole milk	SS	3/3[d]	3/3[d]	3/3[d]	3/3[d]
	Plastic	3/3	3/3	3/3	3/3
	Wood	(f+) 3/3	(f+) 3/3	(f+) 3/3	(f+) 3/3
0.5 g of cream cheese	SS	(f+) 3/3[d]	(f+) 3/3[d]	(f+) 3/3[d]	(f+) 3/3[d]
	Plastic	(f+) 3/3	(f+) 3/3	(f+) 3/3	(f+) 3/3
	Wood	(vf+) 3/3	(vf+) 3/3	(vf+) 3/3	(vf+) 2/3

[a] Surfaces 1 to 4 are visibly clean, unless noted otherwise. (f+), faint positive LFD response. (vf+), very faint positive LFD response. Neogen Reveal 3-D peanut LOD: 2 μg peanut per 100 cm^2. Reveal 3-D total milk LOD: 20 μg milk per 100 cm^2. Reveal 3-D egg LOD: 20 μg egg per 100 cm^2 (old version).
[b] Ratio identifies the number of positive LFD responses/total LFDs used.
[c] The first surface with no allergen residue transfer as shown with a 0 of 3 LFD response.
[d] Slight sheen or stain observed.

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TABLE 11. *Transfer of dry allergenic foods to food contact surfaces from a contaminated terry cloth submerged in sanitizer solution (50 ppm of total chlorine) prior to wiping each surface*[a]

Allergen	Food contact surface	Surface 1	Surface 2	Surface 3	Surface 4
0.05 g of whole egg crystals	SS	3/3[b]	3/3	0/3[c]	0/3
	Plastic	3/3	3/3	0/3[c]	0/3
	Wood	3/3	0/3[c]	0/3	0/3
0.05 g of peanut powder	SS	3/3[d]	(vf+) 1/3	0/3[c]	0/3
	Plastic	3/3	(vf+) 3/3	0/3[c]	0/3
	Wood	1/3	0/3[c]	0/3	0/3
0.05 g of NFDMP	SS	3/3	0/3[c]	0/3	0/3
	Plastic	3/3	0/3[c]	0/3	0/3
	Wood	(vf+) 1/3	0/3[c]	0/3	0/3

[a] Surfaces 1 to 4 are visibly clean unless noted otherwise. (vf+), very faint positive LFD response. NFDMP, nonfat dry milk powder. Neogen Reveal 3-D peanut LOD: 2 μg peanut per 100 cm^2. Reveal 3-D total milk LOD: 20 μg milk per 100 cm^2. Reveal 3-D egg LOD: 10 μg egg per 100 cm^2 (new enhanced egg kit).
[b] Ratio identifies the number of positive LFD responses/total LFDs used.
[c] The first surface with no allergen residue transfer, as shown with a 0 of 3 LFD response.
[d] Very slight residue observed.

surface may provide one explanation for the many faint positive LFD results detected on wood, compared with the positive LFD results registered on the smooth SS or textured plastic surfaces. Additionally, the lower protein content in the mayonnaise compared with the egg powder may have been responsible for the mixed and faint positive results for allergen transfer on surface 4. One disparity of note in Table 10 is with the 0.1 g of peanut butter transfer experiment between SS surface 3 in which 0 of 3 LFD results were observed and SS surface 4, with 1 of 3 positive LFD responses. A possible explanation is that peanut butter present on the wipe did not make contact with SS coupon 3 but was able to transfer to SS surface 4 during the wiping step. Experiments with whole fluid milk and cream cheese showed milk transfer to all SS, and plastic surface 4 from the dry wipe, with only faint positives noted on the wood surface.

Prior studies have shown that reusable wiping cloths harbored bacteria when they were not stored in sanitizing solutions *(10, 19)*. The Food Code guidelines on use limitations for wipe cloths, as discussed in Subparagraph 3-304.14 (B)(1), were followed to determine the extent of allergen transfer from a wet terry wipe cloth that is contaminated with allergen *(23)*. The objective was to simulate current recommendations for use and storage of a cloth, by submerging the allergen-contaminated wipe cloth in sanitizer solution before wiping each surface. Storage of the cloth in sanitizer solution prior to wiping each surface resulted in no dry allergen transfer to some surface 2 and no transfer to surface 3 (Table 11) for the dry forms of peanut and egg allergens investigated in this study. The NFDMP, on the other hand, showed no transfer to surface 2 when the cloth was stored in sanitizer solution prior to wiping surfaces. The detection of allergen residue on surface 1 was expected because the allergen was added directly to the wet sanitizer-soaked cloth and transferred immediately to surface 1, with the intentional objective to show allergen transfer from wet allergen contaminated terry cloth to the initial surface. Note that the peanut powder and NFDMP both had minimal transfer of allergen from the cloth to wood surface 1, which may be attributed to the porous nature of the wood surface.

A wet terry cloth contaminated with wet, paste, or sticky allergens (Table 12) that was submerged in sanitizer solution before wiping surfaces transferred allergens to a lesser extent than the dry paper wipes (Table 10). Minimal fluid milk transfer was noted on SS and plastic surface 1, and no detectable milk transfer on surface 2 was observed for all surfaces (Table 12). Interestingly, fluid milk (1 mL) was not detected by LFD on wood surface 1 in all three trials, which may be due to absorption of the milk by the wood surface and/or the wet terry cloth. Cream cheese (2 g) was not detectable on SS or wood surface 3 but was detected in 1 of 3 trials on textured plastic surface 3. The wipe cloths contaminated with 2 g of mayonnaise showed no detectable transfer of egg allergen to surface 3 for SS, plastic, and wood when the cloth was submerged in the sanitizer pail between wiping surfaces. Peanut butter (0.1 g) resulted in the greatest extent of allergen transfer from the wipe cloth to surface 3 SS, plastic, and wood in triplicate tests. However, surface 4 (plastic and wood) resulted in no peanut transfer (0 of 3), while the SS surface 4 had one very faint positive (1 of 3) peanut LFD response.

Overall, the results of the allergen transfer study indicate that the current Food Code *(23)* recommendations for use limitations requiring wipe cloth storage in sanitizer pails between use minimizes allergen transfer from the wipe cloths to surfaces. When soiled wipe cloths are stored in the sanitizer pail, the food present on cloths is likely transferred to the sanitizer solution and increases the food load to the solution. This results in a depletion of active sanitizer (chlorine) in the sanitizer solution and a need to replace the solution when concentrations are below the specific temperature or sanitizer guidelines as stated in the Food Code *(23)*. The practice of preparing fresh sanitizer solution helps prevent the buildup of food soils and allergens in the sanitizer solution, which potentially could contaminate food contact surfaces and also ensures that sanitizer levels are at

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TABLE 12. *Transfer of wet, paste, or sticky allergenic foods to food contact surfaces from a contaminated terry cloth submerged in sanitizer solution (50 ppm of total chlorine) prior to wiping each surface*[a]

Allergen	Food contact surface	Surface 1	Surface 2	Surface 3	Surface 4
2.0 g of mayonnaise	SS	3/3[b,c]	0/3[d]	0/3	0/3
	Plastic	3/3	2/3	0/3[d]	0/3
	Wood	3/3	(f+) 1/3	0/3[d]	0/3
0.1 g of peanut butter	SS	3/3[c]	3/3	2/3	(vf+) 1/3
	Plastic	3/3	3/3	(f+) 3/3	0/3[d]
	Wood	3/3	(vf+) 3/3	(vf+) 1/3	0/3[d]
1 mL of whole milk	SS	(vf+) 1/3	0/3[d]	0/3	0/3
	Plastic	(vf+) 1/3	0/3[d]	0/3	0/3
	Wood	0/3[d]	0/3	0/3	0/3
2 g of cream cheese	SS	(vf+) 3/3	(vf+) 2/3	0/3[d]	0/3
	Plastic	3/3	(f.+) 3/3	1/3	0/3[d]
	Wood	(vf+) 3/3	(vf+) 1/3	0/3[d]	0/3

[a] Surfaces 1 to 4 are visibly clean unless noted otherwise. (f+), faint positive LFD response. (vf+), very faint positive LFD response. Neogen Reveal 3-D peanut LOD: 2 μg peanut per100 cm^2. Reveal 3-D total milk LOD: 20 μg milk per 100 cm^2. Neogen Reveal 3-D egg LOD: 10 μg egg per 100 cm^2 (new enhanced egg kit).
[b] Ratio identifies the number of positive LFD responses/total LFDs used.
[c] Very light sheen observed.
[d] First surface with no allergen residue transfer, as shown with a 0 of 3 LFD responses.

appropriate levels to address microbial concerns. Although most of the coupons were visually clean when examined after wiping, allergens were detected with LFD tests on some of the surfaces. The inability to visually detect food residue on surfaces during the transfer study may be due the very low amounts of allergenic foods on the surfaces and the color and texture of the coupons that prevented visual detection of residue.

Some limitations of this study include the absence of blinded tests for determination of visually clean surfaces, a lack of uniformity of how the allergenic foods were applied to the surfaces, an inability to quantify allergens remaining on the surface, and focusing on a single allergen matrix instead of food allergen mixtures, among others. In addition, the wiping, cleaning, and allergen transfer study was performed on freshly applied food soils. The results would likely have been different if foods were dried onto surfaces prior to wiping because dried food soils can be difficult to remove *(16)*. The manual cleaning process is also subjective and typically conducted to a specific end point, which is often the visually clean standard. Although efforts to conduct the experiments in the same manner were made, subtle differences in the amount of pressure used in wiping and cleaning, absorbency of the wipe, and varying saturation levels of the cloth may impact the effectiveness of allergen removal and transfer. Additionally, the surfaces used in this study were similar in color (white polyethylene plastic and natural maple hardwood) to some of the allergens (NFDMP, whole liquid milk, cream cheese, mayonnaise, peanut butter, and peanut powder) used, which occasionally made visual inspection for allergen residue challenging at times. Future experiments may explore different combinations of allergen food soils, other allergen-specific LFD tests, quantitative tests, various colored surfaces and topologies, as well as a range of different detergent concentrations, including varying time and temperature parameters for cleaning and wiping.

Overall, the nature and amount of allergen on a surface, as well as the type and state of wipe cloth, food contact surface texture and material composition, influenced the effectiveness of wiping and washing treatments on allergen removal and the extent of allergen transfer on surfaces. In summary, the wiping study suggested that wet terry cloth (soaked in tap water or sanitizer solution) and alcohol quat wipes were generally more effective in allergen removal than dry wipes. Additionally, allergenic foods in this study appeared to be more difficult to remove from the textured plastic surface than the SS or wood surfaces. In general, the full cleaning method (wash–rinse-sanitize–air dry) for manual warewashing with detergent and sanitizer was effective at removing most allergenic food residues and tended to be more effective at removing higher allergen loads from surfaces than using wipes or cloths alone. A prescrape step prior to washing improved the removal of peanut butter on surfaces. Due to the nature of peanut butter and its adherence to textured plastic, multiple washings or use of dedicated cutting surfaces are recommended. Contaminated dry paper wipes tended to transfer allergens to subsequently wiped surfaces under the conditions of this study. However, storage of cloths in sanitizer solution between wiping surfaces, as prescribed in the Food Code *(23),* minimized allergen transfer. Many of the surfaces tested in this study had only faint positive responses for the allergen, suggesting that the amount of allergen residue may be near the LOD of the LFD. Although more research is needed to understand the potential health hazard of residues detected by LFDs in this study, using a visibly clean end point in combination with other food safety measures appears to be prudent approaches for allergen removal.

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Further research is needed to quantify the amount of allergen present on surfaces when faint positive results are registered. Additional research is also needed to evaluate the amount of transfer from surfaces with low amounts of allergenic residue to other food items.

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SUPPLEMENTAL MATERIAL

Supplemental material associated with this article can be found online at: https://doi.org/10.4315/JFP-20-025.s1

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Review of statutory and voluntary labelling of food allergens*

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Food allergy represents an increasingly important health problem, with prevalence in Western Europe continuing to rise. While some reactions are mild, others can include life-threatening anaphylactic shock. It is estimated that food allergies affect 1–2% of the adult population and ≤8% of children. Relatively few foods are to blame for a large majority of allergic reactions to food in the UK, with most reactions being to milk, eggs, peanuts (*Arachis hypogea*), nuts, fish, shellfish, soyabean, sesame (*Sesamum indicum* L.) and wheat. There is currently no cure for food allergy and the few available treatments are focused on relieving the specific symptoms. Consumers with food allergies and food intolerances rely on food labelling to enable them to make informed choices about the foods they eat. Whilst there have recently been important advances in the labelling of food allergens, these advances relate only to requirements for the labelling of the deliberate use of specified food allergens in foods sold pre-packed. In other areas the development of guidance for food manufacturers and retailers on how to assess the risks of possible allergen cross-contamination during food production and manufacture, and then to determine appropriate advisory labelling, is well advanced. Work to address the issue of how to provide appropriate allergen information for foods sold loose, or in catering establishments, is also in progress.

Food allergens: Labelling: Legislation: Voluntary guidance

Food intolerance and food allergy are both types of food sensitivity. In the past the term 'intolerance' was used as a generic term and included food allergies. However, more recently, the generic terms 'food sensitivity' or 'food hypersensitivity' have been used increasingly to describe both food allergy and food intolerance (Johansson *et al*. 2004).

Food intolerance is a reproducible adverse reaction to a food or food ingredient that does not involve the immune system. It is used to describe a range of adverse responses to food, including reactions resulting from enzyme deficiencies and pharmacological effects. Examples of food intolerance include lactose intolerance or reactions to histamine found naturally in some foods.

Food allergy can be defined as a reproducible adverse reaction to a food or food ingredient that involves the immune system. The foods that most commonly trigger allergic reactions in the UK and Europe are peanuts (*Arachis hypogea*), tree nuts (which include cashew (*Anacardium occidentale* L.), almond (*Amygdalus communis* L.), hazelnut (*Corylus avellana*), pecan (*Carya illinoensis* (Wangenh.) K. koch), walnut (*Juglans regia*), Brazil nut (*Bertolletia excelsa*), pistachio nut (*Pistacia vera*) and macedemia nut and Queensland nut (*Macedemia temifolia*)), fish and shellfish, eggs and milk (Young *et al*. 1994; Food and Agriculture Organization, 1995). The majority of these reactions are mediated by IgE, which is part of the normal immune system response to foreign proteins that in those individuals with food allergies is inappropriately directed towards everyday food constituents.

Allergic reactions mediated by IgE are immediate and can be severe, triggering the immune system, in particular mast cells, to release inflammatory products such as histamine. Mast cells are present below the surface of the skin and in the membranes of the eyes, nose, respiratory tract and intestine. When triggered, the release of histamine from these mast cells causes symptoms such as itchy rashes, rhinitis, asthma, eczema, dilation of blood vessels, flushing, swelling (e.g. of the lips and face), difficulty breathing and ultimately collapse. These symptoms can appear within minutes or up to several hours after the individual has eaten the food to which they are allergic (Taylor, 1987).

Although food allergies are normally mediated via IgE, in coeliac disease (also known as gluten intolerance or gluten sensitivity) the reaction is mediated by a different

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Ig, IgG, and the types of reaction experienced in individuals with coeliac disease are distinct from those experienced by individuals with a food allergy. In such individuals consumption of gluten (a storage protein found in wheat, rye, barley and oats) causes intestinal villous atrophy (flattening) and its physiological consequences of malabsorption and malnutrition.

It is widely accepted that the prevalence of food allergy in general is increasing in line with other atopic conditions (Howarth, 1998; Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment, 2002; UK Parliament Health Committee, 2004). The prevalence of allergies to particular foods is not known, although ≤20–30% of the general population perceive themselves to have a food allergy or some other adverse reaction to food (Young *et al*. 1994; Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment, 2002; Woods *et al*. 2002). However, the true prevalence of food allergy is estimated to be between 1 and 2% in adults and approximately 5–8% in children (Helm & Burks, 2000).

In Western Europe and the USA most immunological adverse reactions are caused by a limited number of foods. The prevalence of allergy to particular foods varies geographically, probably as a result of different regional dietary practices and dissimilar exposure to allergens (Hourihane, 1998). Peanuts, tree nuts, fish and shellfish cause the majority of allergic reactions in adults in the UK. In children 90% of the reactions are caused by cow's milk, chicken's eggs, wheat, peanuts, tree nuts and soyabean protein. Allergy to cow's milk is the most common food allergy in childhood and affects 2–7% of babies >1 year old. It is more common in babies with atopic dermatitis. A baby who has cow's milk allergy can react to small amounts of milk protein that are either passed to the baby through the mother's breast milk from dairy products she has eaten, or derived from cow's milk or formula based on cow's milk given to the baby.

A key aim of the Food Standards Agency, set out in the 2005–10 Strategic Plan (Food Standards Agency, 2005), is to enable consumers to make informed choices. There is no cure for food allergy and those individuals affected have to adopt management strategies to ensure that they do not consume even small amounts of the foods to which they react. Thus, they need information from food manufacturers, retailers and caterers. Discrepancies between food content and labels can lead to adverse reactions in individuals with sensitivity to particular food components. Conversely, overuse of precautionary labelling can unnecessarily restrict consumer choice and devalue the labelling itself.

Types of allergen labelling

Labelling information requirements are covered by legislation, which sets out the sort of information that needs to be provided, and can also prescribe how that information is presented. For example, the ingredients present in a food have to be listed in decreasing order by weight. Most food labelling requirements in the UK are set out in European legislation, which is then implemented in national legislation, with parallel provisions made in England, Scotland, Wales and Northern Ireland.

However, food manufacturers and retailers may decide voluntarily to provide additional information, beyond what is set out in the legislation. Whilst this information may be helpful for consumers, there can sometimes be confusion if such information is not provided in a consistent way. In such situations, the development of 'best practice' guidance may be helpful.

Statutory labelling requirements

The labelling of most food in the UK is governed by the provisions of the Food Safety Act 1990 (UK Parliament, 1990) and the Food Labelling Regulations 1996 (UK Parliament, 1996) and its subsequent amendments, which set out provisions for the labelling, presentation and advertising of food. The Food Labelling Regulations 1996 (UK Parliament, 1996) require that most pre-packed foods, subject to certain exemptions, carry: a name; a list of ingredients and the amount of the main ingredient used; a date mark; any special storage conditions or conditions of use; the name and address of the manufacturer, packer or EU seller; instructions for use; the place of origin of the food, if failure to give this information might mislead the consumer.

In addition to these provisions, Directive 2000/13/EC of the European Parliament (European Commission, 2000; which consolidates Council Directive 79/112/EEC (European Commission, 1979)) sets out general requirements relating to the listing of ingredients used in foods. However, this legislation contained a number of exemptions that meant that the consumer with food allergies or food intolerances would not always have access to all the information they needed. For example, there was a provision (commonly known as the 25% rule) that meant that if a compound food (e.g. a sponge finger in a trifle or a sausage as a topping on a pizza) made up <25% of the final food, then there was no legal requirement to list all the ingredients used in that compound food ingredient. The consequences of this provision led to pressure for Directive 2000/13/EC (European Commission, 2000) to be amended so that there would be a requirement for full ingredient listing for common food allergens.

The European Directive 2003/89/EC (European Commission, 2003), which amends Directive 2000/13/EC, came into effect in November 2004. This legislation establishes a list of allergenic food ingredients that must be indicated on the label when they or their derivatives are used in food sold pre-packed in the EU. This legislation has a wide scope and includes all food ingredients, including carry-over additives, additives used as processing aids, solvents and media for additives and flavourings. The provisions also apply to alcoholic beverages. New national rules that amend the Food Labelling Regulations 1996 (UK Parliament, 1996) and implement Directive 2003/89/EC (European Commission, 2003) were implemented in 2004 in England by the Food Labelling (Amendment) (No. 2) Regulations 2004 (UK Parliament, 2004), and there is parallel legislation in Scotland (Scottish Parliament, 2004),

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Wales (National Assembly of Wales, 2004) and Northern Ireland (Northern Ireland Assembly, 2004).

Directive 2003/89/EC (European Commission, 2003) abolishes the 25% compound ingredient exemption, and some other existing labelling exemptions will no longer be accepted for allergens. Previously, it was possible to declare some ingredients only as a category, such as vegetable oil. The new rules will require that the source is indicated for all allergenic ingredients, so that, for example, if vegetable oil contains peanut oil it must be specified in the label. Similarly, the source of a natural flavour such as a nut will have to be indicated, rather than being labelled only as 'natural flavour'.

Annex IIIa of Directive 2003/89/EC (European Commission, 2003) currently lists twelve allergenic foods and food ingredients (cereals containing gluten, crustaceans eggs, milk, fish, peanuts (*Arachis hypogea*), soyabeans, nuts, sesame (*Sesamum indicum* L.) seeds, celery (*Apium graveolens*), mustard (*Sinapsis alba* L.) and sulphite (10 mg/kg or >10 mg/l)) for which labelling is required. Whenever the listed ingredients are used in the production of foodstuffs, they must be labelled. However, some individuals are sensitive to allergens that are not on the list, and so it is important that they continue to check ingredients lists carefully. Furthermore, allergenic foods can be added to this list on the advice of the European Food Safety Authority.

There is a transitional period of 1 year in the implementation of this Directive to enable food manufacturers to make the necessary changes to food labels. Thus, products without this labelling cannot be marketed after 25 November 2005, although products already labelled before this time can continue to be sold, whilst stocks last.

A number of factors are responsible for determining whether or not, after exposure to an allergen, an individual with an allergy will experience an adverse reaction. For example, in the case of peanuts some individuals react to as little as 0·1 mg peanut protein, while others can tolerate ≤1 g before suffering an allergic reaction. In addition, as well as inter-individual variability, there is also variability in the same individual on different occasions. For example, for individuals whose allergic reactions to foods include respiratory symptoms, adverse reactions to a given amount of the food allergen can be markedly more severe when concurrent asthma is poorly controlled. Thus, it is not possible to set definitive thresholds for acceptable levels of the different food allergens, as is common practice for setting acceptable levels of chemicals in food (European Food Safety Authority, 2004).

However, some highly processed food ingredients derived from these listed allergenic foods are very unlikely to pose a threat for consumers with food allergies. In addition, other substances that may trigger allergic reactions can be used in such a way that the finished product would not be a risk for individuals with food allergies. During the negotiations on Directive 2003/89/EC (European Commission, 2003), the European Commission accepted that provision should be made for exemption from the labelling requirements for those derivatives that could be demonstrated not to pose a risk to consumers with an allergy. The food industry was therefore invited to submit dossiers of existing information to the European Food Safety Authority to support the exemption of certain derived products. Those derived products that the European Food Safety Authority considered, on the basis of the existing information, to be unlikely to trigger reactions in consumers with an allergy will be exempt, on a provisional basis, from the labelling requirements of 2003/89/EC (European Commission, 2003) that come into force in November 2005. However, industry will have to submit further information on these ingredients for evaluation by the European Food Safety Authority so that a final list of exempt derived ingredients can be developed.

This list of provisionally-exempt derived ingredients (see Table 1) has now been published as an Annex to Directive 2005/26/EC (European Commission, 2005), and a permanent list of exemptions is scheduled to be published by November 2007. Fully-refined peanut oil is not included on this list of exempt derived ingredients because the European Food Safety Authority was of the opinion that, on the basis of existing information, it was possible that this ingredient could cause allergic reactions in individuals who are highly allergic to peanuts. This ruling will have implications both for the food industry, who will have to specifically label the use of this oil, and for consumers who are allergic to peanuts, whose food choices will be further restricted. However, it is possible that further information that would support the exemption of this ingredient could be submitted for evaluation by the European Food Safety Authority.

Voluntary initiatives

As mentioned earlier, some food manufacturers and retailers want to go beyond the statutory labelling requirements and provide additional information for consumers about their products. One area in which such additional information is increasingly being provided relates to the possibility of cross-contamination with allergens during food manufacturing. To date, this information has predominantly referred to possible cross-contamination with nuts and is often indicated using phrases such as 'may contain nuts'. Additionally, whilst allergen-labelling legislation, like most food-labelling legislation, is applicable only to pre-packed foods, there is increasing demand from consumers with food allergies for allergen information about foods sold non-pre-packed. This category can include foods sold loose, such as in a bakery or at a delicatessen counter, food sold pre-packed for direct sale, such as sandwiches, or foods sold in catering establishments.

'May contain'

Consumers who shop for individuals with food allergies and intolerances need clear specific labelling of both deliberate allergenic ingredients and possible cross-contamination in order to be able to make informed food choices. The presence of an undeclared, unintended allergen in food destined for consumption is potentially life-threatening. However, modern processing methods mean that foods not intended to contain a particular allergenic

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Table 1. List of food ingredients and substances provisionally excluded from Annex IIIa of Directive 2000/13/EC (European Commission, 2000) as amended by Directive 2003/89/EC (European Commission, 2003), based on opinions from the European Food Safety Authority Panel on Dietetic Foods, Nutrition and Allergy (European Food Safety Authority, 2004–5)

Ingredients	Products thereof provisionally excluded
Cereals containing gluten	Wheat-based glucose syrups including dextrose
	Wheat-based maltodextrins
	Glucose syrups based on barley
	Cereals used in distillates for spirits
Eggs	Lysozyme (produced from egg) used in wine
	Albumin (produced from egg) used as a fining (clarifying) agent in wine and cider
Fish	Fish gelatine used as a carrier for vitamins and flavours
	Fish gelatine or isinglass used as a fining agent in beer, cider and wine
Soyabean	Fully-refined soyabean oil and fat
	Natural mixed tocopherols (E306), natural D-α-tocopheryl succinate from soyabean sources
	Phytosterols and phytosterol esters derived from vegetable oils obtained from soyabean sources
	Plant stanol ester produced from vegetable oil sterols from soyabean sources
Milk	Whey used in distillates for spirits
	Lactitol
	Milk (casein) products used as fining agents in cider and wines
Nuts	Nuts used in distillates for spirits
	Nuts (almonds (*Amygdalus communis* L.), walnuts (*Juglans regia*)) used (as flavour) in spirits
Celery (*Apium graveolens*)	Celery leaf and seed oil
	Celery seed oleoresin
Mustard (*Sinapsis alba* L.)	Mustard oil
	Mustard seed oil
	Mustard seed oleoresin

ingredient may be produced in the same factory, or even on the same production line, as one containing that ingredient. For example, plain biscuits may be made on the same production line as the nut-containing variety. The potential for allergen contamination of the plain product that is normally suitable for an individual with an allergy can be important.

The statutory labelling requirements for the allergenic foods listed in Directive 2003/89/EC (European Commission, 2003) do not cover the unintentional presence of those allergens in pre-packed foods that can result from cross-contamination with the allergen at some point during the manufacture or transport of the food. Whilst it is helpful for those individuals with severe food allergies to be alerted to such possible cross-contamination, there is general agreement between the food industry, consumers and enforcement bodies that excessive use of these food-allergen warning labels not only restricts consumer choice but also devalues the impact of warnings. There is also concern that the variability between different food manufacturers and retailers in the way in which they convey information about possible allergen cross-contamination leads to consumer confusion. In addition, such advisory labelling is felt by some consumers to be difficult to find and difficult to see.

At the end of 1997 the Ministry of Agriculture, Fisheries and Food wrote to food manufacturers and retailers, asking them to improve their quality control measures and manufacturing processes in order to avoid the use of what was then called ‘defensive labelling’. Some companies already had measures in place to minimise nut trace contamination and had introduced food labels such as ‘may contain nuts’ to warn consumers of the possible presence of nuts in the product.

However, since that time the use of ‘may contain’ warning labels on food products has increased. This situation may have been as a consequence of foods becoming more complex and/or in response to the increasing incidence of food allergy in the UK population. Research conducted for the Food Standards Agency in 2001 and 2002 (Anaphylaxis Campaign, 2001; COI Communications, 2002) has identified this issue as a major problem for consumers with food allergies. The use of logos, wording, style and format was found to vary markedly between different products and between different retailers, as did the process used to decide whether to use nut trace contamination labelling (Anaphylaxis Campaign, 2001; COI Communications, 2002). Following discussions with all stakeholders (food industry, consumers and enforcement bodies), the Food Standards Agency (2005) has made a commitment to produce ‘best practice’ guidance on this issue by 2006. This guidance, which is being produced in consultation with all interested stakeholders, provides advice for food producers and retailers on how to assess the risks of cross-contamination of a food product with an allergenic food or food ingredient. The outcome of such a risk assessment will then determine appropriate advisory labelling. It is also important that consumers with food allergies and food intolerances understand the meaning of any advisory labelling used on a product so that they can make appropriate food choices. A draft of this guidance will be the subject of a formal public consultation exercise, and it is anticipated that the final guidance will be published in 2006.

Non-prepacked foods

There is a diverse range of organisations and establishments that are involved in the provision of non-pre-packed foods for direct sale. These foods are often sold loose and through various outlets, including catering establishments. Anecdotal evidence suggests that most food-allergy

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incidents, including deaths, happen outside the home and can be traced to foods that are not pre-packed, such as those sold in catering establishments.

The Food Standards Agency (2004) has produced 'best practice' guidance for caterers to help them respond to customers who are seeking information about whether particular dishes sold in their establishment contain the ingredient to which the customer is sensitive. Although foods sold non-pre-packed are currently exempt from the allergen-labelling legislation, the Food Standards Agency is consulting stakeholders with the aim of developing possible options for improving the provision of information on the use of allergens in such situations. Again, there will be a formal public consultation on the preferred options.

Allergen labelling in other countries

Although different legislation and guidelines have been developed by various national and international organisations, they often share some common themes. For example, the Food Standards Australia New Zealand (2002) advises that there are eight major allergens (seafood, milk, peanuts, tree nuts, sesame seeds, soyabean, wheat and eggs) that must be declared on the food label, however small the amount added. In the USA the Food Allergen Labelling and Consumer Protection Act (US Congress, 2004) will require, beginning from 1 January 2006, that food manufacturers identify, in plain common language, the presence of any of the eight major food allergens. The legislation requires that food labels indicate the presence of major food allergens used in flavourings, spices, additives and colourings. This Act also compels the Department of Health and Human Services to: improve the collection of food allergy data; convene a panel of experts to review food allergy research efforts; report to Congress on the number of allergen inspections done of food manufacturing facilities over a 2-year period, and the ways in which these facilities can reduce or eliminate cross-contamination; consider revisions of the Food Code (Department of Health and Human Services, 2001) to provide allergen-free preparation guidelines for restaurants and food service establishment; investigate consumer preference pertaining to advisory food labelling such as precautionary 'may contain' statements.

Conclusion

Food labelling information is vitally important for those individuals who have food allergies to enable them to make informed choices about the foods they eat. Whilst there have recently been significant advances in the labelling of food allergens, these relate only to requirements for the labelling of the deliberate use of specified food allergens in foods sold pre-packed. In other areas the development of guidance for food manufacturers and retailers on how to assess the risks of possible allergen cross-contamination during food production and manufacture, and then to determine appropriate advisory labelling, is well advanced. Work to address the issue of how to provide appropriate allergen information for foods sold loose, or in catering establishments is also in progress.

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Serving Up Allergy Labeling: Mitigating Food Allergen Risks in Restaurants

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Allergens in restaurant food cause many allergic reactions and deaths. Yet no federal, state, or local law adequately protects people from these harms. Although federal law requires the labeling of "major food allergens" in packaged food, there are no allergen labeling requirements for restaurant-type food. In addition, existing food safety requirements for restaurants are inadequate to prevent allergen cross contact.

The existing legal scholarship on food allergens in restaurants is limited. Much of the legal scholarship on labeling in restaurants focuses on menu labeling—the provision of calorie and other nutrition information to combat obesity. The requirements of Section 4205 of the Patient Protection and Affordable Care Act exemplify this type of labeling. Although the literature describes the problem of food

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allergens in restaurants, it has not fully explored potential regulatory solutions. This Article explores how, as a first step, menu labeling regulation can inform the development of food allergen regulation to reduce the risks that allergens pose in restaurants and similar retail establishments. It also discusses how menu labeling can help anticipate and respond to potential opposition and challenges to allergen requirements.

Using menu labeling as a guide, this Article argues that certain chain restaurants and similar retail establishments should be required to furnish "major food allergen" labeling upon consumer request in order to advance public health. Labeling changes alone, however, are insufficient to protect people with food allergies. Restaurants should also be required to employ science-based practices to prevent allergen cross contact and ensure their workers are trained on food allergen management. Although state and local governments may play an important role addressing food allergen management in restaurants and advancing public health, ultimately federal action is needed.

INTRODUCTION

Exposure to a food allergen can be deadly.[1] For the estimated nearly 5% of adults and 8% of children with food allergies, eating out may entail significant risk.[2] One study found that "[n]early half of reported fatal food allergy reactions over a 13-year period were caused by food from a restaurant or other food establishment."[3] In another study, nearly 14% of people in a registry of people with peanut and tree nut allergies reported that an allergic reaction had occurred in a restaurant or other food establishment.[4] A follow-up study found that in most of the cases examined, someone in the establishment knew that

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1 Joshua A. Boyce et al., *Guidelines for the Diagnosis and Management of Food Allergy in the United States: Summary of the NIAID-Sponsored Expert Panel Report*, 31 NUTRITION RES. 61, 63 (2011).

2 Scott H. Sicherer & Hugh A. Sampson, *Food Allergy: Epidemiology, Pathogenesis, Diagnosis, and Treatment*, 133 J. ALLERGY & CLINICAL IMMUNOLOGY 291, 291 (2014); *see also infra* Section I.A (discussing prevalence of food allergies and the variations in and limitations of existing data).

3 Taylor J. Radke et al., *Restaurant Food Allergy Practices—Six Selected Sites, United States, 2014*, 66 MORBIDITY & MORTALITY WKLY. REP. 404, 404 (2017); *see also* Christopher Weiss & Anne Muñoz-Furlong, *Fatal Food Allergy Reactions in Restaurants and Food-Service Establishments: Strategies for Prevention*, 28 FOOD PROTECTION TRENDS 657, 658 (2008).

4 *See* Terence J. Furlong et al., *Peanut and Tree Nut Allergic Reactions in Restaurants and Other Food Establishments*, 108 J. ALLERGY & CLINICAL IMMUNOLOGY 867, 867 (2001).

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the food causing the reaction contained peanut or tree nut and that in the remaining cases contamination was reported.[5] In half of the cases where someone in the establishment knew that the food contained peanut or tree nut, the allergen was "hidden," preventing its visual identification.[6] These harms are avoidable. Yet many restaurants lack a comprehensive allergen management system.

There are no federal labeling requirements for common allergens in restaurant-type food.[7] Federal guidance on preventing allergen cross contact is inadequate.[8] And even recently enacted state laws intended to make restaurant-type food safer for people with food allergies fall short. They are generally focused on increasing allergen awareness and training for certain restaurant workers rather than requiring more comprehensive plans and procedures to provide information about the presence of common food allergens and prevent cross contact.[9]

Much of the legal scholarship on labeling in restaurants is focused not on the provision of food allergen information but on the provision of calorie and other nutrition information to consumers as a means to address public health concerns related to obesity.[10] The calorie and nutritional labeling provisions are commonly referred to as "menu labeling" because the information is provided on menus and menu boards.[11] Although the existing literature has described the problems

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5 *Id.* at 868.

6 *Id.*

7 *See infra* Section I.B.

8 *See infra* Section I.C.1. Cross contact is when "a residue or other trace amount of an allergenic food is unintentionally incorporated into another food." *Food Allergies: Reducing the Risks*, FDA: CONSUMER UPDATES, https://www.fda.gov/forconsumers/consumerupdates/ucm089307.htm (last updated Dec. 18, 2017); *see also Avoiding Cross Contact*, FOOD ALLERGY RES. & EDUC., https://www.foodallergy.org/life-with-food-allergies/living-well-everyday/avoiding-cross-contact (last visited Aug. 11, 2018) (noting that cross contact is "not universally used in the food service industry" and that "[t]he commonly used term is cross-contamination").

9 *See infra* Section I.C.2. As this Article was going to press, the Township of Edison, New Jersey approved an ordinance that provides that as of April 1, 2019, restaurants "must identify on a menu all food items that contain or are prepared with" any of the following: "milk, eggs, peanuts, tree nuts, fish, shellfish, soy and wheat," or "monosodium glutamate ('MSG') and commercial sulfites used as a food preservative or additive." Edison Township, N.J., Ordinance O.2015-2018 (Aug. 22, 2018). The ordinance also provides that by that same date restaurants "must indicate on their public display menu sign . . . that such menus are available." *Id.* Of note, the ordinance does not address the prevention of cross contact. *Id.*

10 *See* Laura E. Derr, *When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004*, 61 FOOD & DRUG L. J. 65, 156–57 (2006).

11 Menu labeling generally refers to requirements that certain restaurants provide calorie and other nutrition information to consumers on menus, menu boards, or other labeling. *See,*

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posed by the lack of food allergen labeling and management requirements, it has not thoroughly explored possible solutions. This Article explores how menu labeling can and should inform the regulation of allergen labeling and management in restaurants. This examination is timely as the final compliance date for the Food and Drug Administration's (FDA) menu labeling rule was May 7, 2018.[12]

This Article approaches the issue of food allergens in restaurants and similar retail establishments from a public health law perspective.[13] It considers how law can help to reduce allergic reactions triggered by food allergens in restaurants, while respecting the autonomy of individuals with food allergies. Using lessons drawn from menu labeling, this Article argues that certain chain restaurants that sell standardized menu items should be required to make labeling for "major food allergens" in restaurant-type foods available to consumers upon request.[14]

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e.g., Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,160 (Dec. 1, 2014) (codified at 21 C.F.R. pts. 11, 101).

[12] *See* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments, 82 Fed. Reg. 20,825, 20,825 (May 4, 2017).

[13] Public health law considers "the legal powers and duties of the state, in collaboration with its partners . . . to ensure the conditions for people to be healthy and . . . the limitations on the power of the state to constrain the autonomy, privacy, liberty, proprietary, or other legally protected interests of individuals." PUBLIC HEALTH LAW AND ETHICS: A READER 9 (Lawrence O. Gostin ed., 2d ed. 2010).

[14] These allergens are milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans. Federal Food, Drug, and Cosmetic Act (FDCA) § 201(q), 21 U.S.C. § 321(q) (2012). These eight allergens or groups of allergens account for 90% of food allergies in the United States. FDCA § 403 note, 21 U.S.C. § 343 note. This Article does not address the management of food allergens in schools, prisons, and airplanes due to the unique considerations that they pose. Schools, prisons, and airplanes are also not covered by FDA's interpretation of the menu labeling provisions of the Patient Protection and Affordable Care Act (ACA). *See* Food Labeling, 79 Fed. Reg. at 71,169, 71,171; FDA, GUIDANCE FOR INDUSTRY: A LABELING GUIDE FOR RESTAURANTS AND RETAIL ESTABLISHMENTS SELLING AWAY-FROM-HOME FOODS – PART II (MENU LABELING REQUIREMENTS IN ACCORDANCE WITH 21 CFR 101.11) (Apr. 2016), https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm461963.pdf; *see also* Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, § 4205, 124 Stat. 119 (2010) (codified at FDCA §§ 403, 403A, 21 U.S.C. §§ 343, 343-1). For a discussion of food allergen management in airplanes and schools see, e.g., John G. Browning, *Keep Your Hands Off My Nuts—Airlines, Peanut Allergies, and the Law*, 77 J. AIR L. & COM. 3, 4 (2012); Michael Borella, *Food Allergies in Public Schools: Toward a Model Code*, 85 CHI.-KENT L. REV. 761 (2010); Heather Martone, *2.2 Million Children Left Behind: Food Allergies in American Schools–A Study of the Food Allergy and Anaphylaxis Management Act*, 18 J.L. & POL'Y 775, 776 (2010). *See also* 21 U.S.C. § 2205 (Supp. IV 2016); CTRS.

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Labeling changes alone, however, are not enough because without other changes, labeling may increase the risks for consumers with food allergies. For example, if food is mislabeled or has an allergen due to cross contact, a person with a food allergy may consume the food thinking that it is safe and have an allergic reaction. Although a full examination of measures to prevent allergen cross contact, train restaurant workers, and educate the public about food allergies is beyond the scope of this Article, such measures are also needed to help prevent allergic reactions triggered by restaurant foods. This Article recognizes that preventing food allergen cross contact and ensuring accurate labeling in restaurants will likely raise difficult and complex questions. Existing processes should be used to begin to address these questions.

This Article also draws from the literature on the regulation of menu labeling to explore how federal, state, and local governments might require food allergen labeling and management. As in the menu labeling context, the enactment of comprehensive food allergen requirements at the local and state levels may serve as the catalyst for federal reform. Ultimately, this Article argues that changes to federal law are needed to address the labeling and management of food allergens in restaurant-type food.

This Article proceeds in several parts: Part I provides an introduction to food allergies and the risks that food allergens in restaurants may pose to consumers who have allergies. It then describes the federal allergen labeling requirements for prepackaged food and the corresponding gap in the regulation of allergen labeling for restaurant-type food. It also discusses other laws bearing on food allergens in restaurants and their limitations. Part II provides an overview of efforts to regulate menu labeling, including New York City's menu labeling rules, Section 4205 of the Patient Protection and Affordable Care Act, and FDA's menu labeling regulations.[15] Part III draws on this examination to argue for allergen labeling requirements for restaurants and accompanying management requirements, and to address counterarguments, including that food allergen requirements would be too difficult or costly for restaurants. Part IV then draws on the earlier examination of menu labeling to explore how federal, state, and local

FOR DISEASE CONTROL & PREVENTION, VOLUNTARY GUIDELINES FOR MANAGING FOOD ALLERGIES IN SCHOOLS AND EARLY CARE AND EDUCATION PROGRAMS (2013).

[15] FDCA §§ 403, 403A, 21 U.S.C. §§ 343, 343-1 (codifying portions of section 4205 of the ACA); Food Labeling, 79 Fed. Reg. at 71,156; N.Y.C., N.Y., HEALTH CODE § 81.50 (2006), *invalidated by* New York State Rest. Ass'n v. N.Y.C. Bd. of Health, 509 F. Supp. 2d 351, 352 (S.D.N.Y. 2007); N.Y.C., N.Y., HEALTH CODE § 81.50 (2008).

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governments could enact these changes and the potential benefits of federal action.

I
RESTAURANTS, FOOD ALLERGIES, AND THE LIMITATIONS OF EXISTING LAW

A. Food Allergies and Restaurants

A food allergy is an adverse immune response to food.[16] Food allergy management necessarily depends heavily on avoidance of the allergen.[17] Food allergens are the "specific components of food or ingredients within food . . . that are recognized by allergen-specific immune cells and elicit specific immunologic reactions, resulting in characteristic symptoms."[18] In 2011, an expert panel sponsored by the National Institute of Allergy and Infectious Diseases concluded that there are "no medications . . . recommended . . . to prevent . . . food-induced allergic reactions from occurring in an individual with [an] existing [food allergy]."[19] Accordingly, the first line of treatment is allergen avoidance.[20] For allergic individuals, failure to avoid food allergens can result in a reaction, including anaphylaxis, "a serious allergic reaction that is rapid in onset and may cause death."[21]

Determining the prevalence of food allergies in the United States is difficult and estimates vary.[22] A 2010 review and analysis of the available evidence regarding the prevalence of allergies found that they "affect more than 1% or 2% but less than 10% of the US population."[23]

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16 Boyce et al., *supra* note 1, at 64 (defining food allergy as "an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food"). Food allergies are distinct from food intolerances. *Id.* at 65.

17 *Id.* at 69–73 (treatment guidelines); A. Wesley Burks et al., *ICON: Food Allergy*, 129 J. ALLERGY & CLINICAL IMMUNOLOGY 906, 915 (2012).

18 Boyce et al., *supra* note 1, at 64.

19 *Id.* at 69 (emphasis omitted).

20 *Id.*

21 *Id.* at 66 tbl.1 (noting various symptoms of food-induced allergic reactions).

22 *See, e.g.*, NAT'L ACADS. SCIS., ENG'G, & MED., FINDING A PATH TO SAFETY IN FOOD ALLERGY: ASSESSMENT OF THE GLOBAL BURDEN, CAUSES, PREVENTION, MANAGEMENT, AND PUBLIC POLICY (Virginia A. Stallings & Maria P. Oria eds. 2017); *see also* Scott H. Sicherer, *Epidemiology of Food Allergy*, 127 J. ALLERGY & CLINICAL IMMUNOLOGY 594, 594, 597–98 (2011) (discussing study limitations).

23 Jennifer J. Schneider Chafen et al., *Diagnosing and Managing Common Food Allergies: A Systematic Review*, 303 JAMA 1848, 1849, 1853 (2010) (focusing on allergies to "cow's milk, hen's egg, peanut, tree nut, fish, and shellfish"); *see also* KRISTEN D. JACKSON ET AL., NCHS DATA BRIEF NO. 121, TRENDS IN ALLERGIC CONDITIONS AMONG

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More recent estimates indicate that food allergies likely affect almost 5% of adults and 8% of children,[24] although one recent study estimated the prevalence of food allergies and intolerances to be about 4%.[25] The prevalence of food allergies is thought to be increasing.[26] Despite the fact that "more than 170 foods have been identified as being potentially allergenic,"[27] only a few foods account for the majority of food allergic reactions.[28]

Unanticipated exposure to food allergens is not uncommon. Each year there are approximately 203,000 emergency room visits for food-related acute allergic reactions in the United States, which translates to one visit every three minutes.[29] Anaphylaxis to food leads to an estimated 30,000 emergency room visits and an estimated 150 deaths each year in the United States.[30] Most anaphylactic reactions take place outside of the home, with 25% taking place while dining at restaurants.[31] Even when allergic individuals are actively avoiding the allergen, allergic reactions can occur.[32] A number of fatal reactions have occurred at restaurants or in association with restaurant food.[33]

CHILDREN: UNITED STATES, 1997–2011 (2013) (reporting on trends in food allergy prevalence for children).

24 Sicherer & Sampson, *supra* note 2, at 292.

25 Warren W. Acker et al., *Prevalence of Food Allergies and Intolerances Documented in Electronic Health Records*, 140 J. ALLERGY & CLINICAL IMMUNOLOGY 1587, 1589 (2017) (estimating the prevalence of food allergies and intolerances to be 3.6%).

26 *See* JACKSON ET AL., *supra* note 23; Sicherer & Sampson, *supra* note 2, at 292. In addition, new foods may pose allergy risks. Diane Thue-Vasquez, *Genetic Engineering and Food Labeling: A Continuing Controversy*, 10 SAN JOAQUIN AGRIC. L. REV. 77, 93 (2000).

27 Burks et al., *supra* note 17, at 906.

28 *Id.* at 906–07; Hugh A. Sampson, *Update on Food Allergy*, 113 J. ALLERGY & CLINICAL IMMUNOLOGY 805, 807 (2004) (stating that "[m]ilk, egg, and peanut account for the vast majority of food-induced allergic reactions in American children" and "peanut, tree nuts, fish, and shellfish account for most of the food-induced allergic reactions in American adults").

29 Sunday Clark et al., Letter to the Editor, *Frequency of US Emergency Department Visits for Food-Related Acute Allergic Reactions*, 127 J. ALLERGY & CLINICAL IMMUNOLOGY 682, 682 (2011); *Facts and Statistics*, FOOD ALLERGY RES. & EDUC., https://www.foodallergy.org/life-food-allergies/food-allergy-101/facts-and-statistics (last visited Feb. 13, 2018). Anaphylaxis is an acute allergic reaction. *Id.*

30 FDA, FOOD FACTS, FOOD ALLERGIES: WHAT YOU NEED TO KNOW (2017). And anaphylaxis may be underreported. *See* F. Estelle R. Simons, *Anaphylaxis*, 125 J. ALLERGY & CLINICAL IMMUNOLOGY S161, S161 (2010).

31 J. Leftwich et al., *The Challenges for Nut-Allergic Consumers of Eating Out*, 41 CLINICAL & EXPERIMENTAL ALLERGY 243, 247 (2010).

32 Furlong et al., *supra* note 4, at 868.

33 *See* Weiss & Muñoz-Furlong, *supra* note 3, at 658–59; *see also* Roxanne Dupuis et al., *Food Allergy Management Among Restaurant Workers in a Large U.S. City*, 63 FOOD CONTROL 147 (2016); Furlong et al., *supra* note 4, at 869; Hugh A. Sampson, *Peanut Allergy*, 346 NEW ENG. J. MED. 1294 (2002); S. Allan Bock et al., Letter to the Editor,

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At the same time, Americans are increasingly turning to restaurants and other retail food establishments for food away from home,[34] and the growth in demand for food away from home is expected to continue over the remainder of the decade.[35] From 1960 to 2000, "spending on away-from-home foods as a percentage of total food expenditure . . . steadily [rose] by approximately 5–6% per decade."[36] More Americans ate out in 1999–2000 than in 1987, and they did so with a greater frequency.[37] In 2002, the National Restaurant Association (NRA) reported that Americans over the age of seven, on average, eat 218 restaurant meals a year.[38] Another report found that on average those aged 16–34 eat out 3.8 times a week, compared to 2.8 times a week for those aged 35–74.[39] The share of caloric intake from food prepared away from home has also increased.[40] And in 2014, for the first time on record, the monthly sales at restaurants surpassed those at

Further Fatalities Caused by Anaphylactic Reactions to Food, 2001–2006, 119 J. ALLERGY & CLINICAL IMMUNOLOGY 1016 (2007).

34 HAYDEN STEWART ET AL., U.S. DEP'T OF AGRIC., AGRIC. ECON. REP. NO. 829, THE DEMAND FOR FOOD AWAY FROM HOME: FULL-SERVICE OR FAST FOOD? (2004) [hereinafter STEWART ET AL., FOOD AWAY FROM HOME]; HAYDEN STEWART ET AL., U.S. DEP'T OF AGRIC., ECON. INFO. BULL. NO. 19, LET'S EAT OUT: AMERICANS WEIGH TASTE, CONVENIENCE, AND NUTRITION (2006) [hereinafter STEWART ET AL., LET'S EAT OUT].

35 STEWART ET AL., FOOD AWAY FROM HOME, *supra* note 34, at 2.

36 Ashima K. Kant & Barry I. Graubard, *Eating Out In America, 1987–2000: Trends and Nutritional Correlates*, 38 PREVENTIVE MED. 243, 243 (2004). *But see Table 10—Food Away from Home as a Share of Food Expenditures*, U.S. DEP'T OF AGRIC. ECON. RES. SERV.: FOOD EXPENDITURES (Jan. 26, 2016), https://www.ers.usda.gov/data-products/food-expenditure-series/food-expenditure-series/#Food [https://web.archive.org/web/20170223202214/https://www.ers.usda.gov/webdocs/DataFiles/Food_Expenditures__17981/FoodExpenditures_table10.xls] (showing that overall, from 1929 to 2014, food away from home as a share of food expenditures increased, but there were years that it decreased); BIING-HWAN LIN & JOANNE GUTHRIE, U.S. DEP'T OF AGRIC., ECON. INFO. BULL. NO. 105, NUTRITIONAL QUALITY OF FOOD PREPARED AT HOME AND AWAY FROM HOME, 1977–2008 (2012) (noting a decline from 2006–2007 to 2010). Although away from home food estimates include schools, as noted earlier, this Article does not address allergen labeling and management in schools. *See supra* note 14.

37 Kant & Graubard, *supra* note 36, at 247.

38 *See* CTR. FOR SCI. IN THE PUB. INTEREST, ANYONE'S GUESS: THE NEED FOR NUTRITION LABELING AT FAST-FOOD AND OTHER CHAIN RESTAURANTS (2003).

39 CHRISTINE BARTON ET AL., BOS. CONSULTING GRP., MILLENNIALS PASSIONS: FOOD, FASHION, AND FRIENDS (2012).

40 LIN & GUTHRIE, *supra* note 36, at iii. Changes in survey methodology may have contributed to the reported increase. *Id.* at 3–4; *see also* Ji Hee Choi & Lakshman Rajagopal, *Food Allergy Knowledge, Attitudes, Practices, and Training of Foodservice Workers at a University Foodservice Operation in the Midwestern United States*, 31 FOOD CONTROL 474, 474 (2013) (discussing the foodservice industry in the United States).

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grocery stores.[41]

Although restaurants obviously provide food, they "are about more than what you get on the plate."[42] Among other things, they can provide leisure and social enjoyment,[43] serve as loci for the conduct of business,[44] and help facilitate travel.[45] Indeed, the broader significance of restaurants in the United States is reflected in the centrality of restaurant accessibility to the civil and disability rights movements.[46]

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41 *Restaurant Sales Surpass Grocery Store Sales*, NAT'L RESTAURANT ASS'N: NEWS & RES. (May 13, 2015), https://www.restaurant.org/News-Research/News/Restaurant-sales-surpass-grocery-store-sales-for-t [https://web.archive.org/web/20150515012802/https://www.restaurant.org/News-Research/News/Restaurant-sales-surpass-grocery-store-sales-for-t].

42 *Four Critics, One Restaurant's Food, Sound, Design, Fashion*, WASH. POST: MAG. (Mar. 27, 2014), https://www.washingtonpost.com/lifestyle/magazine/four-critics-one-restaurants-food-sound-design-fashion/2014/03/27/292d6732-9a6d-11e3-b931-0204122c514b_story.html?noredirect=on&utm_term=.4547fae86f1c; Inga-Britt Gustafsson, *Culinary Arts and Meal Science—A New Scientific Research Discipline*, 4 FOOD SERV. TECH. 9 (2004); *see also* NAT'L REST. ASS'N, 2017 RESTAURANT INDUSTRY POCKET FACTBOOK (2017) [hereinafter 2017 FACTBOOK].

43 *See, e.g.*, 2017 FACTBOOK, *supra* note 42; *see also* ALAN WARDE & LYDIA MARTENS, EATING OUT: SOCIAL DIFFERENTIATION, CONSUMPTION AND PLEASURE 18 (2000). For example, one sociological study of food consumption outside the home in England in the 1990s, found that diners claim a "great sense of pleasure and satisfaction . . . from eating out" and that "[e]ating out is a major . . . conduit for sociable interaction." WARDE & MARTENS, *supra*, at 215–27.

44 *See, e.g.*, Anna Nicholson Bass, *From Business Dining to Public Speaking: Tips for Acquiring Professional Presence and Its Role in the Business Curricula*, 3 AM. J. BUS. EDUC. 57, 60–61 (2010) (discussing dining etiquette and noting that "[y]our manners at business meals can affect your success in being hired and promoted and in conducting business with clients"); Wendy Gerzog Shaller, *Reforming the Business Meal Deduction: Matching Statutory Limitations with General Tax Policy*, 24 DUQ. L. REV. 1129 (1986). For example, one survey found that "49 percent of chief financial officers said their most successful business meetings, outside the office, were conducted at a restaurant." JACQUELINE WHITMORE, BUSINESS CLASS: ETIQUETTE ESSENTIALS FOR SUCCESS AT WORK 81 (2005) (referencing a survey).

45 *See, e.g.*, Katzenbach v. McClung, 379 U.S. 294, 304 (1964) (holding that Congress "had a rational basis for finding that racial discrimination in restaurants had a direct and adverse effect on the free flow of interstate commerce"). In *Katzenbach*, the Supreme Court noted that during the Congressional Hearings on the Civil Rights Act,

> there was an impressive array of testimony that discrimination in restaurants had a direct and highly restrictive effect upon interstate travel by Negroes. This resulted, it was said, because discriminatory practices prevent Negroes from buying prepared food served on the premises while on a trip, except in isolated and unkempt restaurants and under most unsatisfactory and often unpleasant conditions. This obviously discourages travel and obstructs interstate commerce for one can hardly travel without eating.

Id. at 300.

46 *See, e.g.*, *id.* at 294; Press Release, U.S. Dep't of Justice, U.S. Attorney's Office, E. Dist. of Pa., U.S. Attorney Launches Review of 25 Restaurants for Compliance with Americans with Disabilities Act (Mar. 11, 2015), https://www.justice.gov/usao-edpa/pr/us-attorney-launches-review-25-restaurants-compliance-americans-disabilities-act; HARRIS

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Both the Civil Rights Act of 1964 and the Americans with Disabilities Act contain provisions regarding restaurants.[47] As one civil rights activist remarked in 1960, the "sit-ins and other demonstrations are concerned with something much bigger than a hamburger or even a giant-sized Coke."[48] Access to restaurants is a part of full first-class citizenship,[49] and restaurants are an important component of culture in the United States.[50]

But the act of eating out, which many may take for granted, may pose significant risks for individuals with a food allergy, and they may seek to avoid these risks by not eating out or only eating at certain restaurants.[51] This is consistent with research suggesting that "food allergic patients may . . . perceive that they . . . are more physically restricted (for example, in terms of travel, occupational opportunities, or attending social events) compared to non-food allergic people."[52] Several studies suggest that food allergies can negatively affect quality

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INTERACTIVE, THE ADA, 20 YEARS LATER, KESSLER FOUNDATION/NOD SURVEY OF AMERICANS WITH DISABILITIES 8, 31 (2010), http://www.2010disabilitysurveys.org/pdfs/surveyresults.pdf [https://web.archive.org/web/20101105124512/http://www.2010disabilitysurveys.org/pdfs/surveyresults.pdf] (reporting results of survey of Americans with disabilities and identifying "going to restaurants" as one of "13 very important indicators of the quality of life and standard of living of Americans with disabilities"); MILES WOLFF, LUNCH AT THE FIVE AND TEN: THE GREENSBORO SIT-INS: A CONTEMPORARY HISTORY 64–65 (1970); 134 CONG. REC. S5107 (daily ed. Apr. 28, 1988) (statement of Sen. Lowell Weicker).

47 *See* 42 U.S.C. § 2000a(a) (2012) (Title II); 42 U.S.C. § 12182 (2012). For a discussion of food allergy as a potential disability under the Americans with Disabilities Act, see Section I.C.4.

48 LET NOBODY TURN US AROUND: VOICES OF RESISTANCE, REFORM, AND RENEWAL 393 (Manning Marable & Leith Mullings eds., 2d ed. 2009) (quoting Ella Baker, *Bigger than a Hamburger*, S. PATRIOT, June 1960, at 18).

49 *Id.*

50 *See* THE RESTAURANTS BOOK: ETHNOGRAPHIES OF WHERE WE EAT (David Beriss & David Sutton eds., 2007).

51 Furlong et al., *supra* note 4, at 868–69 (reporting that 19% of families that reported a reaction in a restaurant or other food establishment indicated "that they would reduce their frequency of eating out" and that, after reactions in restaurants, "families altered their approach to restaurants and other food establishments"); Natalie J. Avery et al., *Assessment of Quality of Life in Children with Peanut Allergy*, 14 PEDIATRIC ALLERGY & IMMUNOLOGY 378, 380 (2003) (stating that "[u]nexpectedly, 60% of [Peanut Allergy (PA)] subjects made mostly positive comments about restaurants," although "[t]he majority did clarify . . . that they always go to the same restaurant because they cater for people with PA"); *see also* Ryan Ahuja & Scott H. Sicherer, *Food-Allergy Management from the Perspective of Restaurant and Food Establishment Personnel*, 98 ANNALS ALLERGY, ASTHMA & IMMUNOLOGY 344, 346 (2007).

52 Jantine Voordouw et al., *Subjective Welfare, Well-Being, and Self-Reported Food Hypersensitivity in Four European Countries: Implications for European Policy*, 107 SOC. INDICATORS RES. 465, 467 (2012).

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of life.[53] One parent of a child with a food allergy described "every potential outing/trip/travel [as] a puzzle as to how to make it somewhat safe and find out what and where to eat."[54] Food allergies can affect the quality of life of those with food allergies as well as their families and caregivers due to "[t]he constant threat of exposure, need for vigilance and expectation of outcome."[55]

The significant gaps in some food service workers' training, knowledge of food allergies, and proper food allergen management,[56] may increase the risk eating out poses to individuals with food allergies. For example, one study of food allergy practices in six cities found that only 44.4% of surveyed managers, 40.8% of food workers, and 33.3% of servers "reported receiving food allergy training while working at their respective restaurants."[57] Another survey of food service workers in limited-service Philadelphia restaurants found that there were "fundamental knowledge gaps regarding how to reduce the risk of and respond to food allergy adverse events."[58] That survey found that "no single respondent could identify all seven steps necessary for safe food preparation" that the researchers gleaned from the ServSafe Allergens online course and Food Allergy Research & Education materials.[59] Furthermore, the survey found "that the majority of participating food service workers could identify . . . zero

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53 *See, e.g.*, Darío Antolín-Amérigo et al., *Quality of Life in Patients with Food Allergy*, 14 CLINICAL & MOLECULAR ALLERGY 1 (2016); Voordouw et al., *supra* note 52.

54 Derr, *supra* note 10, at 75.

55 *See* Antolín-Amérigo et al., *supra* note 53, at 2; *see also* Voordouw et al., *supra* note 52; B.M.J. de Blok et al., *A Framework for Measuring the Social Impact of Food Allergy Across Europe: A EuroPrevall State of the Art Paper*, 62 ALLERGY 733 (2007).

56 *See, e.g.*, Dupuis et al., *supra* note 33; Ahuja & Sicherer, *supra* note 51. The failures may not solely be a result of restaurants, however, as consumers with food allergens may take risks. *See, e.g.*, Matthew J. Greenhawt et al., *Food Allergy and Food Allergy Attitudes Among College Students*, 124 J. ALLERGY & CLINICAL IMMUNOLOGY 323 (2009); Margaret A. Sampson et al., *Risk-Taking and Coping Strategies of Adolescents and Young Adults with Food Allergy*, 117 J. ALLERGY & CLINICAL IMMUNOLOGY 1440 (2006). Of course, some restaurants may do better in accommodating guests with food allergies. *See, e.g.*, Paul Antico, *2018 Top 10 Most Allergy-Friendly Restaurant Chains*, ALLERGY EATS (Mar. 7, 2018), https://www.allergyeats.com/2018-top-10-most-allergy-friendly-restaurant-chains/.

57 Radke et al., *supra* note 3, at 404.

58 Dupuis et al., *supra* note 33, at 152.

59 *Id.* at 152–53. The ServSafe Allergens Course is an allergen training course from the National Restaurant Association Educational Foundation. Nat'l Rest. Ass'n Educ. Found., *ServSafe Allergens*, SERVSAFE, https://www.servsafe.com/ServSafe-Allergens (last visited Feb. 13, 2018). Food Allergy Research & Education (FARE) is an organization that works on behalf of people with food allergies. *History of Fare*, FOOD ALLERGY RES. & EDUC., https://www.foodallergy.org/about-fare/history (last visited Feb. 13, 2018).

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or one of those seven necessary steps."[60] Despite this, respondents expressed "confidence" and an "inflated sense of their own self-efficacy for safe food allergy management."[61] Similarly, a survey of restaurant and food establishment personnel in New York City and Long Island found that the respondents' "comfort level in managing food allergy exceeded [their] knowledge base" and that "there was no correlation of knowledge about [managing food allergy] with comfort level in meal provision" for allergic consumers.[62] This overconfidence is troubling because, in addition to potentially putting customers with food allergies at risk, it may prevent food service workers from taking steps to improve their management of food allergens absent regulation and oversight.[63]

B. The Gap in Federal Law

Federal food labeling law does not address the problem of food allergens in nonpackaged food, such as food often served at restaurants and similar food establishments.[64] Instead, it focuses on labeling

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60 Dupuis et al., *supra* note 33, at 153.

61 *Id.*

62 Ahuja & Sicherer, *supra* note 51, at 345.

63 *See, e.g.*, Anthony T. Robinson & Louis D. Marino, *Overconfidence and Risk Perceptions: Do They Really Matter for Venture Creation Decisions?*, 11 INT'L ENTREPRENEURSHIP MGMT. J. 149, 162 (2015) (discussing overconfidence in the context of venture creation decisions and finding that "the more overconfident tend to perceive fewer risks").

64 *See* Federal Food, Drug, and Cosmetic Act (FDCA) § 403(w), 21 U.S.C. § 343(w) (2012); *Food Allergen Labeling and Consumer Protection Act of 2004 Questions and Answers*, FDA (July 18, 2006), https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106890.htm [hereinafter FDA *Questions and Answers*]. A number of commentators have noted this gap. *See, e.g.*, Derr, *supra* note 10, at 92 ("No mandatory system comparable to packaged food labeling exists for the disclosure of food ingredients to food establishment patrons."); Neal D. Fortin, *The Food Allergen Labeling and Consumer Protection Act: The Requirements Enacted, Challenges Presented, and Strategies Fathomed*, 10 MICH. ST. U. J. MED. & L. 125, 135 (2006) ("Although not strictly speaking an exemption, the Food Allergen Act only applies to food labeled under the authority of the [FDCA]. Thus, products not regulated under the [FDCA], such as meat and poultry, and foods not requiring labeling are also free from the Food Allergen Act's requirements. An important example of the latter is restaurant food, which generally does not require labeling."); Jonathan B. Roses, *Food Allergen Law and the Food Allergen Labeling and Consumer Protection Act of 2004: Falling Short of True Protection for Food Allergy Sufferers*, 66 FOOD & DRUG L.J. 225, 225 (2011) ("FALCPA also falls short because it only regulates packaged food, and fails to regulate allergen labeling in restaurants."); Sydney Knell Leavitt, *Death by Chicken: The Changing Face of Allergy Awareness in Restaurants and What to Do When Food Bites Back*, 42 U. TOL. L. REV. 963, 965 (2011) ("Historically, restaurants have not been required to disclose either the ingredients of the food they serve or the presence of allergens."); Gideon Martin,

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certain food allergens in packaged foods.[65]

The Food Allergen Labeling and Consumer Protection Act (FALCPA) requires food that is or contains a "major food allergen" to have the required food allergen information on the label.[66] FALCPA covers eight "major food allergens"—milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans—as well as food ingredients that contain a protein derived from one of the specified foods.[67] As noted earlier, these eight allergens or groups of allergens account for 90% of food allergies in the United States.[68] The required allergen information can be provided in one of two ways: The label may have "the word 'Contains', followed by the name of the food source from which the major food allergen is derived . . . printed immediately after or . . . adjacent to the list of ingredients."[69] Alternatively, the label may have "the name of the food source from which the major food allergen is derived" in parentheses following "the common or usual name of the major food allergen in the list of the

Comment, *Allergic to Equality: The Legislative Path to Safer Restaurants*, 13 APPALACHIAN J.L. 79, 84 (2013) ("[F]ederal law protects allergy sufferers only when it comes to packaged foods.").

65 FDCA § 403(w), 21 U.S.C. § 343(w).

66 Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, § 203, 118 Stat. 891 (2004) (codified in scattered sections of 21 U.S.C. (FDCA)). A "label" is "a display of written, printed, or graphic matter upon the immediate container of any article." FDCA § 201(k), 21 U.S.C. § 321(k). "[L]abeling" is "all labels and other written, printed, or graphic matter (1) upon an article or any of its containers or wrappers, or (2) accompanying such article." FDCA § 201(m), 21 U.S.C. § 321(m).

The information may appear on other labeling if the Secretary finds that it "is sufficient to protect the public health" and publishes a notice of that finding in the Federal Register. FDCA § 403(w)(3), 21 U.S.C. § 343(w)(3). FDA has stated that the "requirements apply to all packaged foods sold in the U.S. that are regulated under the [FDCA]." FDA, GUIDANCE FOR INDUSTRY: QUESTIONS AND ANSWERS REGARDING FOOD ALLERGENS, INCLUDING THE FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT OF 2004 (EDITION 4); FINAL GUIDANCE (Oct. 2006) [hereinafter FDA FINAL GUIDANCE], *available at* https://www.fda.gov/Food/GuidanceRegulation/ucm059116.htm. Raw agricultural commodities, "foods in [their] raw or natural state," do not require allergen labeling. FDCA §§ 201(r), 403(w), 21 U.S.C. §§ 321(r), 343(w).

67 FDCA §§ 201(qq), 403(w), 21 U.S.C. §§ 321(qq), 343(w). It excludes highly refined oils derived from one of the eight foods as well as ingredients derived from these highly refined oils. *Id.* In addition, it establishes procedures by which a food may be exempted from the allergen labeling requirements. *Id.* FALCPA also directed the Secretary of Health and Human services to issue a proposed rule within two years of its enactment, and then a final rule within four, "to define, and permit use of, the term '*gluten*-free' on the labeling of foods." FDCA § 403 note, 21 U.S.C. § 343 note.

68 FDCA § 403 note, 21 U.S.C. § 343 note.

69 FDCA § 403(w)(1), 21 U.S.C. § 343(w)(1).

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ingredients."[70] The "major food allergen" provisions are self-executing[71] and apply to food labeled on or after January 1, 2006.[72] A food that is not in compliance with FALCPA's labeling requirements is deemed to be misbranded in violation of the Food, Drug, and Cosmetic Act (FDCA).[73] FALCPA also expressly preempts nonidentical state and local allergen labeling requirements.[74]

FDA has indicated that FALCPA's labeling requirements "do not apply to foods provided by a retail food establishment that are placed in a wrapper or container in response to a consumer's order—such as the paper or box used to convey a sandwich that has been prepared in response to a consumer's order."[75] FALCPA, however, is not silent on allergy management issues in restaurants. It directs the Secretary of Health and Human Services to "pursue revision of the Food Code," a model code "to provide guidelines for preparing allergen-free foods in food establishments, including in restaurants, grocery store delicatessens and bakeries."[76]

In addition, the 2011 Food Safety Modernization Act (FSMA) Hazard Analysis and Risk-Based Preventive Controls (HARPC) provisions for food facility operators created a framework for a "prevention-based food safety system" that explicitly addresses allergens as hazards.[77] With respect to food allergens, FSMA requires hazard analysis, preventive controls, monitoring, corrective actions, verification, record keeping, a written plan and documentation, and a

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70 *Id.* FALCPA does not require the name of the food source in parentheses in certain limited circumstances where the name of the food source from which the food allergen is derived appears elsewhere in the ingredient list. *Id.*

71 S. REP. NO. 108-226, at 3 (2004).

72 FALCPA was effective January 1, 2006. FDCA § 201 note, 21 U.S.C. § 321 note.

73 *See* FDCA § 301, 21 U.S.C. § 331 (prohibiting misbranding or causing misbranding of food provided that certain interstate commerce connection requirements are met); FDCA § 403(w), 21 U.S.C. § 343(w).

74 FDCA § 403A(a)(2), 21 U.S.C. § 343-1(a)(2); *see also infra* Section IV.B.3.a.

75 FDA FINAL GUIDANCE, *supra* note 66. They do however apply to foods that are packaged, labeled, and offered as food for human consumption. FDA *Questions and Answers*, *supra* note 64. Simply extending FALCPA to restaurant-type food would leave many unanswered questions. Accordingly, this Article argues that menu labeling for restaurant-type food should be used to inform allergen labeling. *See infra* Parts III & IV.

76 42 U.S.C. § 243 note. The Act specified that the Secretary must "consider guidelines and recommendations developed by public and private entities for public and private food establishments" *Id.*

77 Sarah Besnoff, Comment, *May Contain: Allergen Labeling Regulations*, 162 U. PA. L. REV. 1465, 1475 (2014); *see also* FDA Food Safety and Modernization Act (FSMA), Pub. L. No. 111-353, § 103, 124 Stat. 3885 (2011) (codified in scattered sections of 21 U.S.C. and 42 U.S.C.); FDCA § 418, 21 U.S.C. § 350g.

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reanalysis of hazards.[78] Restaurants and other retail food establishments, however, are excluded from the definition of facility and thus these requirements.[79]

C. Other Limitations of the Law

1. The Food Code

The Food Code, which is published by the Public Health Service and FDA, predates FALCPA, but since FALCPA was enacted, consistent with that Act,[80] the Food Code has been revised to address food allergen management.[81] Despite these revisions, the Food Code continues to have several significant limitations when it comes to protecting people with food allergies.

Prior to FALCPA, the Food Code did not explicitly mention allergens in its text, although it discussed allergen management in explanations in its annexes.[82] The 2005 Food Code, which was published the year after FALCPA, addresses food allergen management in more detail than previous versions of the code.[83] It refers to allergens in the text and discusses FALCPA's labeling requirements.[84] The 2005 code provides that the person in charge of a

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78 FDCA § 418, 21 U.S.C. § 350g. FDA has promulgated regulations implementing these allergen provisions and making "FDA's long-standing position that the CGMPs address allergen cross-contact . . . explicit in the regulatory text." 80 Fed. Reg. 55,908, 55,913 (Sep. 17, 2015) (codified at scattered sections of 21 C.F.R.); 21 C.F.R. § 117 (2017); *see also Frequently Asked Questions About Food Allergies*, FDA: ALLERGENS, https://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAllergens/ucm530854.htm (last visited Aug. 12, 2018).

79 FDCA § 415(c)(1), 21 U.S.C. § 350d(c)(1).

80 *See* 42 U.S.C. § 243 note.

81 *Compare* FOOD CODE (FDA 2005), FOOD CODE (FDA 2009), FOOD CODE (FDA 2013), *and* FOOD CODE (FDA 2017), *with* FOOD CODE (FDA 1993), FOOD CODE (FDA 1995), FOOD CODE (FDA 1997), FOOD CODE (FDA 1999), *and* FOOD CODE (FDA 2001).

82 *See, e.g.*, FOOD CODE annex 3 (FDA 2001); FOOD CODE annex 5 (FDA 2001); FOOD CODE annex 3 (FDA 1997); FOOD CODE annex 3 (FDA 1999). This examination is limited to the Food Code in its current format, beginning with the 1993 Food Code. *FDA Food Code*, FDA, http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm (last updated Feb. 12, 2018). FDA and the Public Health Service have periodically published proposals and recommendations regarding restaurants and food since 1934. *FDA Food Code 1997 – Previous Editions*, FDA, https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm054040.htm [https://web.archive.org/web/20150609141305/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm054040.htm].

83 *Compare* FOOD CODE (FDA 2005), *with* FOOD CODE (FDA 1997), FOOD CODE (FDA 1999), *and* FOOD CODE (FDA 2001).

84 FOOD CODE (FDA 2005).

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food establishment, such as a restaurant,[85] must be able during inspections and upon request to describe foods that are major food allergens and the symptoms of an allergic reaction that an allergen could cause.[86] Consistent with FALCPA, the code also notes that food packaged in a food establishment must be properly labeled for major food allergens.[87] Many foods in restaurants, however, are excluded from this requirement: as noted above, FDA has defined "[p]ackaged" to exclude "a wrapper, carry-out box, or other nondurable container used to containerize food with the purpose of facilitating food protection during service and receipt of the food by the consumer."[88]

An annex to the 2005 code identifies use of "a rigorous sanitation regime to prevent cross contact between allergenic and non-allergenic ingredients" as a means to control allergen hazards, which are associated with "[f]oods containing or contacted by" a major food allergen.[89] In addition, the Food Code states that before an effective Hazard Analysis and Critical Control Point (HACCP) system can be implemented, there must be "a strong foundation of procedures that address the basic operational and sanitation conditions within an operation," which may include allergen management.[90] In general, although the Food Code encourages the "implementation of food safety management systems based on HACCP principles," use "of HACCP at the retail level is voluntary."[91]

Subsequent editions of the Food Code have added additional food allergen management requirements.[92] For example, the person in charge must ensure that "[e]mployees are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties."[93] In addition, the cleaning and sanitizing measures for

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85 *Id.*

86 *Id.*

87 *Id.* § 3-602.11.

88 *Id.* § 1-201.10(B).

89 *Id.* annex 4, tbl.2.

90 *Id.* annex 4, at 479. HACCP "is a systematic approach to identifying, evaluating, and controlling food safety hazards" that "is designed to ensure that hazards are prevented, eliminated, or reduced to an acceptable level before a food reaches the consumer." *Id.* annex 4, at 478; *see also infra* Section III.A.3 (proposing that HACCP be used for the management of food allergens in restaurants).

91 FOOD CODE annex 4, at 478 (FDA 2005).

92 *See* FOOD CODE (FDA 2009); FOOD CODE (FDA 2013).

93 FOOD CODE § 2-103.11 (FDA 2009); *Id.* annex 3, at 327 (identifying food allergies as "an increasing food safety and public health issue" and explaining the revision of the person in charge's duties to include allergy awareness in the food safety training of employees).

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equipment used to prepare raw foods that are major food allergens were strengthened.[94]

Although the Food Code has given more attention to the management of food allergens since the enactment of FALCPA, it has several limitations. As a model code, it lacks the independent force of law.[95] The adoption of the code and its provisions depend on voluntary action by local, state, and federal regulators and legislators.[96] Although FDA "encourages . . . adopt[ion of] the latest version of the Food Code,"[97] jurisdictions may be slow or fail to adopt updated editions of the Code.[98] For example, a 2016 report indicates that at least one agency in each of the fifty states and the District of Columbia had adopted the FDA Food Code; however, in eleven states at least one agency had adopted a version of the Food Code that predates FALCPA.[99] Jurisdictions may fail to adopt the most recent edition of the Food Code because doing so may be time intensive and burdensome. FDA generally publishes a new edition of the code every four years and may also publish supplements.[100] Further adding to the variation, some states have adopted the standards set forth in the Food

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The findings of one study, however, "indicate that employee training might not be occurring according to recommendations." Radke et al., *supra* note 3, at 405.

94 *FDA Releases 2013 Food Code: Updated Code is a Model for State, City, County, Tribal, Territorial Agencies and Industry*, FDA (NOV. 14, 2013), http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm374979.htm [https://web.archive.org/web/20160328075637/https:www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm374979.htm] [hereinafter *FDA Releases 2013 Food Code*]; FOOD CODE § 4-602.11 (FDA 2013).

95 FOOD CODE preface iii (FDA 2017).

96 *Id.*

97 *2017 Food Code*, FDA, https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm595139.htm (last updated Mar. 12, 2018). The preface to the Food Code notes that a state legislative body may enact the Code into a statute, an administrative agency with rulemaking authority may promulgate it as a regulation, or a local legislative body with appropriate powers may adopt it as an ordinance. FOOD CODE preface viii (FDA 2017).

98 *See* FDA, ADOPTION OF THE FDA FOOD CODE BY STATE AND TERRITORIAL AGENCIES RESPONSIBLE FOR THE OVERSIGHT OF RESTAURANTS AND RETAIL FOOD STORES (2016).

99 *Id.* at 4–6. Some states have more than one agency with regulatory oversight over the retail food industry. *Id.* at 2.

100 *See* Drew Falkenstein, *A Call for Uniform Model Food Code Application*, FOOD SAFETY NEWS (Jan. 13, 2010), http://www.foodsafetynews.com/2010/01/a-call-for-uniform-model-food-code-application/#.VZraSGA7b8s (arguing for a nationwide Food Code as a way to "streamline the often complex process of employee training, particularly for national restaurant chains that currently must account for many different regulatory schemes"). The 2017 edition of the Food Code was released in February of 2018. *See FDA Releases 2017 Food Code*, FDA (Feb. 12, 2018), https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm595143.htm; FOOD CODE (FDA 2017).

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Code with modifications[101] and "local regulatory agencies can be using more updated Food Codes than the state."[102]

Jurisdictions' delay or failure to adopt the most recent version of the Food Code is concerning from an allergen management perspective because they may not be benefiting from FDA's "best" and most recent advice regarding retail food safety,[103] as older versions of the Food Code generally have less extensive food allergen provisions. In addition, the jurisdictional variations that result from these delays and failures undermine the uniformity that is one of the goals of the model code.[104]

The lack of uniformity may also increase the regulatory burdens on restaurants that have locations in jurisdictions that have adopted different editions of the Food Code or modified the Food Code.[105] It may also harm people with food allergies by increasing uncertainty and risk. For example, if a person visits a restaurant with locations in two different states, she may be unaware that the locations may be subject to different requirements regarding the management of allergens even if they are part of the same chain.

But even in the highly unlikely event that the "[m]ore than 3,000 state, local and tribal agencies [that] . . . regulate the retail food and foodservice industries in the United States" were to voluntarily adopt a

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101 *See* EcoSure, *Read Any Good Food Code Lately?*, Ecolab: FOOD SAFETY MONITOR, http://www.ecolab.com/~/media/Ecolab/Ecolab%20Home/Documents/DocumentLibrary/PublishedArticles/FSMonitorNewsletter/March%202014/ReadAnyGoodFoodCodeLatelyMarch2014.ashx (last visited Feb. 14, 2018) (providing examples of states adopting modified versions of the Food Code); Eva Merian Spahn, *Keep Away from Mouth: How the American System of Food Regulation Is Killing Us*, 65 U. MIAMI L. REV. 669, 713 (2011) (providing additional example of a modified version of the Food Code).

102 EcoSure, *supra* note 101; *see also* Nicholas R. Johnson & A. Bryan Endres, *Small Producers, Big Hurdles: Barriers Facing Producers of "Local Foods*,*"* 33 HAMLINE J. PUB. L. & POL'Y 49, 77–78 (2011) (stating that "[w]hile each state scheme is different, state-level food regulation typically begins with a food sanitation statute (often modeled on the FDA Food Code) that sets forth general parameters, leaves the precise regulatory details to the state department of public health or its equivalent, and places inspection and enforcement powers in the hands of local health inspectors") (internal citations omitted).

103 FOOD CODE preface iii (FDA 2017).

104 *Id.* preface iv (stating that "[i]ndustry conformance with acceptable procedures and practices is far more likely where regulatory officials 'speak with one voice' about what is required to protect the public health, why it is important, and which alternatives for compliance may be accepted"); Falkenstein, *supra* note 100 (arguing that "[i]t is time for a federal mandate making the FDA's Model Food Code . . . compulsory as a baseline regulatory scheme on all states, territories, and tribal jurisdictions").

105 *See* Falkenstein, *supra* note 100; *see also infra* Section IV.B (discussing benefits and limitations of state and local action).

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uniform Food Code,[106] the current Food Code does not provide a comprehensive approach to allergen management in restaurants. Although the Food Code acknowledges the importance of labels and ingredient information for consumers with food allergies,[107] it does not generally address the labeling of nonpackaged food.[108] Instead, it suggests that "[w]hen food is under the direct control of the operator and provided to the consumer upon consumer request, the consumer has an opportunity to ask about . . . allergens."[109] This suggestion is problematic, however, because the operator may not be equipped to provide sound information.[110] Indeed, there have been reports of consumers who died from an allergic reaction to food served by a restaurant—after the restaurant assured the consumer the allergen was not in the food.[111]

The Food Code's approach to preventing allergen cross contact fails to adequately control major food allergens. For example, in explaining the strengthened cleaning requirements for equipment that has "contacted raw animal foods that are major food allergens," FDA in the 2013 Food Code explicitly recognized that the change is "limited in scope" and "falls short of comprehensive allergen cross-contact control for all eight (8) major food allergens."[112]

As noted earlier, FALCPA directed the Secretary of Health and Human services to "pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments, including in restaurants, grocery store delicatessens and bakeries."[113]

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106 *Retail Food Protection*, FDA, https://www.fda.gov/food/guidanceregulation/retailfoodprotection/ucm2006807.htm (last visited Aug. 12, 2018).

107 *See* FOOD CODE annexes 3 & 4, at 476, 560 (FDA 2017) (stating that "[i]ngredient information is needed by consumers who have allergies to certain food or ingredients" and that "[c]onsumers with food allergies rely heavily on information contained on food labels to avoid food allergens").

108 *See* FOOD CODE §§ 3-602.11–.12 (FDA 2017); *see also id.* annex 3, at 476–77.

109 *Id.* annex 3, at 476.

110 *See supra* notes 56–63 and accompanying text.

111 Jonathan Bridges, *Suing for Peanuts*, 75 NOTRE DAME L. REV. 1269, 1277, 1289 n.19 (2000) (summarizing lawsuits).

112 FOOD CODE annex 3, at 509 (FDA 2013); *see also* FOOD CODE annex 3, at 512 (FDA 2017). In addition, FDA in its Food Code Reference System in response to a question about the potential for allergic reactions when oil used to fry fish is used to fry other foods, noted that although "it is prudent" to prevent cross contact by major food allergens when such contact "can be prevented with little investment in time or resources," "the 2005 Food Code does not address operational procedures to prevent [such] contact." *Food Code Reference System*, FDA, http://www.accessdata.fda.gov/scripts/fcrs/disclaimer.cfm (last visited Feb. 14, 2018) (search "allergen") (registration required).

113 42 U.S.C § 243 (2012).

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FDA noted in the 2005 Food Code that FALCPA directed it to pursue such revisions.[114] But, as one commentator observed, "[t]he FALCPA's failure to mandate what revisions must be made to the Food Code means that the FALCPA's Food Code provision may yield few results, depending on FDA's initiation of further revisions at the agency's discretion."[115] To date, this appears to have been the case.

2. State and Local Allergen Awareness Laws

In 2009, Massachusetts enacted an Act Relative to Food Allergy Awareness (FAAA),[116] becoming the first state to pass a food allergen restaurant awareness law.[117] The act requires that "a person licensed as an innholder or common victualler, when serving food" (1) post an approved food allergy awareness poster in the staff work area, (2) include a notice informing customers of their "obligation to inform the server about any food allergies," and (3) require "[a] person in charge and certified food protection manager" to view a video concerning food allergies as part of a course to obtain certification as an approved food protection manager.[118] Except as specifically provided, the FAAA does not create or change a private cause of action or change the duty under any other statute or the common law.[119] The FAAA requires that the Massachusetts Department of Public Health develop a program by which restaurants can be designated as "Food Allergy Friendly" and maintain a list of such restaurants.[120] The act is intended "to minimize the risk of illness and death due to accidental ingestion of food

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114 FOOD CODE annex 4, at 483 (FDA 2005).

115 Derr, *supra* note 10, at 135.

116 An Act Relative to Food Allergy Awareness, MASS. GEN. LAWS ch. 140, § 6B (2010) [hereinafter Food Allergy Awareness Act]; MASS. DEP'T OF PUB. HEALTH, Q&AS FOR MDPH ALLERGEN AWARENESS REGULATION (2010) [hereinafter Q&AS FOR MDPH], http://www.mass.gov/eohhs/docs/dph/environmental/foodsafety/food-allergen-3-reg-faqs.pdf.

117 *Food Allergies and Restaurants*, FOOD ALLERGY RES. & EDUC., https://www.foodallergy.org/education-awareness/advocacy-resources/advocacy-priorities/food-allergies-and-restaurants (last visited Feb. 14, 2018).

118 Food Allergy Awareness Act § 6B(b)(1)–(2), (c). The FAAA also provides that an alternate person in charge must "be knowledgeable with regard to the relevant issues concerning food allergies as they relate to food preparation." § 6B(c). The Massachusetts Public Health Council has adopted food allergy awareness regulations under the authority of the FAAA. Mass. Pub. Health Council Allergen Regulations, 105 CMR 590.000.

119 Food Allergy Awareness Act § 6B(f).

120 § 6B(g).

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allergens by increasing restaurant industry and consumer awareness" with respect to food allergens.[121]

The FAAA is limited, however, in that it does not require covered establishments to provide ingredient or allergen information for menu items. In addition, although it requires that establishments post a food allergy awareness poster and that a person in charge receive food allergen certification,[122] it does not mandate that food workers take specific measures to prevent cross contact. The Food Allergy Friendly designation program had not been implemented at the time that this Article was written.[123]

Several other states have also enacted food allergy awareness laws for restaurants.[124] Although the particular terms of these laws vary, broadly speaking, these laws share features of the Massachusetts law and are limited in scope. These features include (1) the display of a food allergy awareness poster in the staff area,[125] (2) a notice to customers of their obligation to inform their server about any food allergies,[126] and (3) the designation of a manager who must be knowledgeable regarding food allergies as they relate to food preparation and must complete food allergen training,[127] or the establishment of other training standards.[128] Like the Massachusetts

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121 Q&AS FOR MDPH, *supra* note 116.

122 *See* Food Allergy Awareness Act § 6B.

123 *See* Jessica L. Brewer, Comment, *To Eat or Not to Eat?: How Ohio Can Foster More Confidence Between Restaurants and Food Allergic Individuals*, 41 U. DAYTON L. REV. 303, 321 (2016).

124 *See, e.g.*, MICH. COMP. LAWS § 289.6152(1) (2015); MD. CODE ANN., HEALTH-GEN. § 21-330.2 (West 2013); 23 R.I. GEN. LAWS § 23-20.12-2 (2012); H.R. 2510, 100th Gen. Assemb., Reg. Sess. (Ill. 2017).

125 MICH. COMP. LAWS § 289.6152(1); MD. CODE ANN., HEALTH-GEN. § 21-330.2; 23 R.I. GEN. LAWS § 23-20.12-2; H.R. 2090, 2015 Gen. Assemb., Reg. Sess. (Va. 2015).

A number of other states have considered food allergy awareness bills. *See, e.g.*, S. 49, 2015 Gen. Assemb., Reg. Sess. (Conn. 2015); S. 1072, 2014 Leg., Reg. Sess. (Fla. 2014); S. 422, 2014 Gen. Assemb., Reg. Sess. (Ga. 2014). In addition, a number of states have considered or adopted resolutions designating food allergy or anaphylaxis awareness weeks. *See, e.g.*, S. Con. Res. 67, 2012 Leg., Reg. Sess. (Cal. 2012); S. Res. 1002, 51st Leg., Reg. Sess. (Ariz. 2013).

126 23 R.I. GEN. LAWS § 23-20.12-2.

127 *Id.*; MICH. COMP. LAWS § 289.2129; 410 ILL. COMP. STAT. §§ 625/3.06-07 (2017).

128 VA. CODE ANN. § 35.1-14A (West 2015). The Virginia law also requires that the State Health Commissioner provide written materials for the training of restaurant personnel on "food safety and food allergy awareness and safety." *Id.*

The Michigan law, like the Massachusetts Food Allergy Awareness Act, does not establish or change any private cause of action or change any duty except as it expressly provides. *Compare* Food Allergy Awareness Act, MASS. GEN. LAWS ch. 140, § 6B (2010), *with* MICH. COMP. LAWS § 289.6152.

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law, these laws fail to mandate comprehensive food allergen protections.

Furthermore, at least two cities have enacted food allergen measures for restaurants. In 2009, the New York City Council passed and the mayor approved a local law requiring food service establishments to display, "in a conspicuous location accessible to all employees involved in the preparation and the service of food," a poster containing information on food allergy created by the Department of Health and Mental Hygiene.[129] Similarly, the City of St. Paul, Minnesota, enacted an ordinance requiring restaurants to display an approved food allergy awareness poster in the staff area.[130] Both the New York City and St. Paul measures are limited in scope and, like the state laws discussed above, do not require comprehensive food allergen measures. And, as noted earlier, as this Article was going to press, the Township of Edison, New Jersey, approved an ordinance that will require restaurants to "identify on a menu all food items that contain or are prepared with" any of the eight major food allergens, "as well as monosodium glutamate ('MSG') and commercial sulfites used as a food preservative or additive" and to "indicate . . . that such menus are available."[131] The ordinance also establishes requirements for caterers and establishments operating with plenary retail consumption licenses.[132] It does not, however, address cross contact prevention.[133]

3. Tort Law

A person injured by an allergic reaction to food from a restaurant may be able to recover under several different theories of liability.[134] This section focuses on products liability, specifically failure to warn

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129 N.Y.C., Local Law 17 of 2009, *available at* https://locallaws.dos.ny.gov/sites/default/files/drop_laws_here/ECMMDIS_appid_DOS20150218075531_44/Content/090213438000981d.pdf; N.Y.C., N.Y., ADMINISTRATIVE CODE 17-195 (2017); *see also* N.Y.C., N.Y., HEALTH CODE § 81.0(s) (defining food service establishment); N.Y. DEP'T OF HEALTH & MENTAL HYGIENE, RULES OF THE CITY OF N.Y. ch. 27 (Food Allergy Information) (adopting rules defining the scope and applicability of the food allergen poster law).

130 ST. PAUL, MINN., CODE OF ORDINANCES ch. 331A.11.

131 Edison Township, N.J., Ordinance O.2015-2018 (Aug. 22, 2018).

132 *Id.*

133 *See id.*

134 In addition, a person injured by an allergic reaction to food from a restaurant may have a claim for negligence or breach of warranty. *See, e.g.*, RESTATEMENT (SECOND) OF TORTS § 281 (AM. LAW INST. 1965) (negligence); U.C.C. § 2-313 (AM. LAW INST. & UNIF. LAW COMM'N 2002) (breach of warranty).

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and manufacturing defects, to illustrate tort law's limitations in addressing food allergens in restaurants.[135]

Before turning to an examination of the specifics of these claims, however, it is worth noting two points. First, in contrast to the laws discussed in the prior sections, which seek to prevent allergic reactions to food with preventative measures, "a principal function of tort law is to compensate a victim for the wrongdoing or unreasonable conduct of the tortfeasor."[136] The possibility of damages, however, may be of no value to a person with a food allergy who has suffered a fatal reaction at a restaurant.[137] As Professors Eric Posner and Cass Sunstein have succinctly stated a "dead person cannot be compensated—she is dead."[138] But even if an allergic reaction does not result in death, tort law may not make the person whole. As Professor Sean Hannon Williams has written, "The make-whole account of tort damages is aspirational only. To truly make someone whole would require undoing the injury. This is rarely possible . . . ."[139] Thus, from the perspective of an individual potential plaintiff, the benefits of tort law may be limited.

Second, a search for case law addressing allergic reactions to food identified only a few cases, which is consistent with what others have observed.[140] The limited case law may create uncertainty for potential plaintiffs. The scientific literature suggests that the lack of lawsuits is not due to a lack of potential plaintiffs because a significant number of people with food allergies have experienced allergic reactions in

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135 DAN B. DOBBS ET AL., HORNBOOK ON TORTS 810, 825 (2nd ed. 2016); RESTATEMENT (SECOND) OF TORTS § 402A; RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (AM. LAW INST. 1998).

136 74 AM. JUR. 2D *Torts* § 2 (1974).

137 Andrew J. McClurg, *It's A Wonderful Life: The Case for Hedonic Damages in Wrongful Death Cases*, 66 NOTRE DAME L. REV. 57, 66 (1990) ("A dead person cannot be compensated for his lost life. A trillion dollars would contribute nothing toward making him whole again."). *But see* Sean Hannon Williams, *Lost Life and Life Projects*, 87 IND. L.J. 1745, 1763 (2012) (exploring whether a life can be improved by events after its end). Compensation is of course not the only purpose of tort law; tort law may have a deterrent effect by creating an incentive for restaurants to take measures to make foods safer for those with food allergies. *See, e.g.*, Robert L. Rabin, *Poking Holes in the Fabric of Tort: A Comment*, 56 DEPAUL L. REV. 293, 301 (2007) (describing tort law as "an engine of compensation as well as deterrence").

138 Eric A. Posner & Cass R. Sunstein, *Dollars and Death*, 72 U. CHI. L. REV. 537, 558 (2005).

139 Williams, *supra* note 137, at 1763.

140 *See, e.g.*, Bridges, *supra* note 111, at 1275 (noting that lawsuits due to anaphylactic reactions to nuts appear to be uncommon); Brewer, *supra* note 123, at 310 (identifying only one case involving a person who had an allergic reaction from food served by a restaurant in Ohio); Roses, *supra* note 64, at 232.

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restaurants and other establishments,[141] some of which have been fatal.[142] Therefore, it may be fair to conclude that these cases often settle.[143] The limited case law, however, may "color[] settlement terms in a way adverse to the would-be plaintiffs" who are injured by an allergic reaction to a food.[144]

A person injured by an allergic reaction to an allergen in a restaurant's food may have a failure to warn claim. Failure to warn, unlike manufacturing defects discussed below, has "gravitated toward a negligence approach."[145] Under the approach taken by Third Restatement of Torts, the plaintiff would have to prove by a preponderance of the evidence that the restaurant failed to provide a reasonable warning and that failure rendered the food not reasonably safe.[146] There is some uncertainty about when a restaurant has a duty to warn about common food allergens. On the one hand, a warning that a food contained a common allergen could entirely prevent a customer with a known allergy from having an allergic reaction. On the other hand, when the presence of a food allergen and the risks presented by it are widely known, a warning is unnecessary.[147] In addition, when the risk of an allergic reaction is not "reasonably foreseeable at the time of sale," a warning about the risk is not required.[148] A warning about an allergen "is required when [it] . . . is one to which a substantial number of persons are allergic"; however, this is "not precisely quantifiable."[149] Proving causation may also present challenges. As one commentator has noted, "In the few cases of litigation on the record, virtually all plaintiffs seeking redress under" failure to warn and

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141 *See, e.g.*, Furlong et al., *supra* note 4; *see also* Weiss & Muñoz-Furlong, *supra* note 3.

142 *See* Carol A. Wham & Kanchan M. Sharma, *Knowledge of Café and Restaurant Managers to Provide a Safe Meal to Food Allergic Consumers*, 71 NUTRITION & DIETETICS 265, 265 (2014).

143 *See* Roses, *supra* note 64, at 226 (stating that "the likely reason for the sparse record of litigation is that the vast majority of incidents settle before ever reaching a courtroom").

144 *Id.*

145 DOBBS ET AL., *supra* note 135, at 806, 825.

146 RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY, § 2 (AM. LAW INST. 1998); *see also* DOBBS ET AL., *supra* note 135, at 82; RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (AM. LAW INST. 1965).

147 RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmts. j, k, m ("The ingredient that causes the allergic reaction must be one whose danger or whose presence in the product is not generally known to customers."); *see also* RESTATEMENT (SECOND) OF TORTS § 402A cmt. j.

148 RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmts. k, m.

149 *Id.* § 2; *see also* RESTATEMENT (SECOND) OF TORTS § 402A cmt. j.

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manufacturing or product defect causes of action "have faced difficulties in proving causation and duty to warn about the risk of allergic reaction."[150]

A person injured by a food allergen may also have a manufacturing defect claim, for example, if the food was not intended to have a food allergen but did due to allergen cross contact during preparation. To prove a manufacturing defect claim, the plaintiff would have to show by a preponderance of the evidence that (1) the food had the manufacturing defect at the time it left the restaurant's hands, (2) the food was expected to and did reach the consumer without change, and (3) the food caused the allergic reaction.[151] A food "has a manufacturing defect when it disappoints consumer expectations by departing from its intended design" even though all possible care was exercised in its preparation and marketing.[152] In other words, there is strict liability for these defects.[153] Accordingly, manufacturing defect claims may be easier for a potential plaintiff to prove than failure to warn claims; however, proving that the food was defective, that it was defective when it left the restaurant's hands, and that the defect caused the allergic reaction may still present challenges.[154]

Thus, although tort law may provide some relief for persons injured by reactions to allergens in restaurant-type food and may help make restaurants safer for those with food allergies through its deterrent effect, it does not fill the gaps identified earlier.

4. Disability Law

Although "[c]ourts have repeatedly refused to grant disability status to those with severe food allergies,"[155] severe food allergies may

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150 Roses, *supra* note 64, at 232; *see also* Leavitt, *supra* note 64, at 972–73 (noting that in the context of section 402A of the Restatement (Second) of Torts "plaintiffs face great difficulties establishing that restaurants owe a duty to warn of the presence of allergens and that the restaurants somehow caused the plaintiffs' adverse allergic reactions" and that the *Third Restatement*'s "principles have only been minimally explored in food-allergy cases").

151 DOBBS ET AL., *supra* note 135, at 810. Restatement (Second) of Torts Section 402A, comment f provides that the section "applies to any person engaged in the business of selling products for use or consumption," including "to the operator of a restaurant." RESTATEMENT (SECOND) OF TORTS § 402A cmt. f.

152 DOBBS ET AL., *supra* note 135, at 806, 810; RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2.

153 DOBBS ET AL., *supra* note 135, at 806, 810; RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2.

154 *See* Roses, *supra* note 64, at 232; Leavitt, *supra* note 64, at 972–73.

155 Jason Mustard, Comment, *Nothing to Sneeze At: Severe Food Allergy as a Disability under the ADA Amendments Act of 2008*, 45 GOLDEN GATE U. L. REV. 173, 174 (2015).

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constitute a disability under the Americans with Disabilities Act Amendments Act of 2008 (ADAAA). Due to a lack of case law, however, there is some uncertainty regarding how courts will interpret the ADAAA.

In *Land v. Baptist Medical Center*, a case predating the ADAAA, the mother of a child with a peanut allergy sued Baptist Medical Center under the Americans with Disabilities Act of 1990 (ADA) when it refused to provide day care services for her child after the child had two allergic reactions at the day care.[156] The district court granted summary judgment for Baptist Medical Center on the ADA claim and the United States Court of Appeals for the Eighth Circuit affirmed.[157] The court of appeals stated that "[t]he pivotal question [was] . . . whether [the child's] allergy substantially limits her ability to eat and breathe" and concluded that it did not.[158] The court explained that "[a]lthough [the child] cannot eat foods containing peanuts or their derivatives, the record does not suggest that [the child] suffers an allergic reaction when she consumes any other kind of food or that her physical ability to eat is in any way restricted."[159] In addition, the court stated that "the record shows [the child's] ability to breathe is generally unrestricted, except for the limitations she experienced during her two allergic reactions."[160] Thus the court concluded that the child's allergy did "not substantially or materially limit these major life activities within the definition of disability under the ADA."[161]

However, several commentators have argued that the ADAAA, which expanded the definition of disability, "provides rules of construction that dismantle the *Land* court's holding"[162] and may increase the protections for people with food allergies.[163] Under the ADAAA, disability is defined in part as "a physical . . . impairment that

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156 Land v. Baptist Med. Ctr., 164 F.3d 423 (8th Cir. 1999).

157 *Id.* at 424.

158 *Id.*

159 *Id.* at 425.

160 *Id.*

161 *Id.*; *see also* Bohacek v. City of Stockton, No. CIV S-04-0939 GGH, 2005 WL 2810536, at *5 (E.D. Cal. Oct. 26, 2005) (holding that a child with a peanut allergy "does not have a disability because there is no substantial limitation on his major life activities").

162 *See, e.g.*, Mustard, *supra* note 155, at 188; *see also* 42 U.S.C. § 12102(4)(D)-(E) (2012).

163 *See* Tess O'Brien-Heinzen, *A Complex Recipe: Food Allergies and the Law*, WIS. LAW., May 2010, at 8, 9; Mustard, *supra* note 155, at 175 (arguing that "courts must classify individuals with severe food allergies as having a disability"); Roses, *supra* note 64, at 226 n.8.

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substantially limits one or more major life activities of [an] individual."[164] "Major life activities" include "eating," "breathing," and "the operation of a major bodily function."[165] In addition, the ADAAA provides that "[a]n impairment that is episodic or in remission is a disability if it would substantially limit a major life activity when active."[166]

Case law on whether a severe food allergy may constitute a disability under the ADAAA is limited, but suggests that it may.[167] In addition, a 2012 agreement between the United States Department of Justice and Lesley University recognized that "[f]ood allergies may constitute a disability under the ADA."[168] The University's obligations at issue in the Lesley Agreement do differ from those of restaurants that serve the general public as that agreement involved a complaint involving the University's mandatory meal plan for students living on campus. In a question and answer document discussing the agreement, however, the United States Justice Department indicated that "[a] restaurant may have to take some reasonable steps to accommodate individuals with disabilities where it does not result in a fundamental alteration of that

164 42 U.S.C. § 12102(1).

165 § 12102(2).

166 § 12102(4)(D).

167 *See* Hebert v. CEC Entm't, Inc., No. 6:16-CV-00385, 2016 WL 5003952, at *3 (W.D. La. July 6, 2016), *report and recommendation adopted*, No. 16-CV-0385, 2016 WL 5081009 (W.D. La. Sept. 16, 2016) (holding that parents' allegations that their son's food allergy is a disability "are sufficient to overcome the defendant's first challenge to the sufficiency of the complaint"); Mills v. St. Louis Cty. Gov't, No. 4:17CV0257 PLC, 2017 WL 3128916, at *5 (E.D. Mo. July 24, 2017) (stating that *Land* is of "limited assistance" in determining whether a food allergy is a disability because "the *Land* court analyzed the child's alleged disability pursuant to an approach rejected by the ADAAA" and that plaintiff's allegation of a shellfish allergy was sufficient to state a claim to survive motion to dismiss); Knudsen v. Tiger Tots Cmty. Child Care Ctr., No. 12-0700, 2013 WL 85798, at *3 (Iowa Ct. App. 2013) (reversing district court's grant of summary judgment and remanding for consideration of "whether [the child's] allergy would substantially limit a major life activity 'when active'"); Lopez-Cruz v. Instituto de Gastroenterologia de P.R., 960 F. Supp. 2d 367, 371 n.8 (D.P.R. 2013) (stating that, although "[a] number of courts conclude that an individual does not suffer a disability when an impairment only manifests itself when the individual is exposed to an allergen at work," these "cases were decided prior to the ADA being amended by the ADA Amendments Act of 2008," which "provides that the disability inquiry is to be made without consideration of 'the ameliorative effects of mitigating measures,' . . . and that an impairment occurring episodically may be considered a disability if it substantially limits a major life activity when active"); *see also* Roses, *supra* note 64, at 226 n.8.

168 U.S. DEP'T OF JUSTICE, DJ 202-36-231, SETTLEMENT AGREEMENT BETWEEN THE UNITED STATES OF AMERICA AND LESLEY UNIVERSITY (2012).

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restaurant's operations."[169] Thus, the ADAAA should provide individuals with severe food allergies greater protections than the pre-ADAAA law, although it remains to be seen how courts will interpret the amendments.

II
MENU LABELING

Although current law regarding allergen labeling and management in restaurants is at best limited, there is another context in which restaurant labeling has received substantial attention: menu labeling. This Part discusses New York City's (NYC) 2006 and 2008 menu labeling rules and the legal challenges to these rules. The 2008 rule, and the United States Court of Appeals for the Second Circuit's holding that the rule was not preempted by federal labeling law and did not violate the First Amendment of the United States Constitution, helped pave the way for other cities, counties, states, and, ultimately, the federal government to enact menu labeling requirements. This Part focuses on the aspects of local, state, and federal menu labeling laws, which can be used to inform the regulation of food allergens.

A. Local and State

1. New York City

a. 2006 Menu Labeling Regulation

In September 2006, the NYC Board of Health proposed a menu labeling rule that would have required "some restaurants [to] post calorie information on menus and menu boards."[170] The proposal was

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169 U.S. DEP'T OF JUSTICE, QUESTIONS AND ANSWERS ABOUT THE LESLEY UNIVERSITY AGREEMENT AND POTENTIAL IMPLICATION FOR INDIVIDUALS WITH FOOD ALLERGIES (2013); *see also* 42 U.S.C. § 12188 (2012) (enforcement), § 2000a-3(a) (civil actions for injunctive relief).

170 Press Release, N.Y.C. Dep't of Health & Mental Hygiene, Health Department Proposes Two Changes to City's Health Code for Public Comment: First, to Phase Out Artificial Trans Fat in All Restaurants; Second, to Require Calorie Labeling in Some Restaurants (Sept. 26, 2006), https://web.archive.org/web/20060928231402/http://www.nyc.gov/html/doh/html/pr2006/pr093-06.shtml (accessing Internet Archive from Sept. 28, 2006) [hereinafter Press Release, Changes to City's Health Code]; *see also* Brent Bernell, *The History and Impact of the New York City Menu Labeling Law*, 65 FOOD & DRUG L.J. 839, 845 (2010) (discussing history of NYC's menu labeling law); Michael A. McCann, *Economic Efficiency and Consumer Choice Theory in Nutritional Labeling*, 2004 WIS. L. REV. 1161, 1199 (2004) (discussing earlier efforts to get restaurants in New York, and particularly New York City, to provide nutritional information through voluntary agreements).

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driven, at least in part, by the growth in food consumed outside the home, "a leading cause of excess calorie intake."[171] The proposal "was designed to primarily impact large, chain restaurants,"[172] and the NYC Department of Health and Mental Hygiene estimated that the proposal "would affect about one in ten restaurants" in NYC.[173] The Board of Health hoped that the required calorie information would cause consumers to choose healthier foods and thus decrease calorie consumption and obesity.[174]

Less than three months after it proposed the new rule, the Board unanimously voted to amend the City's Health Code to require food service establishments "that voluntarily disclose[] the nutrition information of" standardized menu items to post calorie information on their menus and menu boards next to each menu item.[175] The Board acted pursuant to its rulemaking authority under the NYC Charter, which gives it "the power to create regulations without any involvement from the City Council or other city or state agencies."[176]

The restaurant industry opposed the rule on both policy and legal grounds.[177] Critics "questioned whether the proposal could achieve the

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171 Sheri Kindel, *The Impact of Calorie Disclosure Regulations on the Consumer and Business Sector*, 10 OHIO ST. BUS. L.J. 245, 248 (2016). The Board had to decide "which restaurants would fall under the rule, what information they would be required to post, and how restaurants should have to display that information." Bernell, *supra* note 170, at 845.

172 Bernell, *supra* note 170, at 839.

173 Press Release, N.Y.C. Dep't of Health & Mental Hygiene, Board of Health Votes to Require Calorie Labeling in Some New York City Restaurants (Dec. 5, 2006), https://web.archive.org/web/20061208225608/http://www.nyc.gov:80/html/doh/html/pr2006/pr113-06.shtml (accessing Internet Archive from Dec. 8, 2006).

174 Bernell, *supra* note 170, at 843 (discussing the rationale for NYC's menu labeling law, namely the role of restaurants in excess calorie consumption, the link between excess consumption and the obesity epidemic, the deaths and health problems associated with the obesity epidemic, and the "calorie information gap").

175 *Id.* at 839; N.Y.C. DEP'T OF HEALTH & MENTAL HYGIENE BD. OF HEALTH, NOTICE OF ADOPTION OF AN AMENDMENT (§ 81.50) TO ARTICLE 81 OF THE NEW YORK CITY HEALTH CODE (2006), https://www1.nyc.gov/assets/doh/downloads/pdf/public/notice-adoption-hc-art81-50.pdf; Press Release, Changes to City's Health Code, *supra* note 170 (stating that the "proposal would only affect restaurants that make calorie information for standard menu items publicly available on or after March 1, 2007"); *Why the Health Department Proposes that Certain Restaurants List Calorie Content on Menus*, N.Y.C. DEP'T OF HEALTH & MENTAL HYGIENE, https://web.archive.org/web/20061003135901/http://www.nyc.gov/html/doh/html/cdp/cdp_pan-calorie-summary.shtml (accessing Internet Archive from Oct. 3, 2006).

176 N.Y.C., N.Y., CHARTER §§ 558, 1043 (2004); Thomas J. Lueck, *City May Ask Restaurants to List Calories*, N.Y. TIMES (Oct. 30, 2006), https://www.nytimes.com/2006/10/30/nyregion/30calories.html.

177 *See* Memorandum from Lynn D. Silver, Assistant Comm'r, Bureau of Chronic Disease Prevention & Control & Candace Young, Dir., Physical Activity & Nutrition, to Thomas R. Frieden, Comm'r 18 (Nov. 27, 2006), https://web.archive.org/web/2007

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stated [health] benefit," whether it was feasible, and whether the regulatory strategy it embodied was appropriate.[178] The New York State Restaurant Association (NYSRA) sued the Board of Health and the NYC Department of Health and Mental Hygiene to block the rule.[179] It argued that (1) the rule, which was to take effect on July 1, 2007, was expressly preempted by the Nutritional Labeling and Education Act of 1990 (NLEA) and FDA's regulations, and (2) the rule violated its members' First Amendment rights.[180]

The United States District Court for the Southern District of New York held that the regulation was preempted by federal law: under the NLEA, if a restaurant makes a voluntary nutrition content claim, the claim must comply with the requirements of FDA's implementing regulations.[181] NYC's menu labeling requirements differed from what was required under the NLEA and the regulations. Thus, the court held that the NLEA expressly "preempts any state regulation of nutrient content claims, including claims made by restaurants, that '[are] not identical to the requirement[s]'" of federal law.[182] The court did not reach the First Amendment claim.[183]

b. 2008 Menu Labeling Regulation

Following the invalidation of the 2006 regulation, the Board of Health proposed a new regulation, which it adopted by resolution on January 22, 2008.[184] The 2008 regulation required covered establishments to clearly and conspicuously post

> calorie information . . . on all menu boards and menus, as well as on food item display tags, adjacent or in close proximity, to the menu

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0222021652/http://www.nyc.gov:80/html/doh/downloads/pdf/cdp/cdp-pan-calorie-comments-response.pdf (accessing Internet Archive from Feb. 22, 2007) (listing organizations opposing the proposal as including the National Restaurant Association, the New York State Restaurant Association, the National Council of Chain Restaurants, Wendy's, McDonald's, and Domino's, among others).

178 *Id.* at 3.

179 Complaint, N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health, 509 F. Supp. 2d 351 (S.D.N.Y. 2007) (No. 07 Civ. 5710), 2007 WL 2778812.

180 *Id.* at 1–2; *N.Y. State Rest. Ass'n*, 509 F. Supp. 2d at 352.

181 *N.Y. State Rest. Ass'n*, 509 F. Supp. 2d at 352.

182 *Id.* at 362–63 (invalidating N.Y.C. HEALTH CODE § 81.50 (2006)).

183 *Id.*

184 N.Y.C. DEP'T OF HEALTH & MENTAL HYGIENE BD. OF HEALTH, NOTICE OF ADOPTION OF A RESOLUTION TO REPEAL AND REENACT §81.50 OF THE NEW YORK CITY HEALTH CODE (2008), https://www1.nyc.gov/assets/doh/downloads/pdf/public/notice-adoption-hc-art81-50-0108.pdf [hereinafter NOTICE OF ADOPTION].

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> item, using a font and format that is at least as prominent in size as that used to post either the name or price of the menu item.[185]

For menu items offered in different flavors and varieties, a range of calories was permitted to be listed.[186] The rule defined "[c]overed food service establishment" as

> a food service establishment within the City of New York that is one of a group of 15 or more food service establishments doing business nationally, offering for sale substantially the same menu items, in servings that are standardized for portion size and content, that operate under common ownership or control, or as franchised outlets of a parent business, or do business under the same name.[187]

The Board explained its focus on chain restaurants, noting that "the measure can be readily and accurately implemented [by chain restaurants], which account for a large and disproportionate proportion of meals served, and which serve food whose consumption has been clearly associated with excessive calorie intake and with obesity."[188]

The restaurant industry continued to resist the revised regulation[189] and, as with the earlier regulation, challenged it in court.[190] The NYSRA argued that federal law preempted the 2008 regulation and that the regulation unconstitutionally infringed on its members' First Amendment rights.[191] But whereas the United States District Court for the Southern District of New York invalidated the 2006 regulation,[192] the 2008 regulation withstood review.[193] The Court of Appeals for the Second Circuit held that "[i]n requiring chain restaurants to post calorie information on their menus, NYC merely stepped into a sphere that Congress intentionally left open to state and local governments" and that "the First Amendment is not violated, where as here, the law in

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185 *Id.* at 11.

186 *Id.* at 13.

187 *Id.* at 12.

188 *Id.*

189 *See* LYNN SILVER & CATHY NONAS, SECTION 81.50 CALORIE POSTING RESPONSE TO COMMENTS 7 (2008) (listing "[o]rganizations in [o]pposition" as including the National Restaurant Association, the International Franchise Association, and several restaurants and establishments).

190 N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health, No. 08 Civ. 1000(RJH), 2008 WL 1752455 (S.D.N.Y. Apr. 16, 2008), *aff'd*, 556 F.3d 114 (2d Cir. 2009).

191 *N.Y. State Rest. Ass'n*, 556 F.3d at 117.

192 N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health, 509 F. Supp. 2d 351, 352 (S.D.N.Y. 2007).

193 *N.Y. State Rest. Ass'n*, 556 F.3d at 117.

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question mandates a simple factual disclosure of caloric information and is reasonably related to NYC's goals of combating obesity."[194]

2. Others

The NYC menu labeling law—and the favorable decision from the Court of Appeals—helped pave the way for other jurisdictions to consider and enact menu labeling requirements.[195] Although a full examination of these laws is beyond the scope of this Article, there are several features that are worth noting.

First, the scope and requirements of these laws varied. For example, within the state of California, there were different menu labeling requirements for San Francisco City and County, San Mateo County, and Santa Clara County. San Francisco's requirements applied to any chain restaurant within the city and county

> offer[ing] for sale substantially the same Menu Items, in servings that are standardized for portion size and content, and is one of a group of 20 or more Restaurants in California that either: (1) operate under common ownership or control; or (2) operate as franchised outlets of a parent company, or (3) do business under the same name.[196]

San Mateo's requirement, however, would have applied to chain food service establishments in the unincorporated county with fifteen or

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194 *Id.* at 117–18.

195 *See* Brief for City and County of San Francisco et al. as Amici Curiae Supporting Respondents, at 2, N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health, 556 F.3d 114 (2d Cir. 2009) (No. 08-1892-cv.), 2008 WL 6513109 (stating that an adverse ruling in the New York menu labeling case "could undermine existing and pending legislation in state and local legislatures across the country"); Bernell, *supra* note 170, at 839–40 (stating that "New York City [menu labeling] law prompted numerous other cities, counties, and states to pass similar laws . . . and eventually led the restaurant industry to drop resistance to the idea and instead seek a unified, national standard for menu labeling"); Ashley Arthur, *Combating Obesity: Our Country's Need for a National Standard to Replace the Growing Patchwork of Local Menu Labeling Laws*, 7 IND. HEALTH L. REV. 305, 314 (2010) (noting that at the time "twenty-six states, Washington D.C., Puerto Rico and numerous cities and counties around the country ha[d] proposed menu labeling legislation"); *see also* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192, 19,229 (proposed Apr. 6, 2011) (codified at 21 C.F.R. pts. 11, 101) (noting preexisting state and local menu labeling laws); Anthony J. Marks, *Menu Label Laws: A Survey*, 29 FRANCHISE L.J. 90, 93 (2009).

196 S.F., CAL., HEALTH CODE § 468 (2008); *see also* S.F., Cal. Ordinance amending the San Francisco Health Code 260-80, File No. 081377 (Nov. 25, 2008) (suspending sections 468.3-468.8); *see also* Arthur, *supra* note 195, at 316 (discussing variations among the menu labeling laws of cities and counties within California).

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more stores in California,[197] and Santa Clara County's requirement covered chain restaurants in the unincorporated area of the county with fourteen or more restaurants in California.[198] As a second example, the requirements among counties in different states also varied. Whereas the three California county requirements discussed above used the number of restaurants in the state to determine coverage, the menu labeling regulation in King County, Washington, "required chain restaurants with 15 or more locations nationwide to" provide nutrition information.[199]

Second, these jurisdictions adopted menu labeling requirements in different ways. Whereas NYC Board of Health adopted menu labeling by a resolution amending the NYC Health Code,[200] other jurisdictions used different mechanisms. For example, in Philadelphia, the city council passed and the mayor signed an ordinance to amend the city's Health Code.[201] In California, state legislators passed and the governor signed a bill to require menu labeling.[202]

Third, in October 2008, California became the first state to pass menu labeling legislation.[203] The California menu labeling law expressly preempted local governments' menu labeling requirements.[204] By preempting local menu labeling requirements, California took a significant step toward promoting more uniform menu labeling requirements. The inclusion of a preemption provision in the California bill may have been "key" in "overcoming restaurant industry opposition."[205] California was the first state to pass menu labeling

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197 Michelle Durand, *Menu-Labeling Bill Yanked*, DAILY J. (Oct. 21, 2008), https://www.smdailyjournal.com/news/local/menu-labeling-bill-yanked/article_94764440-6c68-54a6-8b32-6654baad1e89.html.

198 Press Release, Cty. of Santa Clara, County Adopts Menu Labeling Ordinance for Chain Restaurants with 14 or more Locations in California (June 3, 2008), https://www.sccgov.org/sites/opa/nr/Documents/Menu_Labeling_Ordinance_News_Release_FINAL.pdf; *see also* Press Release, Cty. of Santa Clara, County Repeals Local Menu Labeling Ordinance in Anticipation of State Law Taking Effect Jan. 1, 2009 (Nov. 4, 2008), https://www.sccgov.org/sites/opa/nr/Documents/County-Menu-Labeling-Ord.pdf.

199 Donna B. Johnson et al., *Menu-Labeling Policy in King County, Washington*, 43 AM. J. PREVENTIVE MED. S130, S131 (2012).

200 NOTICE OF ADOPTION, *supra* note 184.

201 Philadelphia, Pa., Ordinance 080167-A (Jan. 1, 2010).

202 S. 1420, 2008 Leg., Reg. Sess. (Cal. 2008).

203 Arthur, *supra* note 195, at 316.

204 S. 1420.

205 KATE ARMSTRONG, PUB. HEALTH LAW CTR., MENU LABELING LEGISLATION: OPTIONS FOR REQUIRING THE DISCLOSURE OF NUTRITIONAL INFORMATION IN RESTAURANTS 9 (2008).

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legislation,[206] and other states, such as Oregon and New Jersey, followed suit.[207] Like the California law, other state menu labeling laws expressly preempted local governments' menu labeling requirements.[208]

The state laws, however, did nothing to address differing menu labeling requirements such as differing requirements among states or among cities and counties in states that had not enacted menu labeling requirements. For example, "the California menu labeling law . . . require[d] restaurants with 20 or more locations *in the state* to post caloric content, carbohydrates, saturated fat, trans fat, and sodium content."[209] By contrast, the New Jersey menu labeling law required chain restaurants with twenty or more locations *nationally* to provide calorie information for menu items listed on a menu, menu board, or similar signage.[210] Such variations were an impetus for federal menu labeling requirements.

B. Federal

1. Legislation

Less than four years after NYC's Health Department first proposed a menu labeling regulation and a little more than two years after NYC enacted a revised menu labeling rule, a national menu labeling requirement was signed into law by President Barack Obama as part of the Patient Protection and Affordable Care Act in 2010 (the ACA).[211] This section discusses the ACA's menu labeling provisions and FDA's implementing regulations.

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206 Arthur, *supra* note 195, at 316.

207 *See, e.g.*, H.R. 2726, 75th Leg. Assemb., Reg. Sess. (Or. 2009); S. 3905, 213th Leg. (N.J. 2009); ME. STAT. tit. 22, § 2500-A (2012); 150 MASS. CODE REGS. § 590.002 (2009); VT. STAT. ANN. tit. 18, § 4086 (West 2011); *see also* BRETON PERMESLY & SUZANNE TRIGG, AM. BAR ASS'N, MENU LABELING—"CHEESE FRIES FOR 700 CALORIES, PLEASE" (2016).

208 *See, e.g.*, OR. REV. STAT. § 616.585 (2017) (providing that "[a] local government may not adopt or enforce a local requirement for the determination or disclosure of nutritional information by a restaurant"); N.J. STAT. ANN. § 26:3E-17(k) (West 2012) (providing that the menu labeling law "shall occupy the entire field of regulation regarding the disclosure of caloric information by a retail food establishment").

209 AMALIA K. CORBY-EDWARDS, CONG. RESEARCH SERV., NUTRITION LABELING OF RESTAURANT MENUS 3 (2012).

210 *Id.*; *see also* N.J. STAT. ANN. § 26:3E-17.

211 Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, § 4205, 124 Stat. 119 (2010) (codified as amended at Federal Food, Drug, and Cosmetic Act (FDCA) §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343, 343-1 (2012)).

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Although Section 4205 of the ACA is the first federal menu labeling law, efforts to enact a federal menu labeling law began at least a decade earlier. In 2003, Representative Rosa DeLauro introduced legislation to create the Menu Education and Labeling Act (MEAL Act).[212] In subsequent years, other legislators introduced additional menu labeling bills, including the Labeling Education and Nutrition Act (LEAN Act).[213] None of the menu labeling bills discussed above that preceded Section 4205 of the ACA, however, were enacted.

Nevertheless, there are some important similarities between these early bills, which focused on the provision of calorie information on menus and menu boards by chain restaurants, and NYC's menu labeling rules and Section 4205 of the ACA.[214] Similarly, the MEAL Act would have required restaurants that were part of a chain with twenty or more locations doing business under the same name to disclose calorie information and certain additional nutrition information on menus, menu boards, and other signs.[215] Dissimilarly, however, the MEAL Act—unlike Section 4205—would have established a federal floor for menu labeling, as it would not have preempted state and local requirements that covered establishments provide additional nutrition information.[216]

The LEAN Act was similar to the MEAL Act in that it would have required chain food service establishments operating twenty or more establishments under the same name to disclose calorie information.[217] And, like section 4205 of the ACA, the LEAN Act would have preempted nonidentical state and local menu labeling requirements for

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212 *See* Menu Education & Labeling Act (MEAL Act), H.R. 3444, 108th Cong. (2003); *see also* MEAL Act, S. 2108, 108th Cong. (2004).

213 *See, e.g.*, Labeling Education and Nutrition Act of 2008 (LEAN Act), H.R. 7187, 110th Cong. (2008); LEAN Act, S. 3575, 110th Cong. (2008); Howard M. Metzenbaum Menu Education and Labeling Act, S. 1048, 111th Cong. (2009).

214 *Compare* N.Y.C., N.Y., HEALTH CODE § 81.50 (2006), N.Y.C., N.Y., HEALTH CODE (2008), *and* FDCA §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343(q)(5)(H), 343-1(a)(4), *with* H.R. 3444.

215 H.R. 3444.

216 *See* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,249 (Dec. 1, 2014) (codified at 21 C.F.R. pts. 11, 101) (stating that FDA "interpret[s] the provisions of section 4205 of the ACA related to preemption to mean that States and local governments may not impose nutrition labeling requirements for food sold in a covered establishment . . . unless the . . . requirements are identical to the Federal requirements"). *Compare* N.Y.C., N.Y., HEALTH CODE § 81.50 (2006), N.Y.C., N.Y., HEALTH CODE (2008), *and* FDCA §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343(q)(5)(H), 343-1(a)(4), *with* H.R. 3444.

217 *Compare* H.R. 3444, *with* S. 3575.

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covered establishments.[218] The NRA and other trade associations supported the LEAN Act.[219] Less than a month after bills to create the LEAN Act were introduced, the Coalition for Responsible Nutrition Information (CRNI), which includes the NRA, issued a press release announcing support for "[a] *uniform* national nutrition standard" that is "*efficient* and effective."[220]

The NRA supported Section 4205 of the ACA. The NRA described Section 4205 as "a win for both consumers and restaurateurs," noting that the law would replace the "confusing" patchwork of "regulations and laws a growing number of cities, counties and states have passed," which posed burdens for restaurateurs.[221]

Section 4205 amended the FDCA to require nutrition labeling of standard menu items at chain restaurants.[222] Specifically, a "restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name . . . and offering for sale substantially the same menu items" must disclose calorie information for standard menu items as well as daily caloric intake information on menus and menu boards.[223] Section 4205 also requires that specific, identified nutritional information be available to the consumer in a written form upon request.[224] The required disclosures must be done "in a clear and conspicuous manner."[225] Section 4205 excludes certain foods from its requirements, including items not

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218 *Compare* FDCA §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343(q)(5)(H), 343-1(a)(4), *with* S. 3575; *see also* Food Labeling, 79 Fed. Reg. at 71,248.

219 *See* Jodi Schuette Green, *Cheeseburger in Paradise? An Analysis of How* New York State Restaurant Association v. New York City Board of Health *May Reform Our Fast Food Nation*, 59 DEPAUL L. REV. 733, 744 (2010).

220 News Release, Nat'l Rest. Ass'n, New Coalition Advocates National Nutrition Standard for Chain Restaurants, (Oct. 22, 2008), https://www.restaurant.org/Pressroom/Press-Releases/New-Coalition-Advocates-National-Nutrition-Standar [https://web.archive.org/web/20090125221110/http://restaurant.org:80/pressroom/pressrelease.cfm?ID=1702] (emphasis added); *see also* Green, *supra* note 219, at 744.

221 *Issue: Nutrition Disclosure, Overview: The National Restaurant Association Believes a New Federal Nutrition-Disclosure Standard for Restaurants is a Win for Both Restaurant Operators and Guests*, NRA, PUBLIC POLICY ISSUE BRIEFS, https://web.archive.org/web/20100405191521/http://www.restaurant.org/advocacy/issues/issue/?Issue=menulabel (accessing Internet Archive from Apr. 5, 2010). There has been, however, continuing opposition to Section 4205 and FDA's menu labeling regulations. *See, e.g.*, *infra* note 258.

222 FDCA § 403(q)(5)(H), 21 U.S.C. § 343(q)(5)(H).

223 § 343(q)(5)(H)(i)–(ii). The Act also establishes requirements for self-service food and beverages and vending machines. § 343(q)(5)(H)(iii), (viii).

224 § 343(q)(5)(H)(ii)(III).

225 § 343(q)(5)(H)(ii)(I)–(IV).

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identified on a menu or menu board, daily specials, custom orders, and certain temporary and test foods.[226] If the required menu labeling is not provided, the food is "deemed to be misbranded."[227] A restaurant that is not required to have menu labeling can voluntarily opt into the menu labeling requirements.[228] And, as noted earlier, the menu labeling law expressly preempts certain state and local laws.[229]

2. Regulations

Section 4205 directed the Secretary of Health and Human Services to promulgate proposed regulations to carry out its provisions.[230] Accordingly in 2011, following a request for comments on the implementation of the ACA's menu labeling provisions,[231] FDA proposed regulations.[232] A significant portion of FDA's proposal focused on defining terms needed "[t]o establish the scope of establishments, labeling, and food covered by section 4205."[233] The proposal also discussed whether a "similar retail establishment" should include "grocery and convenience stores, as well as entities such as movie theaters, bowling alleys, bookstore cafes, and all establishments that sell restaurant-like food to consumers."[234] It also considered the definition of restaurant-type food and whether it should include "grab-and-go items."[235] The proposal further discussed how "the primary writing" in Section 4205's definition of "menu or menu boards" should

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226 § 343(q)(5)(H)(vii)(I)(aa)–(cc).

227 *See* § 343; *see also* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Food Establishments, 76 Fed. Reg. 19,192, 19,193 (proposed Apr. 6, 2011) (codified at 21 C.F.R. pts. 11, 101).

228 § 343(q)(5)(H).

229 FDCA § 403A(a)(4), 21 U.S.C. § 343-1(a)(4).

230 § 343(q)(5)(H)(x).

231 Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold from Vending Machines, 75 Fed. Reg. 39,026 (July 7, 2010); Notice of Meeting, 75 Fed. Reg. 43,182 (July 23, 2010).

232 Food Labeling, 76 Fed. Reg. at 19,192. FDA published guidance on the preemptive effect of the federal menu labeling law on state and local laws and a draft guidance on the implementation of the menu labeling law, the latter of which was withdrawn. *See* Guidance for Industry: Questions and Answers Regarding the Effect of Section 4205 of the Patient Protection and Affordable Care Act of 2010 on State and Local Menu and Vending Machine Labeling Laws; Availability, 75 Fed. Reg. 52,426, 52,427 (Aug. 25, 2010); Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010; Withdrawal of Draft Guidance, 76 Fed. Reg. 4360-01 (Jan. 25, 2011).

233 Food Labeling, 76 Fed. Reg. at 19,195, 19,232.

234 *See* CORBY-EDWARDS, *supra* note 209, at 9.

235 *See id.* at 12.

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be interpreted and whether it should be viewed from a customer's perspective.[236]

Congress did not define "restaurant or similar retail establishment,"[237] despite the importance of this term in setting forth the scope of the covered establishments. FDA noted in the preamble to its final rule that the legislative history of Section 4205 is "very sparse" and that, on the few occasions Section 4205 was discussed, "few specifics were raised, including specifics about the scope of the law."[238] In light of Congress's silence and the "ambiguity in the statute as to the breadth of the set of establishments covered," FDA defined a "restaurant or similar retail establishment" as "a retail establishment that offers for sale restaurant-type food, except if it is a school."[239] This definition includes "bakeries, cafeterias, coffee shops, convenience stores, delicatessens, food service facilities located within entertainment venues . . . , food service vendors . . . , food take-out and/or delivery establishments . . . , grocery stores, retail confectionary stores, superstores, quick service restaurants, and table service restaurants . . . if they sell restaurant-type food."[240] In explaining the inclusion of grocery stores that meet the other requirements of Section 4205, FDA favorably referenced comments that noted that grocery stores "sell a great deal of food for immediate consumption" and are "increasingly offering for sale restaurant-type food."[241]

FDA defined "restaurant-type food," a term that does not appear in the statute,[242] as "food that is usually eaten on the premises, while walking away, or soon after arriving at another location."[243] This food may be traditional restaurant food or bulk food used to prepare restaurant food.[244] It may also be the aforementioned foods

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236 *Id.* at 13.

237 *See* Food, Drug, and Cosmetic Act (FDCA) §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343(q)(5)(H), 343-1(a)(4) (2012); Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,165 (Dec. 1, 2014) (codified at 21 C.F.R. pts. 11, 101).

238 Food Labeling, 79 Fed. Reg. at 71,166.

239 *See* FDCA §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343(q)(5)(H), 343-1(a)(4); Food Labeling, 79 Fed. Reg. at 71,165, 71,164, 71,168, 71,254 (defining "restaurant or similar retail food establishment").

240 *Id.* at 71,164.

241 *Id.* at 71,166–68.

242 *See* FDCA §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343(q)(5)(H), 343-1(a)(4).

243 Food Labeling, 79 Fed. Reg. at 71,254 (codified at 21 C.F.R. § 101.11(a)).

244 *Id.* (providing that restaurant-type food may be "[s]erved in restaurants or other establishments in which food is served for immediate human consumption or which is sold for use in such establishments").

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"[p]rocessed and prepared primarily in a retail establishment, ready for human consumption, . . . and offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment."[245] Hence, FDA stated that the final definition of restaurant-type food "focuses on those establishments that offer for sale food that is most like food served in restaurants."[246]

Congress defined "menu" and "menu board" as "the primary writing of the restaurant or other similar retail establishment from which a consumer makes an order selection"; however, it did not define the primary writing.[247] FDA defined "menu or menu board" broadly in light of "the importance for all consumers to have access to nutrition information when making order selections."[248] It interpreted "'primary writing' . . . from a consumer's vantage point" and concluded that this term "can include more than one form of written material."[249] In addition, it stated that "menu" and "menu board" include "any writing of the covered establishment that is the primary writing from which a consumer makes an order selection."[250]

3. Compliance Date

After FDA finalized the menu labeling rule, FDA and Congress delayed the original January 1, 2015, compliance date.[251] Eventually

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245 *Id.* The final rules also define other terms, including "doing business under the same name" and "offering for sale substantially the same menu items." *Id.*

246 *Id.* at 71,166.

247 *See* FDCA § 403(q)(5)(H)(xi), 21 U.S.C. § 343(q)(5)(H)(xi).

248 Food Labeling, 79 Fed. Reg. at 71,177; *see also id.* at 71,209–10 (responding to comments expressing concerns about space constraints on menus and menu boards).

249 *Id.* at 71,176–77 (citing Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Food Establishments, 76 Fed. Reg. 19,192, 19,202 (proposed Apr. 6, 2011) (codified at 21 C.F.R. pts. 11, 101)).

250 *Id.* at 71,177.

251 *See id.* at 71,241; Consolidated Appropriations Act of 2016, Pub. L. No. 114-113, § 747, 129 Stat. 2242, 2282 (2015) ("None of the funds made available [by that] Act may be used to implement, administer, or enforce the final rule . . . until the later of—(1) December 1, 2016; or (2) the date that is one year after the date on which the Secretary of Health and Human Services publishes Level 1 guidance with respect to nutrition labeling . . . ."); Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date, 80 Fed. Reg. 39,675 (July 10, 2015) (extending compliance date to Dec. 1, 2016); A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods—Part II (Menu Labeling Requirements in Accordance With the Patient Protection Affordable Care Act of 2010); Guidance for Industry; Availability, 81 Fed. Reg. 27,067 (May 5, 2016) (announcing availability of guidance and that enforcement will begin on May 5, 2017); Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food

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FDA set May 7, 2018, as the final compliance date.[252] FDA extended the compliance date once in response to "concerns that covered establishments [would] not have adequate time to fully implement the requirements of the rule by the compliance date."[253] Congress then further delayed the compliance date by prohibiting FDA from using any of the funds under the Consolidated Appropriations Act of 2016 to implement, administer, or enforce FDA's final rule until one year after it published guidance on the rule.[254]

Following the change of administrations in January 2017, FDA further extended the compliance date for the rule to May 7, 2018.[255] Although the interim final rule announcing the extension raised questions about the future of the final rule,[256] in November 2017 FDA released draft guidance responding to comments on the implementation of the menu labeling regulation that indicated that FDA planned to finalize the guidance "to provide clarity to the industry on [the] remaining questions ahead of the [May 7, 2018, compliance date]."[257] FDA Commissioner Scott Gottlieb stated that the draft guidance was intended "to make sure implementation of the new menu labeling requirements goes forward on [FDA's] stated timeframe and succeeds for the long-term."[258]

Establishments; Extension of Compliance Date, 81 Fed. Reg. 96,364 (Dec. 30, 2016) (formally extending the compliance date to May 5, 2017).

252 Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments, 82 Fed. Reg. 20,825 (May 4, 2017).

253 Extension of Compliance Date, 80 Fed. Reg. at 39,676.

254 Extension of Compliance Date, 81 Fed. Reg. at 96,365; Consolidated Appropriations Act of 2016 § 747.

255 Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments, 82 Fed. Reg. at 20,825.

256 *Id.* at 20,827 (stating that FDA was "reconsider[ing] the rule consistent with" several Executive Orders aimed at "reducing burdens, reducing costs, maintaining flexibility, and improving effectiveness").

257 FDA, MENU LABELING: SUPPLEMENTAL GUIDANCE FOR INDUSTRY: DRAFT GUIDANCE 4 (Nov. 2017); *see also* FDA, MENU LABELING: SUPPLEMENTAL GUIDANCE FOR INDUSTRY (May 2018).

258 Statement from Scott Gottlieb, Comm'r, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on a Practical Approach to Ensuring Timely Implementation of FDA's Menu Labeling Rule (Nov. 7, 2017), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm584147.htm. Efforts to repeal certain portions of the ACA have not generally included Section 4205, but since 2012, bills to create a "Common Sense Nutrition Disclosure Act" have been introduced in the United States House of Representatives and Senate. *See, e.g.*, Common Sense Nutrition Disclosure Act of 2012, H.R. 6174, 112th Cong. (2012). If enacted, the Common Sense Nutrition Disclosure Act

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Despite the delays, the menu labeling law had an impact even before the final May 7, 2018, compliance date. Some restaurants announced that they would provide menu labeling in advance of FDA's enforcement of the menu labeling requirements.[259] For example, in September 2012, McDonald's announced that it would start listing calorie information on menus that month.[260] Subway announced that it would do the same in April 2016.[261] In addition, other restaurants implemented menu labeling in anticipation of an earlier compliance date.[262]

Section 4205 of the ACA, FDA's final menu labeling rule, and the debate about (and challenges to) menu labeling should inform the regulation of food allergen labeling and management in restaurants. This Article now turns to the regulation of food allergens.

III
CREATING A FRAMEWORK FOR THE REGULATION OF FOOD ALLERGEN LABELING AND MANAGEMENT IN RESTAURANTS

Although the existing literature describes the problem of food allergens in restaurants, it has not fully explored potential solutions.[263]

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would amend the FDCA, among other things, to permit the calorie disclosure required under Section 4205 of the ACA to represent the calories in the whole menu item, per a serving, or per common unit division. Common Sense Nutrition Disclosure Act of 2017, H.R. 772, 115th Cong. (2018); Common Sense Nutrition Disclosure Act of 2017, S. 261, 115th Cong. (2017). It would also permit the calorie information to be provided solely by a menu on the internet where the majority of the restaurant's orders are placed by customers who are not on the premises at the time of order. H.R. 772 (passed House of Representatives Feb. 6, 2018); S. 261. And it would limit restaurants' liability for violations. H.R. 772; S. 261. Earlier versions of the bill contained a provision that would have limited the definition of "restaurant or similar retail establishment" to retail establishments that derive more than 50% of their total revenue from the sale of restaurant-type food. Common Sense Nutrition Disclosure Act of 2013, H.R. 1249, 113th Cong. (2013); Common Sense Nutrition Disclosure Act of 2013, S. 1756, 113th Cong. (2013).

259 *See* Helena Bottemiller Evich, *Trump's Delay of Calorie-Posting Rule Jolts Restaurants*, POLITICO (May 27, 2017, 6:49 AM), https://www.politico.com/story/2017/05/27/trump-restaurant-calorie-posting-rule-238873.

260 *See* Press Release, McDonald's, McDonald's USA Adding Calorie Counts to Menu Boards, Innovating with Recommended Food Groups, Publishes Nutrition Progress Report (Sept. 12, 2012), https://www.prnewswire.com/news-releases/mcdonalds-usa-adding-calorie-counts-to-menu-boards-innovating-with-recommended-food-groups-publishes-nutrition-progress-report-169451836.html.

261 John Kell, *Subway to Add Calorie Information to All U.S. Menus*, FORTUNE (Apr. 5, 2016), http://fortune.com/2016/04/05/subway-calories-us-menus/.

262 *See* Evich, *supra* note 259.

263 *See, e.g.*, Brewer, *supra* note 123, at 312 (proposing "a state law . . . that is bifurcated into mandatory provisions for all Ohio restaurants and a voluntary provision creating an official designation of Food Allergy Friendly"); Derr, *supra* note 10 (discussing potential

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There is no need to start from scratch in designing a regulatory framework to address food allergens in restaurants. Rather, lawmakers should look to menu labeling as a potential model for food allergen labeling and use menu labeling to inform both the substantive requirements and implementation of food allergen measures.

Using menu labeling as a guide, this Part argues that restaurants and similar retail establishments should be required to provide labeling and information about major food allergens and implement measures, including worker training, to prevent allergen cross contact and ensure accurate labeling.[264] This Part also explores how menu labeling can help anticipate and respond to potential opposition to allergen requirements. It begins by setting forth a basic framework for food allergen labeling and accompanying measures and then considers potential benefits of this approach and responds to anticipated critiques. Part IV then considers how the implementation of menu labeling can inform the implementation of food allergen labeling and management measures.

A. A Proposed Framework for Food Allergen Regulation

1. Using Menu Labeling as a Model

There are several similarities between the menu labeling and allergen labeling contexts, which make the regulation of nutrition labeling an apt model for the regulation of allergen labeling.[265] First, the growth in foods prepared outside the home that made the need for menu labeling more acute[266] is the same growth that makes addressing

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reforms including revision of the Food Code, ingredient or allergen disclosure, and training); Roses, *supra* note 64 (arguing for federal legislation giving FDA the power to regulate food allergen labeling in restaurants); Martin, *supra* note 64, at 85 (arguing for federal legislation "which requires training, open conversation between the allergy sufferer and the server, . . . the posting of information. . . . menu labeling, mandatory safety regulations for kitchens, and bolstering emergency response to allergic reactions").

264 This Article uses the term restaurant in the discussion below to refer to restaurants and similar retail establishments unless discussing another source that uses the term differently.

265 There are of course limitations to this model, chief among them the need to prevent cross contact, which arises in the allergen but not the nutrition context. *See infra* Section III.A.3.

266 *See* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192, 19,192 (proposed Apr. 6, 2011) (codified at 21 C.F.R. pts. 11, 101) ("Americans now consume an estimated one-third of their total calories on foods prepared outside the home and now spend almost half of their annual food dollars on foods prepared outside the home.") (internal citations omitted); Bernell, *supra* note 170, at 841–42.

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food allergen labeling and management in restaurants so important.[267]

Second, current food allergen labeling regulation is similar to the regulation of nutrition labeling prior to the enactment of the Affordable Care Act (ACA) menu labeling provisions. Before the enactment of those provisions, labeling requirements were generally more stringent for foods in packaged form than for restaurant-type foods: calorie and certain other nutritional information was generally not required for restaurant-type foods. Specifically, before the ACA, the FDCA generally provided that food in packaged form is "misbranded unless its label or labeling bears nutrition information" but included exemptions for food sold in restaurants.[268]

Similarly, in the allergen context, the FDCA requires the labeling of major food allergens for packaged food, but there is no comparable requirement for restaurant-type food.[269] As one United States Senator remarked in the menu labeling context, "It makes no sense that American consumers can go to a grocery store and find nutrition information on just about anything, but then they are totally in the dark when they go to a restaurant for dinner."[270] The same can be said regarding major food allergen information. Congress enacted menu labeling requirements for certain chain restaurants in the 2010 ACA and, in so doing, took a significant step toward making nutrition information available for standard menu items at these establishments.[271] The gap in allergy labeling for restaurant-type food, however, remains.[272]

Third, both the lack of menu labeling information pre-ACA and the current lack of allergen labeling create a situation where consumers may be unaware of certain characteristics of the food they are consuming—nutrition information in the menu labeling context and

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267 *See supra* Section I.A.

268 Food, Drug, and Cosmetic Act (FDCA) § 403(q)(5)(A)(i)–(ii), 21 U.S.C. § 343(q)(5)(A)(i)–(ii) (2006). The ACA amended these exemptions. *See* FDCA 403(q)(5)(A)(i)–(ii), 21 U.S.C. § 343(q)(5)(A)(i)–(ii) (2012).

269 FDCA § 403(w), 21 U.S.C. § 343(w); *see also supra* Section I.B.

270 Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,167 (Dec. 1, 2014) (codified at 21 C.F.R. pts. 11, 101) (quoting Senator Harkin, 155 CONG. REC. S5522 (May 14, 2009)).

271 *See* Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, § 4205, 124 Stat. 119 (2010); *see also* Arthur, *supra* note 195, at 313 (drawing an analogy "between putting a restaurant's nutrition information at the point of purchase and labeling food products sold in a grocery store").

272 *See* FDCA § 403(w), 21 U.S.C. § 343(w); *see also* FDA *Questions and Answers*, *supra* note 64.

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food allergen information in the food allergen context.[273] In both situations, the lack of information is linked to health risks. The overconsumption of calories is a risk factor for being overweight and obese, which in turn increase the risk of certain chronic health diseases, including coronary heart disease and type two diabetes.[274] The consumption of a food containing an allergen puts people with food allergies at risk of an allergic reaction.[275] Both menu labeling and allergen labeling aim to increase the amount of information available to consumers so they can make better-informed choices about which foods they eat to try to reduce negative health consequences.[276]

Although there are many similarities between the nutrition labeling and allergy labeling contexts, one of the primary objections to menu labeling—that it may not change people's food choices and reduce the number of calories consumed—is unlikely to carry over to the food allergen context.[277] This is because although a consumer might not change her food choices today to reduce the possibility of developing a chronic disease in the future,[278] a consumer with a food allergy that is immediate and possibly life-threatening may go to great lengths to avoid the allergen.[279]

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273 *See* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192, 19,192 (Apr. 6, 2011) (codified at 21 C.F.R. pts. 11, 101) ("Consumers are generally unaware of, or inaccurately estimate, the number of calories in restaurant foods. In one survey of 193 adults, the participants underestimated the calorie content in foods prepared outside of the home they perceived to be "healthier" food choices by nearly half, an average of almost 650 calories per item.") (internal citations omitted).

274 Food Labeling, 79 Fed. Reg. at 71,156.

275 *See* Section I.A.

276 *See* H.R. REP. NO. 111-299, pt. 1, at 738 (2009).

277 *See, e.g.*, Lauren Slive, Note, *Closing the Kitchen? Digesting the Impact of the Federal Menu Labeling Law in the Affordable Care Act*, 22 U. FLA. J.L. & PUB. POL'Y 255, 263 (2011) (noting "[e]arly evidence regarding the effectiveness of calorie disclosures on menus to influence healthier choices has been mixed"); Bernell, *supra* note 170, at 868 (discussing studies on the impact of New York City's Regulation 81.50). Other critiques of menu labeling are discussed in Section III.B.2 *infra*.

278 *See* David Orentlicher, *Health Care Reform and Efforts to Encourage Healthy Choices by Individuals*, 92 N.C. L. REV. 1637, 1643 (2014) (stating that "it often is difficult for people to exercise self-control when weighing present costs and benefits with future costs and benefits").

279 *See* Boyce et al., *supra* note 1, at 63. *But see* Greenhawt et al., *supra* note 56, at 326 (noting the majority of the college students who responded to the survey "reported that they did not always avoid the food item to which they reported an allergy"); Sampson et al., *supra* note 56, at 1442 (noting that a majority of the adolescent and young adult respondents "admitted to eating at least a tiny amount of a food that was known to contain an allergen").

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In addition, although menu labeling has been the subject of much debate and criticism,[280] this may be an asset for those seeking to create and implement allergen labeling and management requirements. Proponents of allergen labeling can look to menu labeling to help them anticipate and respond to arguments that are likely to arise in the allergen context. Indeed, the regulation of allergen labeling in restaurants is likely to raise questions similar to those already addressed in the menu labeling context. These questions include: What establishments should be covered? How should any disclosure requirements be made feasible for covered establishments? How should allergen information be made accessible and understandable to consumers?[281] This Article now turns to these questions.

2. Labeling Food Allergens

Although any allergen labeling requirements must comply with any applicable procedural requirements—such as those for legislation and notice-and-comment rulemaking—and these procedural requirements will likely improve any resulting framework, there is no need to reinvent the wheel. Congress and FDA have already considered the menu labeling requirements.[282] Accordingly, this Article proposes that, like the menu labeling requirements, as an initial matter, a food allergen requirement should cover any "restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name . . . and offering for sale substantially the same menu items."[283] In addition, like the menu labeling provisions

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[280] *See, e.g.*, Slive, *supra* note 277, at 294; Christine Cusick, *Menu-Labeling Laws: A Move from Local to National Regulation*, 51 SANTA CLARA L. REV. 989, 1004 (2011); Kindel, *supra* note 171, at 264.

[281] *See* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156 (Dec. 1, 2014) (codified at 21 C.F.R. pts 11, 101); Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192 (proposed Apr. 6, 2011) (codified at 21 C.F.R. pts 11, 101); Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold from Vending Machines, 75 Fed. Reg. 39,026 (July 7, 2010).

[282] *See* Food, Drug, and Cosmetic Act (FDCA) §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343(q)(5)(H), 343-1(a)(4) (2012); Food Labeling, 79 Fed. Reg. at 71,156 (final rule); Food Labeling, 76 Fed. Reg. at 19,192 (proposed rule); Disclosure of Nutrient Content Information, 75 Fed. Reg. at 39,026; *see also* Food Labeling, 79 Fed. Reg. at 71,167 (final rule) (noting the "very sparse" legislative history of section 4205).

[283] *See* FDCA § 403(q)(5)(H)(i), 21 U.S.C. § 343(q)(5)(H)(i); *see also* Food Labeling, 79 Fed. Reg. at 71,253–54 (defining covered establishment) (codified at 21 C.F.R. § 101.11(a)).

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which permit an establishment to voluntarily opt in to the menu labeling requirements,[284] any allergen labeling and management requirements should permit establishments that do not meet the mandatory coverage requirements to opt in to become a covered establishment.[285]

Covered establishments should be prominently identified as such. In addition, covered establishments should indicate that written allergen information is available upon request and should be required to provide accurate labeling indicating whether or not a "major food allergen" is present in a given food upon request.[286] The labeling requirement could apply to standard menu items, like the ACA menu labeling, or it could apply to all restaurant-type foods.[287] Requiring labeling regarding major food allergens would cover a substantial portion of the documented food allergies in the United States and "the foods most likely to result in severe or life-threatening reactions."[288] It would also help to eliminate information deficit with respect to food allergens in restaurants and bring the requirements for nonpackaged foods in restaurants closer to those for packaged foods.

The notice and provision of information requirements also could be modeled on menu labeling, which requires that all forms of the menu and menu board include a clear and conspicuous statement about the availability of additional written nutrition information for standard menu items upon request and that such information be provided upon request.[289] In addition, although the focus of this Article is on food

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284 FDCA § 403(q)(5)(H)(ix), 21 U.S.C § 343(q)(5)(H)(ix); Food Labeling, 79 Fed. Reg. at 71,258 (codified at 21 C.F.R § 101.11(d)). In the preamble to the final menu labeling rule, FDA noted that it had not received any voluntary registrations from restaurants or similar retail food establishments opting in to menu labeling coverage. Food Labeling, 79 Fed. Reg. at 71,245.

285 *See* Food Labeling, 79 Fed. Reg. at 71,253 (codified at 21 C.F.R. § 101.11(a)) (defining covered establishment for menu labeling).

286 *See* FDCA §§ 201(qq), 403(q)(5)(H)(ii)(III)–(IV), 21 U.S.C. §§ 321(qq), 343(q)(5)(H)(ii)(III)–(IV).

287 FDCA § 403(q)(5)(H)(i), 21 U.S.C. § 343(q)(5)(H)(i). In the menu labeling context, FDA has defined "standard menu items" as "restaurant-type food that is routinely included on a menu or menu board or routinely offered as self-service food or food on display." Food Labeling, 79 Fed. Reg. at 71,254. The preamble to the final menu labeling rule identifies "condiments, daily specials, temporary menu items, custom orders, . . . food that is part of a customary market test; and self-service food and food on display that is offered for sale for less than a total of 60 days per calendar year or fewer than 90 consecutive days in order to test consumer acceptance" as items that are not standard menu items. Food Labeling, 79 Fed. Reg. at 71,158.

288 *Id.*; FDA *Questions and Answers*, *supra* note 64.

289 21 C.F.R. § 101.11(b)(2)(ii).

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allergen labeling, foods should also be subject to measures to prevent allergen cross contact as discussed below.[290]

3. Preventing Cross Contact

One important limitation of nutrition menu labeling as a model for the regulation of food allergens in restaurants is that, in the food allergen context, labeling major food allergens alone is not sufficient to protect individuals with a food allergy.[291] In fact, requiring labeling of major food allergens without accompanying measures to prevent cross contact may increase the risk to allergic individuals. For example, if labeling indicates that a food does not contain peanuts (a major food allergen), but the food has had cross contact with peanuts, the labeling may give a person with a peanut allergy a false assurance of safety. Thus, it is important that any measure to address food allergens require science-based measures to prevent cross contact and ensure accurate labeling. Although preventing cross contact in restaurants may be difficult, and there are a number of decisions that must be made about how to prevent such contact, these difficulties and questions should not be a justification for continued inaction. Instead, existing lawmaking processes should be used to begin to address these challenges and uncertainties.

One possibility would be to require covered restaurants to implement an allergen control plan that uses HACCP principles to control the risks of major food allergens.[292] As noted in Section I.C.1, although the Food Code does incorporate HACCP principles and

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290 The Author intends to consider more fully in future work the issue of allergen cross contact and management but includes here a brief discussion of one possible approach—the use of HACCP principles along with worker training and public education.

291 Menu labeling does require some training. *See* CORBY-EDWARDS, *supra* note 209, at 16 (discussing costs for employee training in FDA's Preliminary Regulatory Impact Analysis).

292 For a discussion of the components of an allergen control plan for food processing plants, see *Components of an Effective Allergen Control Plan: A Framework for Food Processors*, FOOD ALLERGY RES. & RESOURCE PROGRAM, https://farrp.unl.edu/3fcc9e7c-9430-4988-99a0-96248e5a28f7.pdf (last visited Oct. 7, 2018); *see also* FDA, GUIDANCE FOR INDUSTRY: JUICE HACCP HAZARDS AND CONTROLS GUIDANCE FIRST EDITION (Mar. 2004) (providing guidance regarding HACCP principles for juice processors, including controls for allergens). Principles drawn from HARPC could also inform any requirement. *See* Food, Drug, and Cosmetic Act §§ 301(uu), 418, 21 U.S.C. §§ 331(uu), 350g (2012); 21 C.F.R. pt. 117; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food, 80 Fed. Reg. 55,908 (Sep. 17, 2015) (codified at scattered sections of 21 C.F.R.).

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identifies food allergens as hazards, for the most part, use of HACCP is currently voluntary at the retail level.[293]

Although HACCP, which focuses on preventing food safety problems,[294] has faced resistance,[295] it is "widely recognized as the best approach for improving food safety."[296] It is focused on identifying food safety hazards, identifying the steps to control them, and implementing those steps, including corrective action plans.[297]

HACCP is based on seven principles: First, conducting an analysis of hazards (i.e., "biological, chemical or physical agent[s] that [are] reasonably likely to cause illness or injury in the absence of [their] control") such as major food allergens.[298] Second, determining critical control points at which preventative measures can be applied to prevent, eliminate, or reduce to an acceptable level a food safety hazard.[299] Third, establishing critical limits to which hazards must be controlled.[300] Fourth, establishing monitoring procedures "to assess whether a CCP is under control and produce an accurate record for future use in verification."[301] Fifth, establishing corrective actions for when a deviation from the HACCP plan occurs. Sixth, establishing verification procedures to "determine the validity of the HACCP plan and that the [HACCP] system is operating according to the plan."[302] And seventh, establishing record-keeping and documentation

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293 FOOD CODE annex 4, at 552, 559 (FDA 2017) ("Food Allergens As Food Safety Hazards"); *see also* FDA, MANAGING FOOD SAFETY: A MANUAL FOR THE VOLUNTARY USE OF HACCP PRINCIPLES FOR OPERATORS OF FOOD SERVICE AND RETAIL ESTABLISHMENTS 6–7 (2006).

294 FDA, HACCP PRINCIPLES & APPLICATION GUIDELINES (1997), https://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm (last updated Dec. 19, 2017) [hereinafter HACCP GUIDELINES] (defining HACCP as "[a] systematic approach to the identification, evaluation, and control of food safety hazards"); Neal D. Fortin, *The Hang-Up with HACCP: The Resistance to Translating Science into Food Safety Law*, 58 FOOD & DRUG L.J. 565, 567 (2003) [hereinafter Fortin, *The Hang-Up with HACCP*].

295 For a discussion of some of the possible barriers to incorporating HACCP into food safety law, as well as suggestions for how to overcome them, *see also* Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 567, 571 (examining the resistance to HACCP and measures to create a more efficient food safety system).

296 *Id.* at 567. HACCP has been used for juice, fish, and fishery products. *See* 21 C.F.R. pts. 120, 123 (2017).

297 Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 566; HACCP GUIDELINES, *supra* note 294.

298 HACCP GUIDELINES, *supra* note 294; Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 566.

299 HACCP GUIDELINES, *supra* note 294.

300 *Id.*

301 *Id.*

302 *Id.*

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procedures to document that the system is consistently working correctly.[303] As Neal D. Fortin notes, HACCP as "a science-based, preventative, and risk control system" has several benefits—it "creates a complete system to ensure food safety," recognizes the food industry's responsibility for food safety, and represents a "continuous method" of food safety—but its "preventative nature may be its most significant design achievement."[304] Before implementing HACCP principles, restaurants should have systems in place to control their basic operational and sanitation conditions.[305] Therefore, any HACCP requirement should include a requirement that appropriate prerequisite programs are in place.

4. Training Employees

As noted in Section I.A, servers may be overly confident that they know how, and are able to, safely serve a customer with a food allergy.[306] In addition, despite the Food Code's recommendations, as also noted in Section I.A, a study of restaurant food allergy practices in six cities found that only 44.4% of restaurant managers, 40.8% of food workers, and 33.3% of servers surveyed "reported that they had received training on food allergies while working at their respective restaurants."[307] These knowledge and training gaps underscore the need for required food allergy training for food workers. Any allergen labeling and management requirements should include empirically tested comprehensive food allergy training for workers as well as establishment-specific training on the restaurant's policies, processes, and procedures.[308]

5. Recognizing the Role of Consumers

Consumers also have an important role to play with respect to food allergen safety in restaurants as studies have shown that people with food allergies may not inform restaurants of their allergies. For example, one study of registrants with seafood allergies reporting restaurant reactions found that "[o]nly 21% [of the participants] with a

303 *Id.*; Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 566.

304 Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 567–68.

305 HACCP GUIDELINES, *supra* note 294 ("The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs.").

306 *See supra* Section I.A; Ahuja & Sicherer, *supra* note 51; Dupuis et al., *supra* note 33.

307 Radke et al., *supra* note 3, at 404.

308 *See* Dupuis, *supra* note 33, at 153.

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known allergy disclosed their allergy to the restaurant."[309] A study of allergic reactions to peanuts and tree nuts in restaurants and other food establishments found that "[o]f 106 registrants with previously diagnosed allergy who ordered food specifically for ingestion by the allergic individual, only 45% gave prior notification about the allergy to the establishment."[310] And a study of deaths from food-induced anaphylaxis noted that twelve of the thirty-one fatalities identified between 2001 and 2006 "were caused by individuals with [a] peanut or tree nut allergy consuming desserts . . . prepared away from home, and without having properly inquired about the ingredients."[311]

Accordingly, consumers should be prompted to inform their server of their allergy. This could be done through a written notice on menus and menu boards. Again, menu labeling, which requires a notice of the significance of calorie information as well as the availability of additional nutritional information, may be instructive with respect to the placement of the notice.[312] The Massachusetts allergy law could also inform any such requirement; it requires a notice on printed menus and menu boards stating, "Before placing your order, please inform your server if a person in your party has a food allergy."[313]

B. Discussion

1. Potential Benefits

Adopting food allergen labeling and management requirements may reduce injuries and deaths due to allergic reactions to restaurant

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309 T.J. Furlong, *Seafood Allergic Reactions in Restaurants*, 117 J. ALLERGY & CLINICAL IMMUNOLOGY S41 (2006).

310 Furlong et al., *supra* note 4, 867–68. Customers may not inform restaurants of their allergy because they are concerned about "the social implications of disclosing their nut-allergic status" and do not want to be seen as "simply being fussy or picky about what they ate." Leftwich et al., *supra* note 31, at 248. In addition, customers with allergies may "fear[] a conservative reaction from restaurant staff that would inappropriately and unnecessarily further constrain an already restricted range of food choices." *Id.*

311 Bock et al., *supra* note 33, at 1016; *see also* Furlong et al., *supra* note 4, at 868 (also noting that in 78% of the allergic reactions associated with a food establishment "the episode was caused by a food that was known by someone in the establishment to contain [peanut] or [tree nut] as an ingredient").

312 Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,256 (Dec. 1, 2014) (codified at 21 C.F.R. § 101.11(b)(9)); *see also id.* at 71,254 (codified at 21 C.F.R. § 101.11(a)) (defining menu or menu board); *id.* at 71,209–10 (responding to comments expressing concerns about space constraints on menus and menu boards).

313 105 MASS. CODE REGS. 590.009 (2017).

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food.[314] In addition to potentially advancing public health, these proposed changes would respect the autonomy of people with food allergies. This proposal may expand the food choices for people with food allergies by providing them access to information about major food allergens in many restaurant foods to enable them to make better-informed decisions about where and what to eat. Expanding access to information to facilitate more informed and hopefully better consumer choices is, similarly, a primary aim of menu labeling.[315] If the mandatory coverage of any food allergen requirements was identical to that of federal menu labeling, the requirements would cover approximately 298,600 establishments in 2130 chains.[316]

Without these measures, people with food allergies may be unable to obtain accurate information about the risk that restaurant foods may pose.[317] Allergen labeling and management requirements may also enhance the ability of those with food allergies to participate in everyday life activities because restaurants do far more than simply provide food: they serve as locations for social and business activities, help facilitate travel, and affect culture.[318] Requiring restaurants to provide labeling and adopt measures to prevent cross contact may decrease the risks that restaurants pose for people with food allergies and reduce accidental allergen exposures and the concomitant costs.[319]

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314 *See* Section I.A.

315 *See, e.g.*, Arthur, *supra* note 195, at 312; Bernell, *supra* note 170, at 843; Michelle I. Banker, *I Saw the Sign: The New Federal Menu-Labeling Law and Lessons from Local Experience*, 65 FOOD & DRUG L.J. 901, 916 (2010). Proponents of menu labeling also argued that "it may encourage restaurants to reduce the calories in standard menu items, reduce portion sizes, or offer new healthy alternatives." *See* Banker, *supra*, at 917; *see also* ELISE GOLAN ET EL., U.S. DEP'T OF AGRIC., NO. 793, AGRICULTURAL ECONOMIC REPORT, ECONOMICS OF FOOD LABELING 16 (2000) (noting that one "type of benefit arising from government intervention in labeling could be those stemming from product reformulation").

316 *See* FDA, FDA-2011-F-0172, FOOD LABELING: NUTRITION LABELING OF STANDARD MENU ITEMS IN RESTAURANTS AND SIMILAR RETAIL ESTABLISHMENTS, FINAL REGULATORY IMPACT ANALYSIS 7 (2014) (discussing the 2014 Regulatory Impact Analysis for FDA's final menu labeling rule and the estimated number of covered establishments).

317 *See supra* Section I.A (discussing restaurant worker knowledge and confidence about food allergen safety). This is similar to the difficulties people experienced in getting accurate nutrition information about restaurant-type foods before menu labeling.

318 *See* M.N. Primeau et al., *The Psychological Burden of Peanut Allergy As Perceived by Adults with Peanut Allergy and the Parents of Peanut-Allergic Children*, 30 CLINICAL & EXPERIMENTAL ALLERGY 1135 (2000) (finding that the parents of children with a peanut allergy reported considerable disruption in their daily activities); *see also* supra notes 42–50 and accompanying text.

319 *See* Dipen A. Patel et al., *Estimating the Economic Burden of Food-Induced Allergic Reactions and Anaphylaxis in the United States*, 128 J. ALLERGY & CLINICAL IMMUNOLOGY 110 (2011) (estimating the economic costs of food allergy and anaphylaxis);

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At the same time, however, it is important to acknowledge that even with robust and well-implemented food allergen labeling and management requirements, no restaurant would likely ever be entirely safe for those with food allergies. Accordingly, it is important for people with food allergies to be educated regarding this risk, so that they can make informed decisions about whether or not to accept it.[320]

Covered establishments may also benefit if they gain new customers. These customers may include people who did not eat at restaurants or who limited the restaurants that they ate at due to food allergy concerns. The new customers may also include friends, family, colleagues, and business associates of persons with food allergies. An increase in customers may help offset some of the compliance costs. Of course, no system is fail-safe, and some people with food allergies may still decide not to eat at restaurants due to the risk of an allergic reaction, even if food allergy labeling and management were regulated.

Restaurant workers may believe that their current knowledge and practices are sufficient to safely serve consumers with food allergies, which may dissuade restaurants from opting in to an allergen regulatory scheme. Nevertheless, a restaurant might decide to opt into a regulatory system. For example, establishments that are part of a smaller chain or not part of a chain at all may not have the resources or expertise to create a system for the labeling and management of food allergens from scratch, but they may be willing to opt in to an already established system if the benefits of doing so are less than the compliance costs. In addition, consumer demand for allergen labeling may increase as consumers become accustomed to having access to labeling at covered restaurants. Restaurants may also opt in to allergen requirements if they see that these measures are profitable for other restaurants. Thus, the

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see also Ruchi Gupta et el., *The Economic Impact of Childhood Food Allergy in the United States*, 167 JAMA PEDIATRICS 1026, 1027 (2013) (examining "the overall economic impact of [childhood] food allergy").

320 The risk of undeclared food allergens (e.g., due to mislabeling or cross contact) should not be a reason to not require restaurant food allergen labeling as this risk is not unique to the restaurant context. There is a risk that packaged foods required to have food allergen labeling under FALCPA may contain undeclared allergens or contain allergens as a result of cross contact. *See Recalls, Market Withdrawals, & Safety Alerts*, FDA (June 2, 2018), https://www.fda.gov/Safety/Recalls/default.htm (listing, among other things, recalls for undeclared allergens); Tiffany Maberry, *A Look Back at 2017 Food Recalls*, FOOD SAFETY MAGAZINE (Feb. 6, 2018), https://www.foodsafetymagazine.com/enewsletter/a-look-back-at-2017-food-recalls/ ("Undeclared allergens still dominate when it comes to food products needing to be pulled from store shelves. Last year, 218 food products posed health risks to unknowing consumers because allergenic ingredients were not properly displayed on product labels.").

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regulation of food allergens in restaurants may create benefits for both consumers and restaurants.

2. Response to Anticipated Critiques

The aim of requiring food allergen labeling and management in certain restaurants is to advance public health. Several of the anticipated critiques addressed below prioritize goals, values, and concerns other than public health.[321]

a. Coverage

Covered restaurants and advocates for people with food allergies may object under the Equal Protection Clause of the United States Constitution to allergen labeling requirements only applying to establishments that have standardized menus and are part of a larger chain. As the Supreme Court has stated, however, there is "no requirement of equal protection that all evils of the same genus be eradicated or none at all."[322] Additionally, "[t]he legislature may select one phase of one field and apply a remedy there, neglecting the others."[323] Accordingly, allergen labeling and management requirements should survive an Equal Protection challenge. In the menu labeling context, commentators have considered whether the focus on large chain restaurants violates the Equal Protection Clause of the United States Constitution.[324] They concluded that these laws should survive an equal protection challenge because the laws seem rationally related to a legitimate government interest.[325] If allergen labeling and management requirements enable consumers with food allergies to make better food choices, then these requirements should

321 *See* Jacqueline Fox, *Reforming Healthcare Reform*, 50 U. RICH. L. REV. 557, 599–600 (2016) ("It is likely true that the vast majority of people would agree that the goals of the public health system are to reduce morbidity and mortality. Methods for achieving these goals can be in conflict with other goals and values such as those related to the proper scope of government, allocation of scarce resources, and autonomy. But it does not seem extreme to assume that people generally would prefer, in the absence of other issues, for there to be less illness and injury. . . ."); *see also* Banker, *supra* note 315, at 919 (discussing opposition to menu labeling and stating that "loss of revenue to any company is not necessarily a legitimate 'cost' from a public health perspective").

322 Ry. Express Agency v. New York, 336 U.S. 106, 110 (1949).

323 Williamson v. Lee Optical of Okla., Inc., 348 U.S. 483, 489 (1955).

324 Cusick, *supra* note 280, at 1010–11; Lainie Rutkow et al., *Preemption and the Obesity Epidemic: State and Local Menu Labeling Laws and the Nutrition Labeling and Education Act*, 36 J.L. MED. & ETHICS 772, 786 (2008) [hereinafter Rutkow et al., *Preemption and the Obesity Epidemic*]; Bernell, *supra* note 170, 863–64.

325 *See, e.g.*, Bernell, *supra* note 170, at 863–64; Cusick, *supra* note 280, at 1011.

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be rationally related to the government's legitimate interest in protecting and promoting health by reducing deaths and injuries from allergic reactions.

There are several potential benefits to having allergen labeling requirements cover the same establishments as the ACA menu labeling provisions.[326] Large chain restaurants with menu standardization are likely to have a certain level of sophistication due to their size, chain status, and standardized menus,[327] characteristics which may also carry over into their policies, processes, and procedures. Thus, these restaurants may be better equipped to implement the labeling requirements and thereby avoid giving people with food allergies a false sense of safety while actually increasing their risk.

Focusing on chain restaurants with substantially the same menu items across locations may also reduce the compliance costs for restaurants as they may be able to use economies of scale (e.g., in the creation of signs and other labeling).[328] In addition, if the covered establishments are identical to those covered by Section 4205 of the ACA, it will simplify the coverage determination for establishments. Further, it may help reduce administration and enforcement costs. For example, it may reduce costs if compliance with both menu labeling and allergen requirements could be assessed during the course of a single inspection. Thus, allergen labeling requirements modeled on the coverage of the federal menu labeling requirements should survive an Equal Protection challenge and may have several benefits.

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326 The current analysis uses the ACA menu labeling provisions and regulations as of January 2018 as a model, but if Congress or FDA changed these, whether it continues to make sense to use them as a model would need to be evaluated. *See, e.g.*, Common Sense Nutrition Disclosure Act of 2017, H.R. 772, 115th Cong. (2018) (proposing to amend the menu labeling requirements); Common Sense Nutrition Disclosure Act of 2017, S. 261, 115th Cong. (2017) (also proposing to amend).

327 *See* Derr, *supra* note 10, 154–55 (noting in passing that "[i]ngredient or allergen disclosure understandably may be more feasible—and beneficial (due to their prevalence and national scope)—for chain restaurants with standardized ingredients and menus than for independent restaurants"). This is not to say that there may not be some establishments that lack such sophistication or that all smaller nonchain restaurants lack such sophistication. Size has been used as an indicator of sophistication in other contexts. *See, e.g.*, Greg Oguss, Notes & Comments, *Should Size or Wealth Equal Sophistication in Federal Securities Laws?*, 107 NW. U. L. REV. 285 (2012) (critiquing the treatment of size as sophistication in securities law).

328 The recipes for standardized menu items, however, could vary between establishments with respect to inclusion of food allergens required to be labeled.

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b. Market

Critics may also argue that the government should not interfere with the free market by requiring these measures. They may argue that if food allergen labeling and management measures were in sufficient demand, restaurants would take them voluntarily. Opponents of menu labeling have made similar arguments,[329] arguing that (1) "compelled menu labeling . . . amounts to an unwarranted and paternalistic government intrusion into private decision-making and interferes with the free market" and (2) is "anticompetitive because requiring all restaurants to disclose nutrition information eliminates the competitive edge of those restaurants . . . that use voluntary provision of nutrition information as a marketing point for attracting health-conscious consumers."[330]

Allergen labeling requirements, however, may strengthen the market by providing information so that consumers with food allergies can make better informed and more efficient choices. Similar to the menu labeling context, restaurants may not provide labeling without government intervention because they may not fully account for the costs of not providing labeling[331]—specifically, allergic reactions.[332] Consumers failing to report allergic reactions to restaurants may contribute to this problem.[333] If restaurants do not fully account for the costs of failing to prevent allergic reactions, then they may take inadequate precautions.[334]

Relatedly, restaurant workers may fail to recognize their shortcomings with respect to allergen management.[335] These shortcomings may mean that information about the safety of food from an allergen management perspective is unavailable or unreliable.[336] Thus,

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329 *See, e.g.*, Stephanie Rosenbloom, *Calorie Data to be Posted at Most Chains*, N.Y. TIMES (Mar. 23, 2010), http://www.nytimes.com/2010/03/24/business/24menu.html?scp=1&sq=menu%20labeling&st=cse; Slive, *supra* note 277, at 265.

330 Banker, *supra* note 315, at 919–20 (discussing arguments raised by opponents of menu labeling).

331 In the menu labeling context, "obesity produces external costs to society by increasing health care costs." *Id.* at 920.

332 *See* Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 578 (discussing a law and economics analysis of food safety and arguing that the failure to communicate safety and risk creates inefficiencies); *see also* Section I.C.3 (discussing tort law).

333 Furlong, *supra* note 309, at S41.

334 *See* Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 578.

335 *See supra* Section I.A.

336 *See* Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 584 ("Market controls have proven inadequate to provide the level of safety that consumers desire largely because information on the safety of food generally is unavailable either before or after purchase.").

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providing consumers with accurate information about food allergens in restaurant food "may enhance economic efficiency by helping consumers identify and purchase products they want most"—food that will not trigger an allergic reaction.[337]

c. Information Access

Similar to the opponents of the menu labeling requirements, covered establishments may argue that allergen labeling requirements impose burdensome information production requirements requiring them to determine whether a food contains any major food allergen as an ingredient.[338] Covered establishments, however, likely already have access to the food allergen information that they would need for allergen labeling, thus reducing this burden. First, many reported food allergy attacks occurred at establishments where someone in the establishment knew the food contained an allergen[339] but this information was not communicated to the person with a food allergy. Second, FALCPA reduces the burden on restaurants to identify the allergens. Many foods that restaurants use are already required to be labeled for major food allergens under FALCPA, giving establishments an efficient way to determine if an ingredient contains an allergen.[340] And for raw agricultural commodities, which are not subject to the food allergen labeling requirements under FALCPA, the identity of the product should be clear to the restaurant since the food is "in its raw or

337 Robin M. Nagele, *Keeping Consumers in the Dark: How the National Bioengineered Food Disclosure Standard Threatens Transparency and Food Security*, 57 Jurimetrics J. 529, 543 (2017); *see* GOLAN ET EL., *supra* note 315, at 12–13 (discussing mandatory labeling as a way to correct asymmetric or imperfect information and "provide consumers with greater access to information and . . . increase the efficiency of the market"); Jennifer L. Pomeranz, *Compelled Speech Under the Commercial Speech Doctrine: The Case of Menu Label Laws*, 12 J. HEALTH CARE L. & POL'Y 159, 193 (2009); *see also* 15 U.S.C. § 1451 (2012) ("Informed consumers are essential to the fair and efficient functioning of a free market economy.").

338 *See, e.g.*, Katherine Wilbur, *The Informed Consumer Is a Healthy Consumer? The American Obesity Epidemic and the Federal Menu Labeling Law*, 23 LOY. CONSUMER L. REV. 505, 522 (2011) ("Many restaurant and pro-business advocates are concerned that the burden of the law falls unfairly on restaurants because restaurants are now required to pay for the cost of determining the calorie content of each meal . . . ."); Slive, *supra* note 277, at 265.

339 Furlong et el., *supra* note 4, at 867–68 (finding that in 78% of 106 reactions of registrants "with previously diagnosed allergy who ordered food specifically for ingestion by the allergic individual . . . . [S]omeone in the establishment knew the food contained peanut or tree nut as an ingredient").

340 *See* Food, Drug, and Cosmetic Act (FDCA) § 403(w), 21 U.S.C. § 343(w) (2012); *see also* FDA *Questions and Answers*, *supra* note 64; Derr, *supra* note 10, at 153.

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natural state."[341] Under current law, a restaurant that receives food labeled under FALCPA is not required to pass that allergen information on to the consumer whom it could benefit. By limiting allergen labeling requirements to major food allergens, covered restaurants would have the needed information about major food allergens in foods that they use and serve.

Restaurants may counter that even with FALCPA they may have difficulty obtaining accurate information about potential food allergens due to the use of advisory label warnings, such as "May Contain," which FALCPA left "untouched."[342] But restaurants, particularly large chains, are uniquely suited to help discourage overuse of advisory label warnings and shape the supply chain through their purchasing decisions[343]: restaurants could insist that their suppliers not use advisory labeling in place of good manufacturing practices (GMPs).[344] This would be consistent with the requests of "the Grocery

341 FDCA § 201(r), 21 U.S.C. § 321(r) (defining "raw agricultural commodity" as "any food in its raw or natural state").

342 Besnoff, *supra* note 77, at 1469, 1483–84; Derr, *supra* note 10, at 86–88. FALCPA did require that the Secretary of Health and Human Services (HHS) submit a report on advisory labeling. *See* FDCA § 201 note, 21 U.S.C. § 321 note (requiring HHS to submit a report to Congress on advisory labeling); FDA, FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT OF 2004 PUBLIC LAW 108-282 REPORT TO THE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS, UNITED STATES SENATE AND THE COMMITTEE ON ENERGY AND COMMERCE UNITED STATES HOUSE OF REPRESENTATIVES (2006), *available at* https://web.archive.org/web/20060925225306/http://www.cfsan.fda.gov/~acrobat/alrgrep.pdf (accessing Internet Archive from Sept. 25, 2006) (discussing cross contact and advisory labeling).

It remains to be seen how the Food Safety Modernization Act (FSMA) Hazard Analysis and Risk-Based Preventive Controls (HARPC) provisions and FDA's regulations implementing these provisions will affect the use of these warnings on packaged foods, if at all. In the preamble to its final HARPC regulations, FDA indicated that its prior "guidance on the reasonable steps that should be taken to prevent allergens from being unintentionally incorporated into the food and the limited use of allergen advisory statements is still applicable." Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food, 80 Fed. Reg. 55,908, 56,034–35 (Sept. 17, 2015) (codified at scattered sections of 21 C.F.R.) (stating that "establishing regulatory policy or requirements, such as a long-term strategy regarding use of allergen advisory labeling . . . is outside the scope of" the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule); *see also* FDCA § 418, 21 U.S.C. § 350g; 21 C.F.R. pt. 117.

343 *See, e.g.*, Graciela Ghezán et al., *Impact of Supermarkets and Fast-Food Chains on Horticulture Supply Chains in Argentina*, 20 DEV. POL'Y REV. 389, 399 (2002) (discussing how multinational supermarkets and fast-food chains have changed supply chains); Jaap van der Kloet & Tetty Havinga, *Private Food Regulation from a Regulatee's Perspective* 9 (Nijmegen Sociology of Law Working Papers Series, Paper No. 2008/07) (stating that "purchasing power of supermarkets makes retail food safety standards in fact obligatory for many manufacturers").

344 *See* 21 C.F.R. pt. 117.

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Manufacturers of America (GMA) and the National Food Processors Association (NFPA), [which] have urged their members to not use advisory labeling in lieu of following GMPs."[345]

Restaurants may also argue that required food allergen labeling would hinder their ability to substitute ingredients in a pinch. There is nothing in the proposal, however, that would prevent restaurants from updating their labeling as the major food allergen content of their foods changed. Changing the allergen labeling would be necessary only if the substituted ingredient had a major food allergen that the original ingredient did not or vice versa.

Although allergen information requirements would create additional responsibilities for covered establishments, it would be far less costly for establishments to obtain food allergen information than for consumers to do so. In fact, without restaurants' participation, it may be virtually impossible for a consumer to obtain this information. This information asymmetry supports labeling.

d. Cost and Feasibility

Allergy labeling and management opponents may also argue that such measures will be too expensive. Although a full cost-benefit analysis would be needed to assess this argument—and is something that could be done during the enactment process—food allergen measures may be beneficial for restaurants.[346] Again, the experience with menu labeling may be instructive. Opponents of menu labeling argued that "the cost of implementation to restaurants [would] be prohibitive."[347] Proponents countered that most restaurants affected by the menu-labeling laws had already incurred the costs of nutritional analyses of standard menu items.[348] Similarly, in the food allergen labeling context, restaurants largely already have access to information about major food allergens in the foods that they purchase due to FALCPA.[349]

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345 Derr, *supra* note 10, at 87.

346 *See* Section IV.A (discussing the federal rulemaking process); *see also* FDA, FINAL REGULATORY IMPACT ANALYSIS, *supra* note 316 (regulatory impact analysis for menu labeling).

347 *See* Banker, *supra* note 315, at 919; Ellen A. Black, *Menu Labeling: The Unintended Consequences to the Consumer*, 69 FOOD & DRUG L.J. 531, 546 (2014).

348 Banker, *supra* note 315, at 919; Black, *supra* note 347, at 546.

349 *See* Food, Drug, and Cosmetic Act (FDCA) § 403(w), 21 U.S.C. § 343(w) (2012); *see also supra* Section III.B.2.c.

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It may be costlier for restaurants to comply with food allergen requirements than menu labeling requirements as the costs to prevent cross contact may be significant. This would need to be subject to a cost-benefit analysis again, this is something that could be assessed as part of the process of enacting any food allergen requirements. The costs and benefits would depend on the particular contours of the measurements to prevent cross contact and train workers. The benefits of preventing cross contact, however, may also be significant. For example, if fewer people are injured or killed by allergic reactions to restaurant food because of allergen labeling coupled with other allergen management measures, this not only benefits people with food allergies who avoid harm but may also lower liability for restaurants.[350] In addition, covered restaurants may gain customers—both those with allergies to the major food allergens and those who dine with them.[351]

Opponents may argue that regulating food allergens in restaurants would not be feasible for restaurants. The proposal to use menu labeling as a model for allergen labeling is a starting point in that it would need to be accompanied by measures to prevent cross contact, train restaurant workers, and educate the public. The proposed allergen labeling requirements and accompanying measures would need to be further fleshed out and refined—for example, through the legislative and regulatory processes with input from various stakeholders including restaurants and similar retail food establishments, public health professionals, and those with food allergies.[352] Stakeholders and other interested persons could provide feedback regarding what labeling control and management measures would be both effective from a public health perspective and feasible for restaurants. This may be particularly important with respect to measures to prevent cross contact as the menu labeling regulation does not provide a model for such measures.

The food allergen requirements could also be informed by the European Union's experience with its requirement that food businesses, such as restaurants, provide allergen information for non-prepacked foods that contain one or more of fourteen different allergens.[353]

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[350] Brewer, *supra* note 123, at 328.

[351] *Id.* at 326.

[352] *See, e.g.*, *infra* Section IV.A (discussing notice-and-comment rulemaking process).

[353] Regulation 1169/2011 of the European Parliament and of the Council of Oct. 25, 2011, on the provision of food information to consumers, 2011 O.J. (L 304/18); *see also* FOOD STANDARDS AGENCY, QUESTIONS AND ANSWERS ON THE EU FOOD INFORMATION FOR CONSUMERS REGULATION ALLERGEN PROVISIONS (2014); Liz Tucker, *New Food*

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e. Potential Liability

Opponents may also argue that the proposed allergen labeling requirements will increase restaurants' liability. A restaurant may be liable if it provides labeling to a person that incorrectly indicates that a food does not contain a major food allergen, resulting in an allergic reaction. The doctrine of negligence per se may permit a person so injured to use a statutory or regulatory food allergen labeling and management requirement to establish a duty.[354] Most courts would require that a plaintiff prove that she (1) "was injured by a type of risk the statute (or regulation) was intended to prevent" and (2) "was in the class of persons the statute (or regulation) was intended to protect."[355] Even if negligence per se applied, the plaintiff would still have to prove the other elements of negligence.[356] As another example, a person may have a claim for a breach of an express warranty if a restaurant provides labeling indicating that a food does not contain a major food allergen when it does.[357]

The end goal of the proposal, however, is to make restaurants safer for those with food allergies by reducing allergic reactions. If the proposal works as intended, the number of people who are injured by allergic reactions should be reduced, and with it restaurants' liability.[358] But if a restaurant makes a mistake, and that mistake causes a person to be injured or to die, the restaurant should be liable.[359] Such liability may help create a safer system for those with food allergies by acting as a means of regulatory enforcement[360] and by providing feedback to restaurants that they should invest more in food allergen

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Labeling Regulations for the Catering Industry, FOOD SAFETY MAGAZINE (Dec. 2, 2014), https://www.foodsafetymagazine.com/enewsletter/new-food-labeling-regulations-for-the-catering-industry/?mobileFormat=false.

354 David G. Owen, *Proving Negligence in Modern Products Liability Litigation*, 36 ARIZ. ST. L.J. 1003, 1006 (2004).

355 *Id.*

356 *Id.*; *see also* Leavitt, *supra* note 64 (discussing effect of the Massachusetts FAAA on common law causes of action).

357 *See* U.C.C. § 2-313(1)(a)–(b) (AM. LAW INST. & UNIF. LAW COMM'N 2002) (stating in part that "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise" and "[a]ny description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description").

358 *See* Martin, *supra* note 64, at 100–01.

359 *Id.*

360 *Id.*

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safety.[361] In addition, "if restaurants seek liability insurance, the insurers will demand compliance with the law," thereby further reinforcing its requirements.[362]

IV
IMPLEMENTING FOOD ALLERGEN LABELING AND MANAGEMENT REQUIREMENTS

This Part uses the experience with menu labeling to explore how the proposals from Part III might be implemented. It discusses the benefits and limitations of federal action as a means of enacting food allergen labeling and management requirements and argues that federal action, ultimately, may be the best way to advance public health and address food allergen labeling and management in restaurants. Because of the political and other challenges inherent in creating a federal regulatory framework for food allergens in restaurants, this Part also considers some of the benefits and limitations of state and local action. Like in the menu labeling context, local action may spur states and, ultimately, the federal government to regulate the labeling and management of food allergens in restaurants.

A. Federal Action

There is a strong argument that FDA has the authority to promulgate regulations requiring food allergen labeling and management in restaurants under the current law. FDA has jurisdiction over "food," which the FDCA defines, in part, as "articles used for food or drink for man" and "articles used for components of any such article."[363] Restaurant food is "food" under the FDCA.[364] The FDCA prohibits, among other things, the adulteration or misbranding of food "while such article is held for sale (whether or not the first sale) after shipment in interstate commerce."[365] The shipment of components of food (i.e., its ingredients) has been held to give FDA jurisdiction.[366] Thus FDA

361 Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 574.

362 *See* Martin, *supra* note 64, at 101.

363 Food, Drug, and Cosmetic Act (FDCA) § 201(f), 21 U.S.C. § 321(f) (2012).

364 *See id.*

365 FDCA § 301(k), 21 U.S.C. § 331(k). Interstate commerce is "commerce between any State or Territory and any place outside thereof" and "commerce within the District of Columbia or within any other Territory not organized with a legislative body." FDCA § 201(b), 21 U.S.C. § 321(b).

366 *See, e.g.*, United States v. An Article of Food, 752 F.2d 11, 12 (1st Cir. 1985); *see also* Baker v. United States, 932 F.2d 813 (9th Cir. 1991); United States v. 40 Cases, 289 F.2d 343, 345 (2d Cir. 1961); PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES

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would have jurisdiction over food held for sale in restaurants if the food or the ingredients used to make the food were shipped in interstate commerce.[367] Many of the foods sold by large chain restaurants would likely meet this requirement.

Section 701(a) of the FDCA has been interpreted by courts as giving FDA the "authority to promulgate substantive regulations for the efficient enforcement of" the FDCA.[368] The FDCA provides, in part, that a food is misbranded if "its labeling is false or misleading in any particular."[369] Section 201(n) provides that

> determining whether the labeling . . . is misleading there shall be taken into account . . . the extent to which the labeling . . . fails to reveal facts . . . material with respect to consequences which may result from the use of the article to which the labeling . . . relates . . . under such conditions of use as are customary or usual.[370]

FDA has relied on FDCA 701(a) and 201(n) to promulgate regulations requiring mandatory warnings, such as those for certain foods packaged in self-pressurized containers and with certain propellants.[371] Furthermore, the FDCA provides, in part, that a food is

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AND MATERIALS 284 (4th ed. 2014) (listing "cases holding that shipment of product ingredients in interstate commerce is sufficient to confer jurisdiction on FDA").

Before the ACA, in the menu labeling context, commentators stated that FDA had the authority to promulgate regulations requiring restaurants to provide certain information. *See* Rebecca S. Fribush, *Putting Calorie and Fat Counts on the Table: Should Mandatory Nutritional Disclosure Laws Apply to Restaurant Foods?*, 73 GEO. WASH. L. REV. 377, 383 (2005) (stating that "[i]t is generally accepted that the FDCA gives the FDA jurisdiction to regulate restaurant food in ways that include menu labeling"); Sarah A. Kornblet, *Fat America: The Need for Regulation Under the Food, Drug, and Cosmetic Act*, 49 St. Louis U. L.J. 209, 243 (2004) (arguing that "the FDA may find fast food misbranded and its labeling insufficient to provide consumers with knowledge of what they are eating, and it may mandate some type of labeling either on a menu or posted in a restaurant").

367 *See* HUTT ET AL., *supra* note 366, at 281.

368 *See* FDCA 701(a), 21 U.S.C. § 371; Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 617–18 (1973); Nat'l Nutritional Foods Ass'n v. Weinberger, 512 F.2d 688, 696 (2d Cir. 1975) ("Whatever doubts might have been entertained regarding the FDA's power under § 701(a) to promulgate binding regulations were dispelled by the Supreme Court's recent decisions in Weinberger v. Hynson, Westcott & Dunning, Inc. . . . and its companion cases . . . ." (citations omitted)).

369 FDCA § 403(a), 21 U.S.C. § 343(a).

370 FDCA § 201(n), 21 U.S.C. § 321(n).

371 *See, e.g.*, Food, Drug & Cosmetic Products, Warning Statements, 40 Fed. Reg. 8,912, 8,912 (Mar. 3, 1975) (explaining the Commissioner's conclusion that there was "ample authority for the establishment of warning statements" for self-pressurized containers and those with certain propellants); *see also* HUTT ET EL., *supra* note 366, at 401 (providing examples of FDA regulations requiring warnings).

At one point before FALCP was enacted, FDA considered proposing regulations "to require that foods that contain certain protein ingredients include information on the label

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adulterated "if it has been prepared, packed, or held under insanitary conditions . . . whereby it may have been rendered injurious to health."[372] FDA has relied, in part, on sections 402(a)(4) and 701(a) of the FDCA in promulgating its current Good Manufacturing Practice regulations.[373] In addition, in 1974, in the preamble to proposed food service sanitation regulations, FDA stated that the prohibition in section 301(k) of the FDCA on "adulteration of food while held for sale after interstate shipment . . . includes food service sanitation."[374] Because of the authority granted to FDA by the FDCA—and specifically sections 201(n), 301(k), 402(a), and 701(a)—there is a strong argument that FDA has the authority to promulgate regulations requiring food allergen labeling and management in restaurants.[375]

State and local governments, however, may strongly oppose any such action by FDA. For example, the Food and Drug Law casebook by Hutt, Merrill, and Grossman describes FDA as having "ceded the regulation of [restaurants, grocers, and food vending machines] to state and local governments."[376] The casebook authors note that when FDA proposed to make its model ordinance for the regulation of food service establishments mandatory in 1974 via regulation, "[s]tate officials opposed this action, primarily because 'it abridged a long-term understanding between the States and the Federal government regarding the regulation of the food service industry . . .'" and that

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in plain English terms that clearly identifies the presence of these ingredients" and "to require food allergen labeling on spices." Unified Agenda, 68 Fed. Reg. 72,862, 72,890 (Dec. 22, 2003). Although the legal basis for those regulations is not identified in the Unified Agenda, it seems likely it could have been FDCA 701(a) and 201(n). *See* Unified Agenda, 68 Fed. Reg. at 72,890.

372 FDCA § 402(a)(4), 21 U.S.C. § 342(a)(4).

373 *See, e.g.*, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food, 44 Fed. Reg. 33,238, 33,239 (proposed June 8, 1979) (codified at C.F.R. pts. 20, 101).

374 Food Service Sanitation, 39 Fed. Reg. 35,438, 35,438 (proposed Oct. 1, 1974). The proposed regulations were ultimately withdrawn. *See* Food Service Sanitation, 42 Fed. Reg. 15,428, 15,428 (Mar. 22, 1977); *see also infra* note 376 and accompanying text.

375 Courts will generally defer to agency interpretations of ambiguous statutes if the agency's interpretation of the statute is permissible and Congress has "delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *See* Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 841, (1984); United States v. Mead Corp., 533 U.S. 218, 227, (2001); City of Arlington v. FCC, 569 U.S. 290, 293 (2013) (holding that "an agency's interpretation of a statutory ambiguity that concerns the scope of its regulatory authority (that is, its jurisdiction) is entitled to deference under *Chevron*"). *But see* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 126 (holding that "FDA's assertion of jurisdiction [over tobacco products] is impermissible").

376 *See* HUTT ET AL., *supra* note 366, at 281–82.

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"FDA withdrew the proposal, declaring that 'it was never [the agency's] intention to supersede State and local regulation of food service sanitation.'"[377] For similar reasons, states may oppose any allergen labeling and management requirements.

Although there is a strong argument that FDA has authority to promulgate food allergen labeling and management requirements for restaurants, Congress could enact legislation requiring restaurants to provide major food allergen labeling and implement allergen control measures.[378] This would be similar to the approach Congress took with menu labeling in the ACA.[379] Like it did with menu labeling, Congress could direct FDA to promulgate implementing regulations and issue guidance.[380]

The rulemaking process could help to improve any resulting regulatory system by providing interested persons an opportunity to provide feedback on proposed allergy labeling and management requirements. Even if allergy labeling requirements were modeled on the menu labeling requirements as this Article suggests, there would still be many questions and issues to be resolved regarding the labeling requirements as well as accompanying allergen management, worker training, and public education requirements. Questions would include how to best prevent allergen cross contact in covered establishments and the feasibility of different approaches. For example, although an in-depth analysis of the "informal" or notice-and-comment rulemaking process, its benefits, and limitations is beyond the scope of this Article,

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377 *Id.* at 282 (internal citations omitted) (quoting 42 Fed. Reg. at 15,428; 39 Fed. Reg. at 35,438).

378 Several student commentators have argued for national labeling. *See, e.g.*, Roses, *supra* note 64, at 226; Martin, *supra* note 64, at 85.

379 *See* Food, Drug, and Cosmetic Act (FDCA) § 403(q)(5)(H), 21 U.S.C. § 343(q)(5)(H). As noted above, in the obesity context, before the federal menu labeling law, some commentators suggested that FDA promulgate restaurant labeling rules. Fribush, *supra* note 366, at 383; Kornblet, *supra* note 366, at 221.

380 *See* FDCA § 403(q)(5)(H)(x), 21 U.S.C. § 343(q)(5)(H)(x) (providing that within one year of enactment FDA must promulgate proposed regulations to carry out the menu labeling law); *see* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156 (Dec. 1, 2014) (codified at C.F.R. pts. 11, 101); Consolidated Appropriations Act of 2016, Pub. L. No. 114-113, § 747, 129 Stat. 2242 (2015); FDA, MENU LABELING: SUPPLEMENTAL GUIDANCE FOR INDUSTRY: DRAFT GUIDANCE (Nov. 2017); FDA, A LABELING GUIDE FOR RESTAURANTS AND RETAIL ESTABLISHMENTS SELLING AWAY-FROM-HOME FOODS-PART II (MENU LABELING REQUIREMENTS IN ACCORDANCE WITH 21 CFR 101.11): GUIDANCE FOR INDUSTRY (Apr. 2016); FDA, GUIDANCE FOR INDUSTRY: NUTRITION LABELING OF STANDARD MENU ITEMS IN RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS: SMALL ENTITY COMPLIANCE GUIDE (Mar. 2015).

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through this process interested persons—including those potentially affected by an allergy labeling and management rule—could provide feedback on a proposed rule.[381] In addition, the costs and benefits of any proposed rule and regulatory alternatives would be assessed and approached to maximize net benefits.[382]

The primary benefit of federal action as compared to state or local government action would be an increase in uniformity for both consumers and covered establishments if the federal law preempted any inconsistent state and local requirements.[383] For consumers with food allergies, standardized labeling may help them better identify major food allergens. As one commentator noted in the menu labeling context, "[U]niform labeling formats may accelerate the beneficial effects of menu-labeling laws by increasing familiarity with nutrition

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381 *See* 5 U.S.C. § 553 (2012) (describing the "notice and comment" rulemaking process); *see also* Food Labeling, 79 Fed. Reg. at 71,156 (discussing comments on proposed menu labeling rule and publishing final menu labeling rule); Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Food Establishments, 76 Fed. Reg. 19,192 (proposed Apr. 6, 2011) (codified at 21 C.F.R. pts 11, 101). Generally, in notice and comment rulemaking, the agency must give notice of the proposed rule by publishing it in the Federal Register, "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments," and "[a]fter consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose." 5 U.S.C. § 553(c). Courts, Congress, and Presidents have also imposed other requirements on rulemaking. *See, e.g.*, Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 Duke L.J. 1385, 1400 (1992) (discussing judicially, congressionally, and presidentially imposed analytical requirements). This issue of food allergens labeling and management in restaurants and similar retail establishments may also be suited for negotiated rulemaking. *See* Marie Boyd, *Unequal Protection Under the Law: Why FDA Should Use Negotiated Rulemaking to Reform the Regulation of Generic Drugs*, 35 Cardozo L. Rev. 1525, 1554–68 (2014) (discussing negotiated rulemaking).

382 *See, e.g.*, Improving Regulation and Regulatory Review, Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 18, 2011); Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993); 5 U.S.C. §§ 601–612; Unfunded Mandate Reform Act of 1995, Pub. L. No. 104-4, 109 Stat. 48 (1995); *see also* Food Labeling, 79 Fed. Reg. at 71,244 (discussing Regulatory Impact Analysis for final menu labeling rule); FDA, FINAL REGULATORY IMPACT ANALYSIS, *supra* note 316.

383 *See* U.S. CONST. art. VI, cl. 2 (Supremacy Clause). For a discussion of the Supremacy Clause and preemption see Caleb Nelson, *Preemption*, 86 VA. L. REV. 225 (2000). Congress could expressly preempt inconsistent state and local requirements as it did with menu labeling. *See* FDCA § 403A(a)(4), 21 U.S.C § 343-1(a)(4). Even if there was no express preemption, there still could be preemption. *See, e.g.*, Sprietsma v. Mercury Marine, 537 U.S. 51, 65 (2002) ("[A]n express pre-emption clause 'does *not* bar the ordinary working of conflict pre-emption principles,' that find implied pre-emption 'where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'") (internal citations omitted).

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labels and facilitating comprehension of the information provided."[384] A nationwide law may also substantially expand the food choices of people allergic to a major food allergen.

For covered establishments that operate in more than one jurisdiction, it may be easier to comply with a single federal standard than a patchwork of state and local standards.[385] Establishments that are not part of a chain with twenty or more locations doing business under the same name and offering substantially the same menu items may opt in to coverage, further increasing uniformity.[386] For example, an establishment that does not meet the definition of a chain restaurant subject to menu labeling—perhaps because it is part of a chain with only fifteen locations—may prefer to be subject to a federal standard instead of potentially more burdensome differing state and local standards.

A federal food allergen law may also reduce administration and enforcement costs. For example, as noted earlier, if the coverage was coterminous with the coverage of the menu labeling law, a single inspection could be used to determine compliance with both laws, potentially reducing regulatory costs.

Opponents of allergen requirements, however, may argue that the nationwide costs of compliance for covered restaurants are too burdensome. Although the costs may be substantial, there may also be substantial benefits. A nationwide law may generate efficiencies due to economies of scale relative to measures with a narrower applicability. However, given the Trump administration's "focus on deregulation and concerted opposition to new government regulation,"[387] creation of a new federal framework for the labeling and management of food allergens in restaurant-type food may be unlikely in the near term.

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384 Banker, *supra* note 315, at 928.

385 *See* Wilbur, *supra* note 338, at 522–23 (discussing argument "that the federal menu labeling law should preempt all state and local menu labeling rules").

386 *See* Cusick, *supra* note 280, at 1003 (discussing the menu labeling voluntary opt-in provision); Kindel, *supra* note 171, at 255 (also discussing the opt-in provision).

387 Diana R. H. Winters, Essay, *Food Law at the Outset of the Trump Administration*, 65 UCLA L. REV. DISCOURSE 28, 41 (2017); *see also* Binyamin Appelbaum & Jim Tankersley, *The Trump Effect: Business, Anticipating Less Regulation, Loosens Purse Strings*, N.Y. TIMES (Jan. 1, 2018), https://www.nytimes.com/2018/01/01/us/politics/trump-businesses-regulation-economic-growth.html; Reducing Regulation and Controlling Regulatory Costs, Exec. Order No. 13,771, 82 Fed. Reg. 9339 (Jan. 30, 2017).

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B. State and Local Action

Absent federal action, states and localities could help fill the gap by adopting allergen labeling and management requirements. Although such measures would not entirely eliminate the gap in the allergen labeling requirements, they would go further than the existing state and local requirements discussed earlier. Ultimately, state and local food allergen labeling requirements may make federal legislative action more likely. This section discusses the power of states and localities to enact food allergen labeling and management measures, considers potential benefits and limitations of state and local action, and concludes by addressing two potential challenges to these actions.

1. State and Local Powers

States have the power to help fill the gap in food allergen management in restaurants and similar retail food establishments in the absence of preemptive federal legislative and regulatory action.[388] The regulation of food allergen labeling and management in restaurants falls within the states' broad police power for public health,[389] as food allergens pose health and safety risks to allergic individuals.[390]

Although a detailed examination of the powers of political subdivisions of states, as well as the limits and variations of these powers, is beyond the scope of this Article, in many cases, local governments have "broad power to address local issues"[391] and could use this power to help fill the gap in the labeling and management of food allergens in restaurants.[392] Although in other cases the power of

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388 *See* Brewer, *supra* note 123, at 306 (arguing that Ohio should enact legislation regarding food allergens in restaurants).

389 *See* U.S. CONST. amend. X ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."); Jacobson v. Massachusetts, 197 U.S. 11, 24–25, (1905) (describing "police power" as "a power which the state did not surrender when becoming a member of the Union under the Constitution" and stating that "[a]ccording to settled principles, the police power of a state must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health . . ."); *see also* Jacqueline Fox, *Zika and the Failure to Act Under the Police Power*, 49 CONN. L. REV. 1211 (2017).

390 *See supra* Section I.A.; *see also* NAT'L ACAD. SCI., ENG'G, & MED., *supra* note 22, at 10.

391 Lainie Rutkow et al., *Local Governments and the Food System: Innovative Approaches to Public Health Law and Policy*, 22 ANNALS HEALTH L. 355, 358 (2013) [hereinafter Rutkow et al., *Local Governments and the Food System*].

392 *Id.* at 370 (discussing the ability of local governments to enact policies relative to the food system and noting that although the powers of many localities in this area are broad, some are limited).

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localities may be more limited and some may lack the power to regulate food allergen labeling at all. For example, Mississippi law expressly reserves the regulation of nutrition labeling for food, which is defined to include the "allergen content," to the legislature.[393] Illinois law provides that allergen awareness training is an exclusive state function and local regulation of allergen awareness training is prohibited.[394]

2. Potential Benefits and Limitations of State and Local Action

Although state and local laws are unlikely to create uniformity to the same extent as a federal law, these laws may nevertheless increase uniformity relative to the status quo by increasing it within a single jurisdiction. For example, "[a]s a response to pressure from the restaurant industry to have a more uniform law in California, the California legislature introduced statewide [menu labeling] legislation on January 22, 2007" and passed it in October 2008.[395] Different laws among different jurisdictions, however, may generate consumer confusion if restaurants that were part of the same chain were subject to different requirements. Moreover, such variation may be burdensome for restaurants that must comply with different laws. For example, a chain that operates in three different jurisdictions might be subject to no food allergen labeling and management requirements in one jurisdiction and be subject to different requirements in the other two jurisdictions.

A lack of uniformity at the state and local levels, however, may ultimately make federal action more likely. Indeed, the lack of uniformity with respect to menu labeling requirements appears to have been a catalyst for the national menu labeling law. The variation in state and local menu labeling requirements was one of the reasons the NRA and others supported federal menu labeling legislation.

Even within the framework proposed in Part III, there may still be room for state and local experimentation. Such experimentation may lead to innovations that improve food allergen labeling and management in restaurants. For example, questions that remain to be answered within the framework include, among other things, how food allergen labeling should be formatted to effectively communicate food allergen information to consumers, the components of an effective plan to prevent allergen cross contact, and how best to train restaurant staff

393 MISS. CODE. ANN. § 75-29-901 (West 2016).
394 H.R. 2510, 100th Gen. Assemb., Reg. Sess. (Ill. 2017).
395 Arthur, *supra* note 195, at 316–17.

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on food allergen management. Even if a federal allergy law were to preempt states and localities from acting—or a state allergy law were to preempt localities from acting—there may still be gaps left to fill. For example, in the menu labeling context, states or "localities may introduce menu-labeling regulations for restaurants that have fewer than twenty locations"[396] or may petition for an exemption from the preemption requirements.[397] In the context of combating obesity, Professor Paul A. Diller notes that "cities have enacted heightened, innovative regulations," and he argues that they may be particularly well suited to taking such actions due to "the streamlined nature of local lawmaking, combined with the lower campaign and lobbying costs," which "provide[] a more favorable venue for public health interest groups to push for heightened regulation."[398] In this way, states or localities may test reforms that federal officials then adopt.[399] This is consistent with the idea of states and localities as "laboratories of democracy."[400]

In addition, a single food allergen law may help pave the way for other laws, similar to how the 2008 NYC menu labeling regulation paved the way for other local and state menu labeling requirements.

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396 *See* Rutkow et al., *Local Governments and the Food System*, *supra* note 391, at 368–69; Federal Food, Drug, and Cosmetic Act (FDCA) § 403A(a)(4), 21 U.S.C. § 343-1(a)(4) (2012); *see also* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,249–51 (Dec. 1, 2014) (codified at 21 C.F.R. pts. 11, 101) (discussing FDA's interpretation of the menu labeling preemption provisions).

397 *See* FDCA § 403A(b), 21 U.S.C. § 343-1(b).

398 Paul A. Diller, *Why Do Cities Innovate in Public Health? Implications of Scale and Structure*, 91 WASH. U. L. REV. 1219, 1224, 1265–66 (2014); Patrick M. Steel, *Obesity Regulation Under Home Rule: An Argument That Regulation by Local Governments Is Superior to Administrative Agencies*, 37 CARDOZO L. REV. 1127, 1128 (2016).

399 *See* Kristin Madison, *Building A Better Laboratory: The Federal Role in Promoting Health System Experimentation*, 41 PEPP. L. REV. 765, 770 (2014); Michael S. Sparer & Lawrence D. Brown, *States and the Health Care Crisis: Limits and Lessons of Laboratory Federalism*, *in* HEALTH POLICY, FEDERALISM, AND THE AMERICAN STATES 181–200 (Robert F. Rich & William D. White eds., 1996) (discussing states as laboratories and their limitations).

400 New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) (stating that "a single courageous state may . . . serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."); Heather K. Gerken, *Foreword: Federalism All the Way Down*, 124 HARV. L. REV. 4, 9 (2010) (discussing "federalism-all-the-way-down").

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3. Anticipated Challenges to State and Local Action

a. Preemption

Like NYC's menu labeling laws,[401] a state or local food allergen labeling law may be challenged on preemption grounds. Although the existing law is somewhat ambiguous, there is a strong argument that, under current law, state and local food allergen labeling requirements for restaurant-type food are not expressly preempted.[402] Although section 403A of the FDCA contains an express preemption provision that references FALCPA's allergy labeling requirements,[403] that provision should not be read to preempt state and local food allergen labeling requirements for restaurant-type food. And even if that provision is found to preempt such requirements, a state or subdivision of a state can request an exemption from preemption under the FDCA.[404]

Section 403A provides in relevant part that

> no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . any requirement for the labeling of food of the type required by section . . . [403(w) of the FDCA] . . . that is not identical to the requirement of [that] section . . . .[405]

Section 403(w) sets forth the major food allergen labeling requirements.[406]

The express preemption provision in section 403A of the FDCA should not be read to preempt state and local food allergen labeling requirements for restaurant-type food. Specifically, the language "any requirement for the labeling of food of the type required by section . . . [403(w) of the FDCA] . . . that is not identical to the requirement of [that] section" can be read to exclude allergen labeling requirements for restaurant-type food.[407] This is because the allergen labeling requirements in section 403(w) apply to foods required to have a list of ingredients under 403(g) and (i).[408] Those subsections refer to

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401 *See supra* Section II.A.1.

402 As noted above, even if there is no express preemption, state and local requirements could still be preempted. *See supra* note 383.

403 FDCA § 403A(a)(2), 21 U.S.C. § 343-1(a)(2).

404 § 343-1(a); 21 C.F.R. § 100.1 (2017).

405 FDCA § 403A, 21 U.S.C. § 343-1.

406 § 343(w).

407 *See* § 343-1(a)(2).

408 § 343(w).

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requirements for a food "label"—"a written, printed, or graphic matter upon the immediate container of any article."[409] Accordingly, section 403(w) sets forth requirements for foods in a container (packaged foods) and not restaurant-type foods.[410] Thus, state and local allergen labeling requirements for restaurant-type foods should not be preempted under section 403A as there are no federal allergen labeling requirements for these foods and labeling for restaurant-type food would not be a "requirement for the labeling of food of the type required by section . . . [403(w) of the FDCA]."[411]

Even if the express preemption provision were held to apply to state or local food allergen labeling requirements for restaurant-type food,[412] FDCA 403A(b) permits FDA to exempt any state or local requirement from preemption if certain conditions are met.[413] Thus, there is a process by which a state or a political subdivision of a state could

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409 § 321(k).

410 *See* Section I.B; *see also* FDA *Questions and Answers*, *supra* note 64 (What about food prepared in restaurants? How will I know that the food I ordered does not contain an ingredient to which I am allergic?).

411 *See* FDCA § 403A(a)(2), 21 U.S.C. § 343-1(a)(2).

412 In *Cline v. Publix Supermarkets*, Judge Aleta A. Trauger of the United States District Court for the Middle District of Tennessee, Nashville Division, held that the plaintiff's state law claims, "to the extent that they are based on Publix's failing to label the Cookie as containing pecans," were preempted pursuant to FDCA § 403A(a)(2), 21 USC § 343-1(a)(2). No. 3:15-0275, 2017 WL 67945, at *4 (M.D. Tenn. Jan. 6, 2017) (stating that "[t]he preemption clause contained in the FALPCA provides that a party cannot be held liable under state law for allergen labeling activity that is *not* a FALCPA violation"). *But see* notes 406–409 and accompanying text.

The court read FDCA § 403(q)(5)(A)(ii) and FDA's nutritional labeling regulations 21 C.F.R. § 101.9(j)(3) to exempt the cookie (which was baked from scratch in the store bakery, offered for sale, and sold through the store's full-service bakery counter) from FALCPA's allergy labeling requirement. Its interpretation was based on the exemption applying to the ingredient labeling requirements referenced in FALCPA, however, as the court acknowledged the exception in FDCA § 403(q)(5)(A)(ii) "and the corresponding regulations frame this exemption as applying solely to the nutritional labelling requirements laid out in [FDCA § 403(q)] and not to the *ingredient* labeling requirements . . . ." *Cline*, 2017 WL 67945, at *3 n.6. Nevertheless, the Court read the exemption to apply "to all FDCA labeling requirements" saying it is "[t]he only logical reading of the statute." *Id. But see supra* Section I.B & notes 407–411 and accompanying text (discussing FALCPA). The District Court also noted that the parties did not address the preemption clause in their briefs. *Cline*, 2017 WL 67945, at *4.

413 FDCA § 403A(b), 21 U.S.C. § 343-1(b); 21 C.F.R. § 100.1 (2017) (Petitions requesting exemption from preemption for state or local requirements). FDA must find that the requirement "would not cause any food to be in violation of any applicable requirement under Federal law," "would not unduly burden interstate commerce," and "is designed to address a particular need for information which is not met by the requirements of the sections referred to in subsection (a)." FDCA § 403A(b), 21 U.S.C. § 343-1(b); *see also* 21 C.F.R. § 100.1.

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request exemption from the express preemption provision if it was found to apply.[414]

b. Dormant Commerce Clause

Commentators examining menu labeling laws have raised the question of whether these laws violate the "dormant" Commerce Clause doctrine by improperly burdening interstate commerce.[415] A similar question may arise regarding allergen labeling laws. With respect to menu labeling, although one student commentator argued that local menu labeling laws would improperly burden interstate commerce in violation of the dormant Commerce Clause doctrine,[416] other commentators have concluded that these laws would not.[417] The dormant Commerce Clause "refers to the inference that the Interstate Commerce Clause of the U.S. Constitution . . . is not only a basis for affirmative federal lawmaking, but also precludes states from acting in certain ways that threaten trade among the states."[418] The dormant Commerce Clause prohibits "*discrimination* against interstate or out-of-state interests; the imposition of *unreasonable burdens* upon interstate commerce; and (occasionally) *extraterritorial regulation*."[419]

Like the menu labeling laws, allergy laws should not discriminate against out-of-state restaurants on their face.[420] It is possible however that a covered establishment could argue that any allergy labeling and management laws that apply only to larger chains are discriminatory in effect, as the most significant burden is placed on restaurants that operate in multiple states and, therefore, should be subject to strict scrutiny.[421] However, others have argued that a burden is not

414 *See* 21 C.F.R. § 100.1.

415 *See, e.g.*, Lauren F. Gizzi, Comment, *State Menu-Labeling Legislation: A Dormant Giant Waiting to be Awoken by Commerce Clause Challenges*, 58 CATH. U.L. REV. 501, 504 (2009); Rutkow et al., *Preemption and the Obesity Epidemic*, *supra* note 324, at 780; Jennifer L. Pomeranz and Kelly D. Brownell, *Legal and Public Health Considerations Affecting the Success, Reach, and Impact of Menu-Labeling Laws*, 98 AM. J. PUB. HEALTH 1578, 1579 (2008).

416 Gizzi, *supra* note 415, at 504.

417 *See* Rutkow et al., *Preemption and the Obesity Epidemic*, *supra* note 324, at 780; Pomeranz & Brownell, *supra* note 415, at 1579.

418 Daniel Francis, *The Decline of the Dormant Commerce Clause*, 94 DENV. L. REV. 255, 258 (2017).

419 *Id.*

420 *See id.*; *see also* Gizzi, *supra* note 415, at 522–23 (arguing that menu labeling laws are not discriminatory on their face).

421 *See* Gizzi, *supra* note 415, at 504.

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"discriminatory in the proscribed sense just because it applies mainly or even solely to out-of-state or interstate regulatees" and that the Supreme Court has "ignored effect-based discrimination . . . in cases lacking evidence of some kind of undesirably 'protectionist' frame of mind."[422] Furthermore, although a covered establishment could also argue that an allergen law is unlawful if its burdens are "clearly excessive in relation to the putative local benefits,"[423] there is a strong argument that such laws would have substantial local benefits and states should lay out the public health rationales for any such laws.[424] In addition, as one scholar has argued "the practice of 'burden review' . . . has dwindled dramatically."[425]

CONCLUSION

There is a need to regulate food allergen labeling in restaurants as changing consumption patterns mean that an increasing proportion of food is not subject to allergen labeling requirements under current law. Although there are some important differences between the menu labeling and allergen labeling and management contexts, the regulation of food allergens in restaurants is likely to raise similar questions and issues as menu labeling and therefore elicit similar objections. Accordingly, this Article argues that menu labeling should inform both the substance and implementation of food allergen labeling requirements. Food allergen labeling requirements are a starting point. Any allergen labeling requirements also should be accompanied by measures to prevent allergen cross contact, train restaurant workers, and educate the public. As in the menu labeling context, local and state allergen measures may ultimately prompt the creation of a federal regulatory system for food allergens in restaurants. Ultimately, food allergen labeling may make it so that the availability of information on major food allergens does not hinge on whether or not a food is in package form, thus advancing public health by creating a safer food environment for people with food allergies.

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422 Francis, *supra* note 418, at 263, 278.

423 Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970) (internal citation omitted); *see also* Bernell, *supra* note 170, at 863 (stating that since "no menu labeling cases have been decided on this issue, there is no precedent for how a court would answer this question").

424 A fuller analysis would depend on the final scope of the measures, including those to prevent cross contact.

425 Francis, *supra* note 418, at 292.

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JAMA Network Open

Original Investigation | Allergy

Prevalence and Severity of Food Allergies Among US Adults

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Abstract

IMPORTANCE Food allergy is a costly, potentially life-threatening condition. Although studies have examined the prevalence of childhood food allergy, little is known about prevalence, severity, or health care utilization related to food allergies among US adults.

OBJECTIVE To provide nationally representative estimates of the distribution, severity, and factors associated with adult food allergies.

DESIGN, SETTING, AND PARTICIPANTS In this cross-sectional survey study of US adults, surveys were administered via the internet and telephone from October 9, 2015, to September 18, 2016. Participants were first recruited from NORC at the University of Chicago's probability-based AmeriSpeak panel, and additional participants were recruited from the non–probability-based Survey Sampling International (SSI) panel.

EXPOSURES Demographic and allergic participant characteristics.

MAIN OUTCOMES AND MEASURES Self-reported food allergies were the main outcome and were considered convincing if reported symptoms to specific allergens were consistent with IgE-mediated reactions. Diagnosis history to specific allergens and food allergy–related health care use were also primary outcomes. Estimates were based on this nationally representative sample using small-area estimation and iterative proportional fitting methods. To increase precision, AmeriSpeak data were augmented by calibration-weighted, non–probability-based responses from SSI.

RESULTS Surveys were completed by 40 443 adults (mean [SD] age, 46.6 [20.2] years), with a survey completion rate of 51.2% observed among AmeriSpeak panelists (n = 7210) and 5.5% among SSI panelists (n = 33 233). Estimated convincing food allergy prevalence among US adults was 10.8% (95% CI, 10.4%-11.1%), although 19.0% (95% CI, 18.5%-19.5%) of adults self-reported a food allergy. The most common allergies were shellfish (2.9%; 95% CI, 2.7%-3.1%), milk (1.9%; 95% CI, 1.8%-2.1%), peanut (1.8%; 95% CI, 1.7%-1.9%), tree nut (1.2%; 95% CI, 1.1%-1.3%), and fin fish (0.9%; 95% CI, 0.8%-1.0%). Among food-allergic adults, 51.1% (95% CI, 49.3%-52.9%) experienced a severe food allergy reaction, 45.3% (95% CI, 43.6%-47.1%) were allergic to multiple foods, and 48.0% (95% CI, 46.2%-49.7%) developed food allergies as an adult. Regarding health care utilization, 24.0% (95% CI, 22.6%-25.4%) reported a current epinephrine prescription, and 38.3% (95% CI, 36.7%-40.0%) reported at least 1 food allergy–related lifetime emergency department visit.

CONCLUSIONS AND RELEVANCE These data suggest that at least 10.8% (>26 million) of US adults are food allergic, whereas nearly 19% of adults believe that they have a food allergy. Consequently, these findings suggest that it is crucial that adults with suspected food allergy receive appropriate confirmatory testing and counseling to ensure food is not unnecessarily avoided and quality of life is not unduly impaired.

Key Points

Question What are the prevalence and severity of food allergy in US adults?

Findings In a population-based survey study of 40 443 US adults, an estimated 10.8% were food allergic at the time of the survey, whereas nearly 19% of adults believed that they were food allergic. Nearly half of food-allergic adults had at least 1 adult-onset food allergy, and 38% reported at least 1 food allergy–related emergency department visit in their lifetime.

Meaning The findings suggest that food allergies are common and severe among US adults, often starting in adulthood.

+ Supplemental content

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Introduction

Food allergy is a costly,[1] potentially life-threatening[2] health condition that can adversely affect patients' well-being.[3,4] Although population-based studies[5,6] have examined the prevalence of food allergy among children, less is known about the population-level burden of food allergy among adults in the United States. The few population-based studies[7,8] to date that examined adult food allergy have focused on a limited number of specific allergens (eg, peanut) or allergen groups (eg, tree nut, seafood) or have been secondary analyses of federal health surveys, which were not designed to comprehensively characterize food allergy prevalence and severity among US adults. For example, neither the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey[9] nor the US Food and Drug Administration's (FDA's) Food Safety Survey[10] collects information about specific allergic reaction symptoms critical for differential diagnosis of food allergy (eg, food intolerances, oral allergy syndrome). Nevertheless, food allergy prevalence estimates from these recent national surveys exceed 9% of US adults, suggesting that food allergy may affect more US adults than previously acknowledged.

Although some children with food allergy develop natural tolerance, others retain their food allergy as they enter adulthood.[11,12] Adults can also develop new food allergies,[13] and evidence suggests that certain food allergies (eg, shellfish and fin fish) may be more likely than others to develop during adulthood.[8,13] Moreover, studies[14-16] suggest that rates of food allergy–related emergency department (ED) visits may be increasing among children and young adults.

Much remains to be learned about the population-level consequences of adult food allergy in the United States, including the relative frequency and timing of adult- vs childhood-onset food allergy, allergen type, severity, and key sociodemographic and clinical factors of each of these food allergy characteristics. This study aimed to provide comprehensive, nationally representative estimates of the distribution, severity, and factors associated with adult food allergy in the United States.

Methods

Surveys were administered by NORC at the University of Chicago from October 9, 2015, to September 18, 2016, to a sample of US households through a dual-sampling approach using NORC's nationally representative AmeriSpeak panel and the Survey Sampling International (SSI) non–probability-based sample (eMethods in the Supplement). Written informed consent was obtained from all participants during enrollment into the AmeriSpeak panel and SSI web samples. Identical surveys were administered to both samples. All data were deidentified. The NORC Institutional Review Board and Northwestern University Institutional Review Board approved all study activities. The study followed the American Association for Public Opinion Research (AAPOR) reporting guideline.

Survey Development and Design

The surveys extended our national child food allergy survey, administered in 2009 to 2010, which was developed by pediatricians, allergists, health services researchers, and survey methodologists. Expert panel review and key informant cognitive interviews (N = 40) were conducted on the original survey using the approach described previously.[17] Although core constructs from the 2009-2010 survey were retained, additional questions were added to the present instrument to assess emerging research issues that related to the cause and management of adult food allergy. The revised instrument was pretested on 345 interviewees to ensure clarity, relevance, validity, and reliable functioning of all questions and response options. Interviewee data and feedback were reviewed and incorporated into the final 2015-2016 surveys, which were administered via the internet or telephone. All write-in responses were hand coded and reviewed by an expert panel to ensure accuracy of final data. Participants who did not answer the initial question about whether they have

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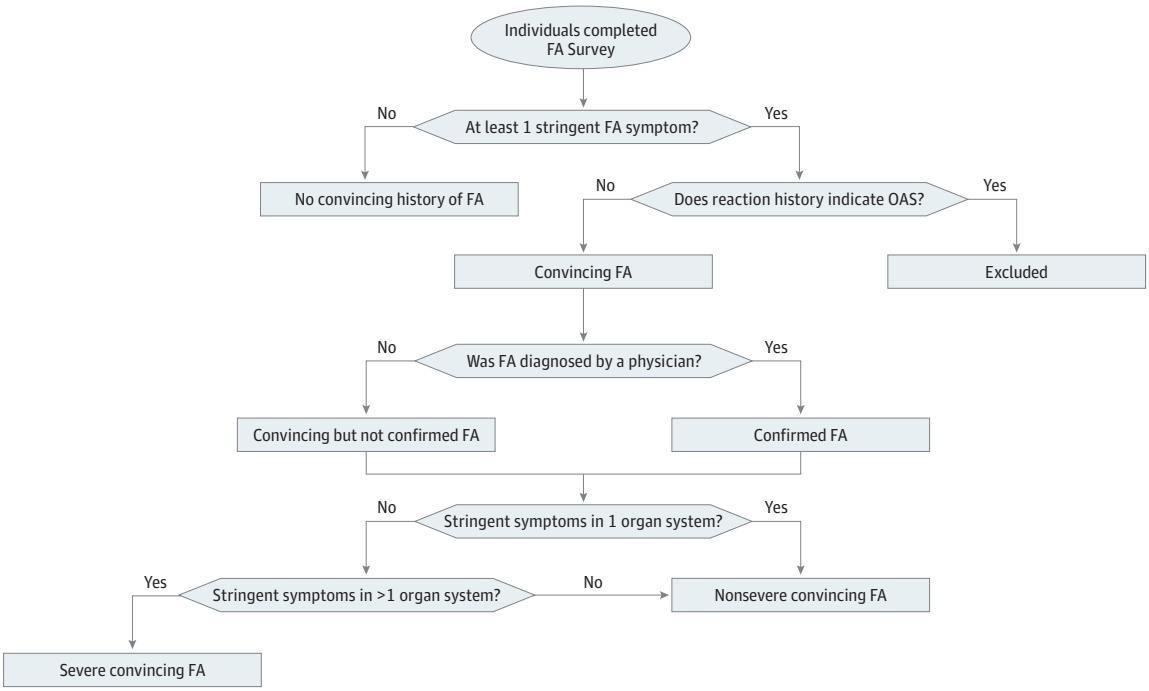
ever had a food allergy were considered to have provided incomplete responses and were not included in any analyses.

Outcome Measures

The primary outcome measures for the study were the prevalence and severity of overall and food-specific convincing adult food allergy. Food allergies were considered to be convincing if the most severe reaction reported to that food included at least 1 symptom on the stringent symptom list developed by our expert panel (eFigure in the Supplement). Reported allergies with reaction symptoms characteristic of oral allergy syndrome or food intolerances were excluded and not considered to be convincing according to the food allergy categorization flowchart summarized in **Figure 1**, even if such allergies were reported as diagnosed by a physician. Only convincing food allergies for which a physician's diagnosis was reported were considered to be physician diagnosed for the purposes of our study. For each convincing allergy, a severe reaction history was indicated by reporting 1 or more stringent symptoms across 2 or more of the following organ systems: skin or oral mucosa, gastrointestinal tract, cardiovascular, and respiratory tract.

If multiple food allergies were reported, each reported food allergy was evaluated separately using the food allergy categorization flowchart. For example, if a respondent reported a nut allergy with a reaction history limited to oral symptoms indicative of oral allergy syndrome as well as a shellfish allergy with a reaction history that included throat tightening, vomiting, and hives, the respondent would be considered to have only a single, severe shellfish allergy and the nut allergy would be excluded. Lifetime physician-diagnosed atopic comorbidities were also assessed using the question, "Have you ever been diagnosed by a doctor with any of the following chronic conditions? Please select all that apply." Response options included asthma, eczema/atopic dermatitis, hay fever/

Figure 1. Convincing, Physician-Diagnosed, and Severe Food Allergy (FA) Categorization Flow Diagram



Stringent symptoms by organ system include skin or oral mucosa (hives, swelling [except lip or tongue], lip or tongue swelling, difficulty swallowing, throat tightening), respiratory tract (chest tightening, trouble breathing, wheezing), gastrointestinal tract (vomiting), and cardiovascular (chest pain, rapid heartbeat, fainting, low blood pressure). Gastrointestinal symptoms commonly associated with intolerance (eg, diarrhea, cramps) were not considered to be stringent symptoms. The following allergies were considered for exclusion as probable oral allergy syndrome (OAS) based on symptom report: fruit, vegetable, peanut, tree nut, wheat, soy, barley, rice, seed, spice, shellfish, and fin fish.

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allergic rhinitis/seasonal allergies, insect sting allergy, latex allergy, medication allergy, and urticaria/chronic hives.

Study Participants and Survey Weighting

Eligible study participants included adults (≥18 years of age) able to complete surveys in English or Spanish who were residing in a US household. As in the 2009-2010 survey, this study relied on a nationally representative household panel to support population-level inference.[5] Study participants were first recruited from NORC at the University of Chicago's probability-based AmeriSpeak panel, where a survey completion rate of 51.2% was observed (7218 responses from 14 095 invitees). The weighted cumulative AAPOR response rate for the AmeriSpeak sample was 8.8%. This rate is a function of the 18.3% rate of originally sampled households successfully recruited into the AmeriSpeak panel when it was established, the 93.8% rate of successfully recruited households who were also successfully retained into the panel so that they were potentially eligible for participation in the present study, and the aforementioned 51.2% completion rate among successfully recruited and retained AmeriSpeak panelists who were approached for this particular study. Each AmeriSpeak respondent was assigned a base, nonresponse-adjusted sampling weight, which was then ranked to external population totals associated with age, sex, educational level, race/ethnicity, housing tenure, telephone status, and census division using iterative proportional fitting to improve external validity. To increase precision of estimates when data were scarce, such as for the prevalence of rare allergies within specific age groups, and ensure sufficient sample size among key subpopulations, prevalence estimates calculated from population-weighted AmeriSpeak responses were augmented by calibration-weighted, non–probability-based responses obtained through the SSI Dynamix platform.[18] SSI is a leading survey research organization with a diverse and large web-based panel of potential participants, who were sampled for the present study using methods designed to minimize self-selection bias. State-of-the-art small-area estimation methods were used, which leverage similarity and borrow strength across all available information in both samples to minimize the bias and variance of resulting estimates to a greater degree than independent analysis of either sample permitted.[19] These methods are frequently used by census bureaus and national survey research organizations because of their efficiency and effectiveness.[20,21] The final, combined sample weight was derived by applying an optimal composition factor that minimizes the mean square error associated with food allergy prevalence estimates. In total, surveys were completed by 40 443 US adults, each of whom received $5 on survey completion.

Statistical Analysis

Complex survey weighted proportions and 95% CIs were calculated to estimate prevalence using the svy: tabulate command using the "ci" and "per" options in Stata statistical software, version 14 (StataCorp).[22] Relative proportions of demographic characteristics were compared using weighted Pearson χ^2 statistics, which were corrected for the complex survey design with the second-order correction of Rao and Scott[23] and converted into *F* statistics. Covariate-adjusted complex survey weighted logistic regression models compared relative prevalence and other assessed food allergy outcomes by participant characteristics. Two-sided hypothesis tests were used, with 2-sided $P < .05$ considered to be statistically significant.

Results

Demographics, Food Allergy Prevalence, and Childhood vs Adult-Onset Allergies

Surveys were completed by 40 443 adults (7210 from the AmeriSpeak panel and 33 233 from the SSI panel; mean [SD] age, 46.6 [20.2] years). As anticipated, the observed completion rate was higher among the probability-based AmeriSpeak panel (51.2% of invited adults) compared with the non–probability-based SSI panel (5.5% of invited adults). The weighted distributions of respondents

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by age, sex, and race/ethnicity (eTable 1 in the Supplement) were consistent with 2016 estimates from the US Census Bureau's Current Population Survey.[24]

Overall, 10.8% (95% CI, 10.4%-11.1%) of US adults were estimated to have 1 or more current convincing food allergies. However, an estimated 19.0% (95% CI, 18.5%-19.5%) of US adults reported at least 1 convincing or nonconvincing FA. (**Table 1**). Among all adults with convincing food allergy, 48.0% (95% CI, 46.2%-49.7%) reported developing at least 1 of their convincing food allergies as an adult, whereas 26.9% (95% CI, 25.3%-28.6%) developed convincing food allergy only during adulthood and 52.0% (95% CI, 50.3%-53.8%) developed convincing food allergy only before 18 years of age.

Table 1. Estimated Current FA Prevalence Rates Among US Adults

Variable	Prevalence of Current FA, % (95% CI)	*P* Value	Prevalence of Adult-Onset Current FA, % (95% CI)	*P* Value
Overall	10.8 (10.4-11.1)	NA	5.2 (4.9-5.4)	NA
Race/ethnicity				
Asian, non-Hispanic	11.4 (9.8-13.3)	<.001	4.8 (3.8-6.1)	<.001
Black, non-Hispanic	11.2 (10.2-12.3)		5.1 (4.4-5.9)	
White, non-Hispanic	10.1 (9.7-10.6)		5.2 (4.9-5.5)	
Hispanic	11.6 (10.5-12.8)		4.6 (3.9-5.4)	
Multiple or other	15.9 (13.6-18.6)		7.2 (5.8-9.0)	
Sex				
Male	7.5 (7.0-7.9)	<.001	3.0 (2.7-3.3)	<.001
Female	13.8 (13.3-14.4)		7.2 (6.8-7.7)	
Age, y				
18-29	11.3 (10.5-12.2)	.002	2.7 (2.4-3.2)	<.001
30-39	12.7 (11.8-13.7)		5.5 (4.8-6.1)	
40-49	10.0 (9.2-10.9)		5.1 (5.0-5.7)	
50-59	11.9 (11.0-12.8)		6.8 (6.1-7.6)	
≥60	8.8 (8.2-9.4)		5.9 (5.4-6.4)	
Household income, US$				
<25 000	10.6 (9.8-11.5)	.002	4.9 (4.4-5.5)	.57
25 000-49 999	10.9 (10.2-11.6)		5.5 (5.0-6.1)	
50 000-99 999	11.6 (11.0-12.3)		5.6 (5.1-6.1)	
100 000-149 000	10.5 (9.6-11.5)		5.0 (4.3-5.7)	
≥150 000	8.8 (7.7-10.0)		4.0 (3.3-5.7)	
Born in the United States				
Yes	10.8 (10.5-11.2)	.37	5.1 (4.9-5.4)	.06
No	10.2 (8.9-11.6)		5.5 (4.6-6.7)	
Census region				
West	11.5 (10.7-12.3)	.07	5.4 (4.9-6.0)	.43
Midwest	10.3 (9.6-11.0)		4.9 (4.4-5.4)	
South	10.4 (9.9-11.0)		5.0 (4.7-5.5)	
Northeast	11.2 (10.3-12.2)		5.5 (4.8-6.3)	
Physician-diagnosed comorbid conditions				
Asthma	20.9 (19.5-22.3)	<.001	9.9 (9.0-10.9)	.77
Atopic dermatitis or eczema	19.2 (17.4-21.1)	<.001	9.0 (7.8-10.4)	.66
Environmental allergies	17.2 (16.3-18.2)	<.001	10.0 (9.3-10.8)	<.001
Insect sting allergy	22.9 (20.5-25.6)	<.001	13.4 (11.5-15.6)	<.001
Latex allergy	28.8 (25.5-32.3)	<.001	18.4 (15.6-21.5)	<.001
Medication allergy	18.5 (17.3-19.8)	<.001	11.3 (10.4-12.4)	<.001
Urticaria or chronic hives	27.8 (22.9-33.3)	<.001	18.8 (14.6-23.8)	<.001
Other chronic conditions	12.7 (11.4-14.2)	.003	7.5 (6.5-8.7)	<.001

Abbreviations: FA, food allergy; NA, not applicable.

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The 5 most common convincing food allergies reported among adults were shellfish (2.9%; 95% CI, 2.7%-3.1%), peanut (1.8%; 95% CI, 1.7%-1.9%), milk (1.9%; 95% CI, 1.8%-2.1%), tree nut (1.2%; 95% CI, 1.1%-1.3%), and fin fish (0.9%; 95% CI, 0.8%-1.0%) (**Table 2**). Multiple convincing food allergies were reported by 45.3% (95% CI, 43.6%-47.1%) of convincingly food-allergic adults (**Table 3**). Roughly half of adults with convincing food allergies reported having a physician-diagnosed convincing food allergy (47.5%; 95% CI, 45.8%-49.3%). Individuals with peanut allergy reported the highest rate of physician diagnosis (72.5% [95% CI, 68.9%-75.8%] of convincing peanut allergies).

Food Allergy Severity and Health Care Use

Among adults with 1 or more convincing food allergies, 51.1% (95% CI, 49.3%-52.9%) reported experiencing at least 1 severe food-allergic reaction (Table 3). A history of severe reactions was most commonly observed among participants with convincing peanut (67.8%; 95% CI, 64.2%-71.1%) and tree nut (61.3%; 95% CI, 56.6%-65.8%) allergies. Among adults with 1 or more convincing food allergies, 24.0% (95% CI, 22.6%-25.4%) reported a current epinephrine prescription and 38.3% (95% CI, 36.7%-40.0%) reported 1 or more lifetime food allergy–related ED visits. A total of 8.6% (95% CI, 7.7%-9.6%) of convincingly food-allergic adults reported 1 or more food allergy–related ED visit within the past year.

Factors Associated With Food Allergies and Related Conditions

Adjusted associations from multiple logistic regression models estimating odds of convincing food allergy and food allergy characteristics are presented in eTable 2 in the Supplement. Significant differences in convincing food allergy prevalence were observed by race/ethnicity, with higher rates among groups other than white compared with white adults. Rates of convincing food allergy were higher among females (13.8%; 95% CI, 13.3%-14.4%) compared with males (7.5%; 95% CI, 7.0%-7.9%). Compared with younger adults, individuals aged 30 to 39 years had elevated rates of

Table 2. Overall and Age-Specific Prevalence of Specific Food Allergies Among All US Adults

	Prevalence, % (95% CI)					
Specific Food Allergy	All Ages	18-29 y	30-39 y	40-49 y	50-59 y	≥60 y
Any food allergy	10.8 (10.4-11.1)	11.3 (10.5-12.2)	12.7 (11.8-13.7)	10.0 (9.2-10.9)	11.9 (11.0-12.8)	8.8 (8.2-9.4)
Peanut	1.8 (1.7-1.9)	2.5 (2.2-2.8)	2.9 (2.5-3.3)	1.8 (1.5-2.1)	1.4 (1.1-1.7)	0.8 (0.7-1.0)
Tree nut	1.2 (1.1-1.3)	1.6 (1.3-1.9)	1.7 (1.4-2.1)	1.1 (0.9-1.4)	1.2 (0.9-1.5)	0.6 (0.4-0.7)
Walnut	0.6 (0.6-0.7)	0.8 (0.7-1.1)	0.9 (0.7-1.3)	0.6 (0.5-0.8)	0.7 (0.5-0.9)	0.3 (0.2-0.4)
Almond	0.7 (0.6-0.8)	0.9 (0.7-1.2)	1.0 (0.7-1.3)	0.7 (0.6-1.0)	0.7 (0.5-0.9)	0.3 (0.2-0.4)
Hazelnut	0.6 (0.5-0.7)	0.7 (0.5-0.9)	0.9 (0.6-1.2)	0.6 (0.4-0.8)	0.6 (0.4-0.8)	0.3 (0.2-0.4)
Pecan	0.5 (0.5-0.6)	0.6 (0.5-0.8)	0.8 (0.5-1.1)	0.6 (0.5-0.8)	0.5 (0.4-0.8)	0.5 (0.4-0.8)
Cashew	0.5 (0.5-0.6)	0.8 (0.6-1.0)	0.8 (0.6-1.1)	0.5 (0.4-0.7)	0.5 (0.3-0.7)	0.2 (0.1-0.3)
Pistachio	0.4 (0.3-0.5)	0.6 (0.4-0.8)	0.6 (0.4-0.8)	0.5 (0.3-0.6)	0.4 (0.3-0.6)	0.1 (0.1-0.2)
Other tree nut	0.2 (0.1-0.2)	0.1 (0.1-0.2)	0.1 (0.0-0.2)	0.3 (0.2-0.6)	0.2 (0.1-0.5)	0.1 (0.1-0.2)
Milk	1.9 (1.8-2.1)	2.4 (2.0-2.9)	2.3 (1.9-2.8)	2.0 (1.6-2.4)	1.9 (1.6-2.2)	1.9 (1.6-2.2)
Shellfish	2.9 (2.7-3.1)	2.8 (2.4-3.2)	3.6 (3.1-4.2)	2.5 (2.2-3.0)	3.3 (2.8-3.8)	2.6 (2.2-3.0)
Shrimp	1.9 (1.8-2.1)	1.8 (1.5-2.1)	2.5 (2.1-3.0)	1.8 (1.4-2.1)	2.2 (1.8-2.6)	1.6 (1.3-1.9)
Lobster	1.3 (1.2-1.4)	1.2 (1.0-1.5)	1.6 (1.3-2.0)	1.3 (1.0-1.5)	1.4 (1.1-1.7)	1.1 (0.9-1.3)
Crab	1.3 (1.2-1.5)	1.2 (1.0-1.5)	1.6 (1.3-2.0)	1.3 (1.0-1.6)	1.6 (1.3-2.0)	1.1 (0.9-1.4)
Mollusk	1.6 (1.4-1.7)	1.6 (1.3-2.0)	2.0 (1.7-2.5)	1.3 (1.1-1.7)	1.7 (1.4-2.0)	1.2 (1.0-1.5)
Other shellfish	0.3 (0.2-0.3)	0.3 (0.1-0.5)	0.1 (0.1-0.2)	0.3 (0.2-0.4)	0.3 (0.2-0.5)	0.3 (0.2-0.4)
Egg	0.8 (0.7-0.9)	1.1 (0.7-1.5)	1.1 (0.9-1.3)	0.7 (0.5-0.9)	0.8 (0.6-1.1)	0.5 (0.3-0.7)
Fin fish	0.9 (0.8-1.0)	1.1 (0.9-1.4)	1.0 (0.8-1.2)	0.8 (0.6-1.1)	1.0 (0.7-1.3)	0.6 (0.4-0.7)
Wheat	0.8 (0.7-0.9)	1.0 (0.7-1.3)	1.0 (0.8-1.3)	0.8 (0.6-1.0)	0.7 (0.5-0.9)	0.6 (0.4-0.8)
Soy	0.6 (0.5-0.7)	0.7 (0.5-0.9)	0.8 (0.6-1.0)	0.6 (0.5-0.8)	0.7 (0.5-0.9)	0.4 (0.3-0.6)
Sesame	0.2 (0.2-0.3)	0.3 (0.2-0.4)	0.3 (0.2-0.5)	0.2 (0.1-0.4)	0.3 (0.2-0.5)	0.1 (0.0-0.2)

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convincing food allergy (12.7%; 95% CI, 11.8%-13.7%), whereas rates were lower for those 60 years or older (8.8%; 95% CI, 8.2%-9.4%). In adjusted models, each assessed chronic atopic comorbidity, including asthma, eczema, allergic rhinitis, urticaria, and latex allergy, was significantly associated with increased odds of convincing food allergy (**Figure 2**).

Adults were more likely to have a physician-diagnosed convincing food allergy if they earned $25 000 or more annually compared with those earning less than $25 000. Having multiple convincing food allergies, a current epinephrine prescription, a history of 1 or more lifetime food allergy–related ED visits, a severe reaction history, comorbid allergic rhinitis, or latex allergies were each associated with increased odds of having 1 or more physician-diagnosed convincing food allergy. When examining factors related to a severe food allergy reaction history, convincingly food-allergic adults older than 50 years had significantly decreased risk of severe food allergy compared with younger adults, whereas black adults (odds ratio [OR], 1.4; 95% CI, 1.1-1.7) and adults with comorbid asthma (OR, 1.4; 95% CI,1.1-1.6) or allergic rhinitis (OR, 1.3; 95% CI, 1.1-1.5) were at increased risk for severe food allergy.

Factors Associated With Epinephrine Prescription and ED Visits

eTable 3 in the Supplement reports factors associated with having a current epinephrine prescription, reporting 1 or more lifetime food allergy–related ED visits, and reporting 1 or more food allergy–related ED visits within the past year. Adults reporting 1 or more lifetime ED visits (OR, 3.2; 95% CI, 2.6-3.9) or severe food allergy (OR, 1.5; 95% CI, 1.2-1.8) had elevated odds of having a current epinephrine prescription, as did adults with peanut (OR, 2.4; 95% CI, 1.9-3.1), tree nut (OR, 3.3; 95%

Table 3. Allergen-Specific FA Characteristics and Health Care Utilization Among Adults With Convincing FA

	Prevalence, % (95% CI)[a]						
Specific FA	Severe Reaction	Adult-Onset FA	Multiple FAs	Physician Diagnosed	Current Epinephrine Prescription	Lifetime History of FA-Related ED Visits	Past 12-mo History of FA-Related ED Visits
All allergens	51.1 (49.3-52.9)	48.0 (46.2-49.7)	45.3 (43.6-47.1)	47.5 (45.8-49.3)	24.0 (22.6-25.4)	38.3 (36.7-40.0)	8.6 (7.7-9.6)
Peanut	67.8 (64.2-71.1)	17.5 (14.8-20.7)	67.8 (64.1-71.3)	72.5 (68.9-75.8)	53.8 (49.9-57.6)	62.3 (58.6-65.9)	19.8 (17.1-22.9)
Tree nut	61.3 (56.6-65.8)	34.6 (30.1-39.4)	90.4 (87.5-92.6)	61.4 (56.6-65.9)	51.5 (46.7-56.2)	54.3 (49.5-59.0)	19.2 (15.6-23.5)
Walnut	51.1 (44.6-57.6)	26.6 (20.8-33.2)	95.1 (92.2-97.0)	53.3 (46.7-59.7)	51.0 (44.5-57.5)	57.0 (50.5-63.4)	18.7 (13.5-25.4)
Almond	57.2 (50.8-63.3)	26.7 (21.4-32.8)	95.7 (92.8-97.5)	63.0 (56.6-69.0)	55.3 (48.7-61.8)	60.7 (54.5-66.7)	24.5 (19.1-30.9)
Hazelnut	55.1 (47.8-62.2)	25.9 (19.8-33.0)	96.2 (92.2-98.2)	58.0 (50.8-64.9)	54.0 (46.6-61.3)	60.6 (53.4-67.3)	19.7 (14.0-26.9)
Pecan	51.4 (44.0-58.6)	29.5 (22.7-37.4)	100	53.2 (45.8-60.4)	56.3 (48.7-63.6)	56.3 (48.9-63.5)	20.1 (14.4-27.3)
Cashew	50.6 (43.6-57.5)	27.7 (21.3-35.2)	96.3 (93.1-98.0)	57.1 (50.2-63.8)	59.3 (52.1-66.1)	58.4 (51.5-65.0)	21.4 (15.7-28.4)
Pistachio	49.6 (41.5-57.7)	28.1 (21.7-35.6)	97.0 (93.9-98.6)	57.9 (49.9-65.5)	56.8 (48.2-65.0)	63.4 (55.7-70.5)	20.9 (14.3-29.6)
Other tree nut	59.7 (44.6-73.1)	30.9 (19.0-46.1)	80.8 (65.7-90.3)	43.0 (29.1-58.1)	52.7 (37.8-67.1)	43.9 (29.7-59.1)	4.5 (1.6-11.7)
Milk	39.3 (35.2-43.5)	22.7 (19.6-26.3)	60.1 (55.9-64.2)	47.1 (43.0-51.3)	24.0 (20.9-27.5)	47.0 (42.8-51.1)	12.0 (9.9-14.4)
Shellfish	56.8 (53.4-60.1)	48.2 (44.8-51.6)	69.9 (66.5-73.2)	42.1 (39.0-45.4)	27.4 (24.7-30.3)	45.3 (42.0-48.7)	11.1 (9.0-13.5)
Shrimp	56.6 (52.6-60.5)	37.2 (33.3-41.3)	76.1 (72.1-79.7)	42.6 (38.8-46.5)	29.8 (26.5-33.4)	47.7 (43.8-51.7)	10.6 (8.6-13.0)
Lobster	48.3 (43.5-53.1)	40.5 (35.8-45.5)	94.1 (91.3-96.1)	35.9 (31.5-40.5)	32.8 (28.6-37.4)	53.0 (48.2-57.8)	12.5 (9.6-16.1)
Crab	48.9 (44.2-53.5)	40.0 (35.4-44.7)	89.7 (86.1-92.4)	35.1 (30.9-39.5)	32.8 (28.7-37.2)	51.9 (47.2-56.6)	11.3 (8.6-14.7)
Mollusk	47.0 (42.4-51.6)	39.2 (34.7-43.8)	81.0 (76.5-84.8)	33.1 (29.2-37.2)	30.3 (26.4-34.5)	50.8 (46.2-55.4)	12.4 (9.3-16.4)
Other shellfish	60.1 (49.6-69.7)	39.2 (29.3-50.0)	89.8 (80.2-95.1)	28.8 (19.9-39.7)	35.9 (25.9-47.4)	50.9 (40.0-61.6)	10.7 (4.6-22.7)
Egg	39.4 (32.8-46.5)	29.0 (23.2-35.6)	65.6 (58.3-72.1)	52.1 (45.1-59.0)	34.0 (28.5-40.0)	55.0 (47.8-61.9)	22.4 (17.6-28.0)
Fin fish	56.5 (51.0-61.7)	39.9 (34.7-45.4)	89.8 (86.2-92.5)	40.9 (35.7-46.3)	37.2 (32.1-42.6)	60.1 (54.7-65.3)	19.9 (15.9-24.7)
Wheat	42.6 (36.2-49.3)	52.6 (46.1-59.0)	68.3 (61.8-74.1)	55.5 (48.9-61.9)	24.6 (20.0-29.9)	43.6 (37.3-50.1)	14.9 (11.1-19.8)
Soy	45.4 (38.9-52.2)	45.4 (38.8-52.2)	81.2 (75.4-85.9)	48.5 (41.9-55.2)	37.3 (31.4-43.6)	48.3 (41.7-55.1)	18.2 (13.6-23.9)
Sesame	39.7 (30.3-49.9)	25.7 (18.1-35.1)	80.3 (67.5-88.9)	37.7 (28.7-47.6)	61.6 (51.3-70.9)	66.2 (54.6-76.2)	31.5 (23.1-41.5)

Abbreviations: ED, emergency department; FA, food allergy.

[a] All columns represent frequency with a denominator of all those with convincing FA to each specified food.

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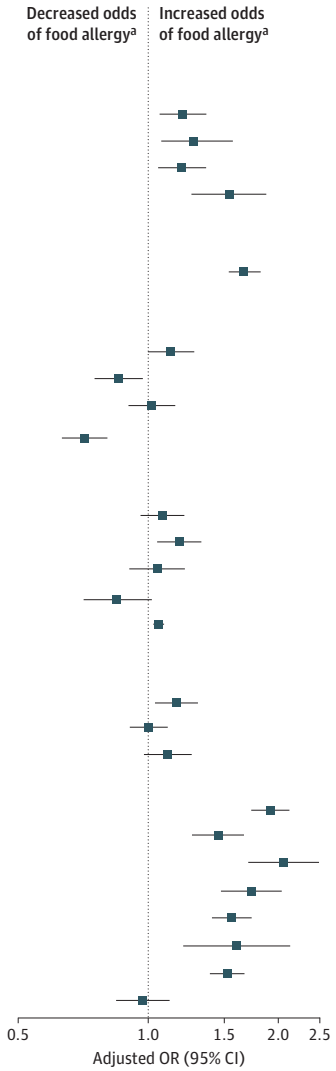
CI, 2.0-5.3), sesame (OR, 3.0; 95% CI, 1.4-6.2), or soy allergy (OR, 1.5; 95% CI, 1.0-2.1) or a comorbid insect sting allergy (OR, 2.0; 95% CI, 1.4-2.9). Adults 50 years or older also had significantly reduced odds of a current epinephrine prescription. Current epinephrine prescription rates varied considerably by food allergy type, with the highest rates observed among adults with sesame (61.6%), peanut (53.8%), or tree nut allergy (51.5%). With respect to lifetime ED visits, adults with multiple food allergies (OR, 1.2; 95% CI, 1.0-1.5), severe food allergy (OR, 1.9; 95% CI, 1.6-2.3), childhood-onset food allergy only (OR, 1.7; 95% CI, 1.4-2.0), a current epinephrine prescription (OR, 3.2; 95% CI, 2.6-3.9), or comorbid asthma (OR, 1.3; 95% CI, 1.0-1.5) had significantly elevated odds of 1 or more food allergy–related ED visits, as did Hispanics and adults earning less than $25 000 per year.

Discussion

The present population-weighted data revealed that an estimated 10.8% of US adults had at least 1 current food allergy during the study period (corresponding to >26 million US adults), whereas 19.0% of adults believed that they were food allergic. These data suggest that there are currently at least 13 million food-allergic adults who have experienced at least 1 severe food-allergic reaction, at least 10

Figure 2. Factors Associated With Current Food Allergy

Factor	Adjusted OR (95% CI)
Race/ethnicity	
White, non-Hispanic[b]	1 [Reference]
Black, non-Hispanic	1.20 (1.06-1.36)
Asian, non-Hispanic	1.28 (1.06-1.54)
Hispanic	1.20 (1.06-1.36)
Multiple/other	1.54 (1.26-1.88)
Sex	
Male[b]	1 [Reference]
Female	1.67 (1.54-1.82)
Age, y	
18-29[b]	1 [Reference]
30-39	1.13 (1.00-1.28)
40-49	0.85 (0.75-0.97)
50-59	1.02 (0.90-1.16)
≥60	0.71 (0.63-0.80)
Income, US$	
<25 000[b]	1 [Reference]
25 000-49 000	1.08 (0.96-1.21)
50 000-99 000	1.18 (1.05-1.33)
100 000-149 000	1.05 (0.90-1.22)
≥150 000	0.85 (0.71-1.02)
Education[c]	1.06 (1.03-1.09)
Census region	
Midwest[b]	1 [Reference]
West	1.16 (1.04-1.30)
South	1.00 (0.91-1.11)
Northeast	1.11 (0.98-1.26)
Comorbidity[d]	
Asthma	1.92 (1.73-2.12)
Eczema	1.45 (1.26-1.67)
Latex allergy	2.06 (1.70-2.48)
Sting/venom allergy	1.73 (1.47-2.04)
Medication allergy	1.56 (1.40-1.74)
Urticaria	1.60 (1.20-2.13)
Allergic rhinitis	1.52 (1.39-1.67)
Other	0.97 (0.84-1.12)



Each square represents the odds ratio (OR) point estimate for each corresponding variable or sample characteristic, adjusting for all other variables in the logistic regression model. Each horizontal line represents the 95% CI. Percentages of all adults in each subgroup and adults with current food allergies in each subgroup are given in eTable 1 in the Supplement.

[a] Compared with the reference group.

[b] Reference group.

[c] Educational attainment was modeled as a continuous variable with the following 7 categories: less than high school, high school, some college, associates, bachelors, masters, and professional or doctorate.

[d] The reference group for each comorbid condition is the absence of that condition.

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million adults who have received food allergy treatment in the ED, and at least 12 million adults with adult-onset food allergy.

This overall estimate of adult food allergy prevalence falls between the 10% estimated from 2007-2010 National Health and Nutrition Examination Survey data by McGowan and Keet[9] and estimates reported by Verrill et al[10] from 2010 FDA Food Safety Survey data, who reported an overall adult food allergy prevalence of 13% and physician-diagnosed food allergy prevalence of 6.5%. However, neither of these previous surveys collected data on reaction symptoms that could be used to identify adults reporting food allergies that are unlikely to be IgE mediated. Given that the most prevalent allergies observed were shellfish and peanut, which prior pediatric work suggests are infrequently outgrown,[25] this finding suggests that the population-level burden of food allergy is likely to increase in the future, absent widespread implementation of effective prevention efforts and/or therapies. Of interest, the current data suggest that shellfish allergy may be a particularly enduring allergy among adults. For example, estimated shellfish allergy prevalence was 2.8% among individuals aged 18 to 29 years and 2.6% among those 60 years or older, a lower rate of decrease across the life span than observed for other food allergies. These relatively high rates of shellfish allergy across the life span, including adult-onset shellfish allergies, require further investigation. Whether these high rates are attributable to different underlying pathophysiological mechanisms among shellfish-allergic patients, greater awareness of shellfish allergy, and/or additional factors remains to be seen and is the subject of ongoing research. Shellfish has long been acknowledged as a persistent allergy,[8,26,27] although adult cohort studies are needed to more definitively establish its natural history.

Among US adults, our data revealed that the burden of shellfish allergy was greatest, affecting an estimated 7.2 million US adults. Milk (affecting an estimated 4.7 million adults), peanut (4.5 million), tree nut (3.0 million), fin fish (2.2 million), egg (2.0 million), wheat (2.0 million), soy (1.5 million), and sesame (0.5 million) were the next most common food allergies.

As summarized in a recent review,[28] racial/ethnic disparities in allergic diseases, such as asthma[29] and eczema,[30] are well established, and data suggest that the burden of child food allergy may also be greater among the population of races/ethnicities other than white, non-Hispanic.[17] However, much less is known about such disparities in adult food allergy. The current data showed that food allergy rates were significantly higher among adults other than white, even after adjustment for income, educational level, numerous physician-diagnosed atopic conditions, and other covariates. These findings are consistent with findings from our previous population-based study[8,17] of child food allergy prevalence, which also found elevated rates of food allergy in non-Hispanic black and Asian children. Although previous examinations of food allergy disparities have largely contrasted sensitization and estimated prevalence rates between non-Hispanic black and white populations,[31,32] the present findings suggest that the scope of future work examining food allergy disparities should be expanded to further investigate racial/ethnic differences among Hispanic adults. In the current study, Hispanic adults were estimated to have comparable rates of food allergy to non-Hispanic black adults, as well as the highest rates of food allergy–related ED visits among all racial groups, despite reporting epinephrine prescription rates comparable to those of white adults.

Clinical food allergy management guidelines recommend intramuscular epinephrine as first-line treatment for food-induced anaphylaxis.[33] All patients diagnosed with a food allergy should be prescribed epinephrine because of the inability to accurately and reliably estimate the severity of future allergic reactions.[34,35] Our data suggest that approximately one-quarter of adults with food allergy possess a current epinephrine prescription, with higher rates among adults reporting a history of severe reactions and lifetime food allergy–related ED visits. These overall rates of epinephrine prescription are comparable to the 23% of peanut- and tree nut–allergic adults reporting an epinephrine prescription in a 2002 prevalence study.[36] However, further analyses suggest that a substantial proportion of adults with food allergy who may be at elevated risk of anaphylaxis do not report having a current epinephrine prescription. For instance, among adults with 1 or more severe,

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physician-diagnosed food allergies who reported at least 1 food allergy–related ED visit in the past year, only 65% reported a current epinephrine prescription. These low rates of epinephrine possession are particularly notable given that nearly 40% of food-allergic adults reported at least 1 lifetime food allergy–related ED visit and more than half reported a history of 1 or more severe food-allergic reactions.

The high rate of severe reactions in our study compared with previous literature[17] is consistent with findings from multiple studies[37-39] showing an association of increased age with more severe allergic reaction symptoms. However, it is also possible that the higher proportion of adults reporting severe reactions is a function of adults' greater cumulative lifetime risk. This idea is supported by the slightly reduced rates of severe reactions and ED visits observed among adults reporting adult-onset food allergy in the present study. More specifically, the significantly elevated odds of severe food allergy observed among adults with comorbid allergic rhinitis extends findings from a large case series where a marked increase in food-induced severe pharyngeal edema was observed among peanut- and tree nut–allergic patients with comorbid allergic rhinitis.[40] Although less than 10% of food-allergic adults reported a food allergy–related ED visit within the past year, this figure increased to 32% among sesame-allergic adults, who also reported the highest epinephrine possession rates in the cohort (62% vs 24% overall). Patients with comorbid asthma were also at increased risk of food allergy–related ED visits, which is consistent with previous work that found an association of asthma with increased anaphylaxis risk.[41]

Adult-onset food allergies are an important emerging health problem. A recent analysis[13] of electronic health record data collected from a network of Chicago-area clinics concluded that although shellfish, tree nut, and fin fish allergies were the most common adult-onset food allergies, it appears to be possible to develop adult-onset food allergies to all major food allergen groups. In the current study, adult-onset allergies were observed to every assessed food. After wheat, the most common adult-onset allergies in our sample were shellfish, soy, tree nut, and fin fish, which were the top 4 allergies identified by Kamdar et al.[13] Furthermore, the observed rates of adult-onset shellfish and fin fish allergy in our sample are not dissimilar to the rates of 60% and 40%, respectively, observed by Sicherer et al[8] more than a decade ago. The most common childhood-onset allergy was peanut, which underlines the importance of early-life primary prevention efforts, such as the targeted early introduction practices advocated by the recent Addendum Guidelines for the Prevention of Peanut Allergy in the United States.[42]

In light of the considerable economic[1] and quality of life[3] consequences associated with allergen avoidance and other food allergy management behaviors, individuals with a suspected food allergy should receive appropriate confirmatory testing and counseling to counter unnecessary avoidance of allergenic food. Greater patient education efforts regarding key differences between food intolerances and allergies also may be warranted.[43] Furthermore, the results of our study suggest that adults need to be encouraged to see their physicians to receive proper diagnosis, epinephrine prescription, and counseling for their food allergy. Given the increasing evidence for the preventive benefits of early allergen exposure during infancy and potential treatment options, adults should be made aware of these new practices to potentially prevent food allergies in their children or consider treatments in the near future.

Limitations

Although double-blinded, placebo-controlled oral food challenges remain the criterion standard for food allergy diagnosis, such methods were not used to confirm self-reported food allergy in the present study because of their expense and impracticality with such a large nationally representative sample and concerns about nonparticipation bias. However, similar to past work,[7] to strengthen the rigor of our self-report questionnaire, stringent criteria were established in collaboration with an expert panel to exclude food allergies for which corresponding symptom report was not consistent with an IgE-mediated food allergy. Nevertheless, given the self-report paradigm used in the present study, bias remains a concern.

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Conclusions

These data suggest that at least 1 in 10 US adults are food allergic. However, they also suggest that nearly 1 in 5 adults believe themselves to be food allergic, whereas only 1 in 20 are estimated to have a physician-diagnosed food allergy. Overall, approximately half of all food-allergic adults developed at least 1 adult-onset allergy, suggesting that adult-onset allergy is common in the United States among adults of all ages, to a wide variety of allergens, and among adults with and without additional, childhood-onset allergies.

ARTICLE INFORMATION

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Author Contributions: Dr Gupta had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Acquisition, analysis, or interpretation of data: All authors.

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Critical revision of the manuscript for important intellectual content: Gupta, Warren, Smith, Jiang, Blumenstock, Davis, Schleimer.

Statistical analysis: Warren, Smith, Blumenstock, Nadeau.

Obtained funding: Gupta, Warren, Smith.

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Supervision: Gupta, Smith, Nadeau.

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SUPPLEMENT.

eMethods. Dual-Sample Complex Survey Sampling and Weighting Methodology

eFigure. List of Allergic Reaction Symptoms Highlighting Stringent Symptoms Indicative of Convincing Food Allergy

eTable 1. Demographic Distribution of Sample, Food-Allergic Adults, Adult- and Childhood-Onset Allergies [Frequency % (95% CI)]

eTable 2. Demographic and Allergic Characteristics Associated With Convincing, Physician-Diagnosed, Adult-Onset, Severe, and Multiple Food Allergies, Adjusted Odds Ratio (95% CI)

eTable 3. Demographic and Allergic Characteristics Associated With Epinephrine Prescription, Lifetime ED Visits, Last Year ED Visits, Adjusted Odds Ratio (95% CI)

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The Prevalence, Severity, and Distribution of Childhood Food Allergy in the United States

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KEY WORDS
food allergy, prevalence, morbidity, disparities, epidemiology

ABBREVIATIONS
RDD—random-digit-dialing
CI—confidence interval

Dr Gupta was responsible for the conception and design of the study, oversaw data acquisition, analysis, and interpretation, and participated in drafting and revision of the manuscript; Ms Springston participated in study design, was responsible for data acquisition, provided support for data analysis and interpretation, and was responsible for drafting and revision of the manuscript; Dr Warrier participated in study design, provided support for data analysis, and interpretation, and provided critical revisions to the manuscript, Dr Smith participated in study design, conducted data analysis, participated in data interpretation, and provided critical revisions to the manuscript; Dr Kumar consulted on study design, contributed to interpretation of data, and provided critical revisions to the manuscript; and Drs Pongracic and Holl oversaw study design, contributed to interpretation of data, and provided critical revisions to the manuscript.

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WHAT'S KNOWN ON THIS SUBJECT: Estimates of food allergy in the United States range from 2% to 8% but are limited by several factors. Previous studies often relied on small samples, lacked data on mode of diagnosis/reaction history, were not specific to children, or were limited in scope to a specific allergen.

WHAT THIS STUDY ADDS: This study includes a representative sample of US households to estimate the overall prevalence of food allergy as well as the prevalence of allergen-specific and severe food allergy. Data also provide a framework for discussions of disparity and the distribution of childhood food allergy in the United States.

abstract

OBJECTIVE: The goal of this study was to better estimate the prevalence and severity of childhood food allergy in the United States.

METHODS: A randomized, cross-sectional survey was administered electronically to a representative sample of US households with children from June 2009 to February 2010. Eligible participants included adults (aged 18 years or older) able to complete the survey in Spanish or English who resided in a household with at least 1 child younger than 18 years. Data were adjusted using both base and poststratification weights to account for potential biases from sampling design and nonresponse. Data were analyzed as weighted proportions to estimate prevalence and severity of food allergy. Multiple logistic regression models were constructed to identify characteristics significantly associated with outcomes.

RESULTS: Data were collected for 40 104 children; incomplete responses for 1624 children were excluded, which yielded a final sample of 38 480. Food allergy prevalence was 8.0% (95% confidence interval [CI]: 7.6–8.3). Among children with food allergy, 38.7% had a history of severe reactions, and 30.4% had multiple food allergies. Prevalence according to allergen among food-allergic children was highest for peanut (25.2% [95% CI: 23.3–27.1]), followed by milk (21.1% [95% CI: 19.4–22.8]) and shellfish (17.2% [95% CI: 15.6–18.9]). Odds of food allergy were significantly associated with race, age, income, and geographic region. Disparities in food allergy diagnosis according to race and income were observed.

CONCLUSIONS: Findings suggest that the prevalence and severity of childhood food allergy is greater than previously reported. Data suggest that disparities exist in the clinical diagnosis of disease. *Pediatrics* 2011;128:e9–e17

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Childhood food allergy is associated with impaired quality of life, limited social interactions, and comorbid atopic conditions.[1–6] Moreover, there is evidence that hospitalizations for anaphylaxis have increased more than fourfold among young people, with food-induced anaphylaxis being the most common cause.[7] Negative outcomes are compounded by limited treatment options, the absence of a cure, and the ubiquitous and often unidentified presence of allergenic foods in social settings. As a result, food allergy can have a profound social and psychological effect on the daily lives of affected children and their families.

Several studies have estimated childhood food allergy prevalence in the United States over the past 2 decades. (Sicherer[8] has reviewed this topic thoroughly.) A frequently cited statistic is 6% to 8% based on a 3-year study by Bock[9] conducted in the early 1980s. More recently, Liu et al reported a prevalence of 4.2% among children age 1 to 5 years using serologic data for peanut, milk, and egg allergy from the 2005 National Health and Nutrition Examination Survey.[10] Branum and Lukacs[3] reported a prevalence of 3.9% among children younger than 18 years of age based on self-report of a food or digestive allergy collected as part of the 2007 National Health Interview Survey. Finally, a recent meta-analysis commissioned by the National Institute of Allergy and Infectious Disease concluded that the prevalence of food allergy among all age groups likely falls between 1% and10%.[11,12]

Important insight has been gained by these past estimates, but the prevalence of childhood food allergy has yet to be definitively established. Previous studies are often limited by small sample size, lack of data on mode of diagnosis and reaction history, are not specific to children, or are limited in scope to a specific allergen.

The extent to which food allergy affects children in the United States also remains unclear. Previous estimates of prevalence have not considered the severity of disease. Furthermore, the underlying pathophysiology of disease is varied, and clinical manifestations encompass a diverse spectrum of symptoms.[13] On ingestion of an allergen, an affected child may experience an immunoglobulin E or non–immunoglobulin E-mediated reaction characterized by symptoms ranging from mild pruritus to delayed gastrointestinal symptoms to life-threatening anaphylaxis.

The heterogeneity and limitations of available data necessitate further analysis of all perceived food allergies on a larger scale. In the study described here, report of allergy, mode of diagnosis, and reaction history were collected from a population-based sample of nearly 40 000 US households with children to better estimate the prevalence, severity, and distribution of childhood food allergy in the United States.

METHODS

A population-based, cross-sectional survey was administered between June 2009 and February 2010 to a representative sample of US households with children. The institutional review boards of Children's Memorial Hospital and Northwestern University approved the study protocol. Consent to participate was implicit in completion and return of the survey.

Survey Development and Design

The survey was developed by pediatricians, pediatric allergists, and health services researchers, with support of an expert panel comprising leaders in the field. Expert panel review and cognitive interviews ($N = 10$) were conducted using the approach described by Gupta et al[14] to ensure general understandability and consistency of response.

The survey was then programmed for electronic administration. Quality-control testing was conducted to assure that skip logic and randomization were met. A pretest of 30 interviews was electronically administered to verify survey functionality and understandability. The survey was subsequently finalized based on pretest results.

The final survey is available on request and includes items assessing participant report of a child's food allergies. Questions were asked about the date of onset, method of diagnosis, and reaction history for each reported allergen. Detailed demographic items were also included.

Study Participants

Eligible participants included adults (those aged 18 years or older) able to complete the survey in Spanish or English who resided in US households with at least 1 child younger than 18 years.

Participants were recruited using a dual-sample approach. A target of 6100 participants was recruited from a Web-enabled panel that is a statistically representative sample of US households with children. This sample included households recruited using probability-based random-digit-dialing (RDD) sampling that had or were provided Internet connectivity to complete the survey. An additional 33 900 participants were targeted from an online sample of US households with children who had access to the Internet. Responses from the Web-enabled panel were used to identify and correct for sampling and nonsampling biases (see "Statistical Analysis").

Participant recruitment and survey administration were conducted by Knowledge Networks, a survey research firm in Menlo Park, California. Knowledge Networks developed and

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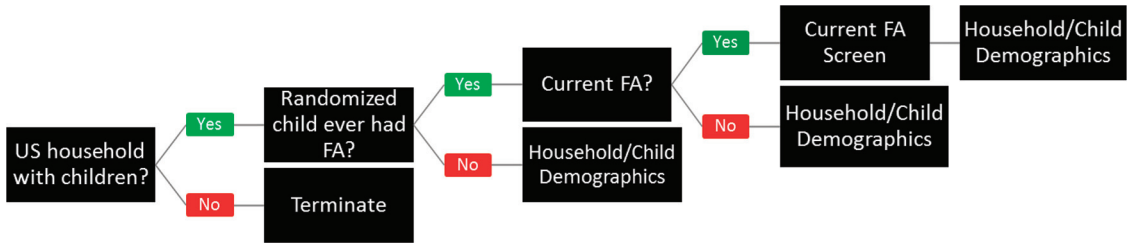

FIGURE 1
Survey scheme based on participant response. FA indicates food allergy.

maintains the Web-enabled panel and secured the online sample. (See the Appendix for details.) Knowledge Networks has documented the reliability and validity of its methodologic approach as well its comparability with the more traditional RDD approach.[15,16]

Data Collection

Current estimates of food allergy prevalence in the literature were used to estimate adequate sample size. Completion of 40 000 surveys was determined to have a power of 0.90 with a significance level of .05 to detect: (1) overall and allergen-specific food allergy prevalence rates from 1% to 9%; and (2) prevalence variability from 1% to 7% among groups as small as 1% of the sample.

In households with multiple children, 1 child was randomly selected and participants were instructed to complete the survey for the selected child as outlined in Fig 1.

Outcome Measures

Primary outcome measures were prevalence and severity of food allergy. The definition of food allergy included report of either a convincing or confirmed food allergy. A convincing food allergy was based on participant report in conjunction with ≥1 of the following reaction symptoms: anaphylaxis (defined as a severe allergic reaction that can lead to death), angioedema of the lips, eyes, or face, other angioedema, coughing, other oropharyngeal symptoms, eczema, flushing, hives, low blood pressure, pruritus, trouble breathing, vomiting, or wheezing. A confirmed food allergy met the latter criteria and also included report of physician-diagnosis with serum-specific immunoglobulin E testing, skin prick testing, or an oral food challenge.

A food allergy was categorized by the expert panel as mild-to-moderate or severe based on reaction history. Mild-to-moderate symptoms were limited to angioedema of the lips, eyes, or face, other angioedema, coughing, other oropharyngeal symptoms, eczema, flushing, hives, pruritus, and vomiting. Severe symptoms included any report of anaphylaxis, low blood pressure, trouble breathing, or wheezing. A reaction including vomiting, angioedema, and coughing in combination was also categorized as severe.

Statistical Analysis

Data were weighted using both base and poststratification weights to adjust for potential biases from sampling design and survey response. Base weights adjusted for under- and oversampling by geographic region, area code, and survey language. After base weight assignment, an additional adjustment was added to reflect the probability of selecting a child within a household. Finally, poststratification weights were assigned using demographic distributions from the December 2009 US Census Current Population Survey and the 2006 Pew Hispanic Center Survey.

Prevalence and severity estimates were calculated as weighted proportions.[17] Multiple logistic regression models, adjusted for survey design and sample weights, were estimated to examine the association between household or child characteristics and the prevalence, diagnosis, and severity of food allergy. Each model was adjusted for household income, race/ethnicity, age, geographic region, and gender. All analyses were conducted with Stata 11.0 (Stata Corp, College Station, TX).

RESULTS

Data were collected for 40 104 children. Incomplete responses for 1624 children were not included in the analysis, yielding a final sample size of 38 480.

Demographic Characteristics

Half (51.1%) of the children surveyed were male, with a mean age of 8.5 years (95% confidence interval [CI]: 8.5–8.6). Race/ethnicity was mutually exclusive, with 56.4% of children reported to be white, non-Hispanic; 21.6% Hispanic; 14.1% black, non-Hispanic; and 4.8% Asian, non-Hispanic (Table 1).

Prevalence

The prevalence of food allergy was 8.0% (95% CI: 7.7–8.3) (Table 2). Multiple food allergies were reported for 2.4% of all children (95% CI: 2.2–2.6),

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TABLE 1 Demographic Characteristics Among All Children Surveyed ($N = 38\,480$) and Children Surveyed With Food Allergy ($N = 3339$)

Variable	Frequency, % (95% CI)		*P*
	All Children	Children With Food Allergy	
Race/ethnicity			.0000
Asian, non-Hispanic	4.8 (4.6–5.1)	6.2 (5.2–7.3)	
Black, non-Hispanic	14.1 (13.7–14.7)	21.7 (19.7–23.9)	
White, non-Hispanic	56.4 (55.8–57.1)	51.1 (49.0–53.2)	
Hispanic	21.6 (20.9–22.2)	18.0 (16.3–20.0)	
Multiple/other, non-Hispanic	3.0 (2.8–3.2)	3.0 (2.3–3.5)	
Gender			.7311
Female	49.0 (48.3–49.6)	49.3 (47.2–51.4)	
Male	51.1 (50.4–51.7)	50.7 (48.6–52.8)	
Age, y			.0000
0–2	16.8 (16.3–17.3)	13.2 (11.9–14.7)	
3–5	17.0 (16.5–17.5)	19.6 (17.9–21.4)	
6–10	26.7 (26.1–27.3)	25.4 (23.6–27.3)	
11–13	17.2 (16.7–17.7)	17.6 (16.1–19.3)	
14–17	22.4 (21.9–22.9)	24.2 (22.4–26.0)	
Household income, $			.0010
<25 000	20.3 (19.7–20.9)	17.6 (15.9–19.5)	
25 000–49 999	28.9 (28.3–29.5)	28.2 (26.3–30.2)	
50 000–99 999	34.6 (34.0–35.1)	36.5 (34.6–38.5)	
100 000–149 999	11.6 (11.2–12.0)	11.8 (10.6–13.12)	
≥150 000	4.7 (4.4–4.9)	5.9 (5.0–6.9)	
Geographic region			.0000
Midwest	21.9 (21.4–22.4)	17.1 (15.7–18.6)	
Northeast	16.7 (16.3–17.2)	17.1 (15.7–18.6)	
South	37.3 (36.6–37.9)	42.9 (40.7–45.0)	
West	24.2 (23.6–24.7)	23.0 (21.3–24.9)	

corresponding to 30.4% of children with a food allergy. Prevalence by allergen was also estimated. Peanut allergy was most common, followed closely by milk and shellfish (Table 2). Significant variation in prevalence according to age was observed for peanut, shellfish, tree nut, egg, and wheat allergy ($P <$ .05) (Table 2).

Severity

The prevalence of severe food allergy among all children was 3.1% (95% CI: 2.9–3.3), corresponding to 38.7% of children with food allergy. Food allergy reactions were most often severe among children with tree nut or peanut allergy (Table 3).

Associations

Odds of having a food allergy are presented in Table 4. The odds of food allergy were significantly higher among Asian and black children versus white children, children in all age groups versus those aged 0 to 2 years, and for children from geographic regions outside the Midwest ($P <$ .05). Odds were significantly lower among children in households with an income <$50 000 vs ≥$50 000 ($P <$ .05). Gender was not significantly association with odds of food allergy in this model.

Odds of having a diagnosed food allergy were also estimated (Table 4). The odds of a confirmed versus convincing food allergy were significantly higher among children with multiple food allergies versus those without multiple food allergies ($P <$ .05). Odds of a confirmed food allergy were significantly lower among Asian, black, and Hispanic children versus white children and for children in households with an income <$50 000 vs ≥$50 000 ($P <$ .05). Gender, age, and geographic region were not significantly associated with diagnosis of food allergy in this model.

Odds of severe versus mild-to-moderate food allergy among food-allergic children were estimated as well (Table 4). The odds of severe food allergy were significantly higher among children in all age groups versus those aged 0 to 2 years, male versus female children, and children with versus without multiple food allergies ($P <$ .05). Odds were significantly lower among children in households with an income <$50 000 vs ≥$50 000 ($P <$ .05). Race and geographic region were not significantly associated with severity of food allergy in this model.

DISCUSSION

Eight percent of children in this study had a food allergy, which corresponds to an estimated 5.9 million children in the United States. Furthermore, 38.7% of the children surveyed had a history of severe reactions, and 30.4% had multiple food allergies.

Previous estimates of childhood food allergy in the United States have ranged from 2% to 8%.[3,9,10] A study conducted by Branum and Lukacs[3] reported the prevalence of childhood food allergy to be 3.9%, whereas a study by Liu et al[10] estimated prevalence at 4.2% for children age 1 to 5 years and 3.8% for children age 6 to 19 years. The study by Branum and Lukacs was notable for its larger sample size and its specificity to children but was based on caregiver report of food allergy or digestive disorder without report of reaction history or presenting symptoms, and, as such, warrants further corroboration. The study by Liu et al is unique in its use of food-specific IgE to confirm the diagnosis of food allergy. However, it is limited to peanut, milk, and egg allergy only (as well as shrimp in the 6- to 19-year age group). The study described here, which included the largest sample of children to date and gathered information for a wide number of food allergens, sug-

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TABLE 2 Prevalence of Common Food Allergies According to Age Group

Age Group	Frequency, % (95% CI)									
	All Allergens ($N = 3339$)	Peanut ($N = 767$)	Milk ($N = 702$)	Shellfish ($N = 509$)	Tree Nut ($N = 430$)	Egg ($N = 304$)	Fin Fish ($N = 188$)	Strawberry ($N = 189$)	Wheat ($N = 170$)	Soy ($N = 162$)
Prevalence among all children surveyed										
All ages ($N = 38\,480$)	8.0 (7.7–8.3)	2.0 (1.8–2.2)	1.7 (1.5–1.8)	1.4 (1.2–1.5)	1.0 (0.9–1.2)	0.8 (0.7–0.9)	0.5 (0.4–0.6)	0.4 (0.4–0.5)	0.4 (0.3–0.5)	0.4 (0.3–0.4)
0–2 y ($n = 5429$)	6.3 (5.6–7.0)	1.4 (1.1–1.8)	2.0 (1.6–2.4)	0.5 (0.3–0.8)	0.2 (0.2–0.5)	1.0 (0.7–1.3)	0.3 (0.1–0.4)	0.5 (0.3–0.7)	0.3 (0.1–0.5)	0.3 (0.2–0.4)
3–5 y ($n = 5910$)	9.2 (8.3–10.1)	2.8 (2.3–3.4)	2.0 (1.7–2.5)	1.2 (0.8–1.6)	1.3 (1.0–1.7)	1.3 (0.9–1.7)	0.5 (0.3–0.8)	0.5 (0.3–0.8)	0.5 (0.3–0.7)	0.5 (0.3–0.7)
6–10 y ($n = 9911$)	7.6 (7.0–8.2)	1.9 (1.6–2.3)	1.5 (1.2–1.8)	1.3 (1.1–1.6)	1.1 (0.87–1.4)	0.8 (0.6–1,1)	0.5 (0.3–0.7)	0.4 (0.3–0.5)	0.4 (0.3–0.5)	0.3 (0.2–0.5)
11–13 y ($n = 6716$)	8.2 (7.4–9.0)	2.3 (1.9–2.8)	1.4 (1.1–1.8)	1.7 (1.3–2.1)	1.2 (1.0–1.6)	0.5 (0.4–0.8)	0.6 (0.4–0.8)	0.4 (0.3–0.6)	0.7 (0.5–0.9)	0.6 (0.4–0.8)
≥14 y ($n = 10\,514$)	8.6 (7.9–9.3)	1.7 (1.4–2.1)	1.6 (1.3–1.9)	2.0 (1.7–2.5)	1.2 (0.9–1.5)	0.4 (0.2–0.5)	0.6 (0.4–0.9)	0.4 (0.3–0.6)	0.3 (0.2–0.4)	0.3 (0.2–0.4)
P	.0000	.0001	.0504	.0000	.0000	.0000	.1045	.7700	.0089	.0509
Prevalence among children surveyed with food allergy										
All ages ($N = 3339$)	—	25.2 (23.3–27.1)	21.1 (19.4–22.8)	17.2 (15.6–18.9)	13.1 (11.7–14.6)	9.8 (8.5–11.1)	6.2 (5.2–7.3)	5.3 (4.4–6.3)	5.0 (4.2–6.0)	4.6 (3.8–5.6)
0–2 y ($n = 469$)	—	22.2 (17.4–27.8)	31.5 (26.6–36.8)	7.5 (4.7–11.9)	5.4 (3.6–8.1)	15.8 (12.0–20.4)	4.0 (2.3–6.9)	7.5 (5.2–8.2)	4.0 (2.2–7.2)	4.2 (2.7–6.5)
3–5 y ($n = 539$)	—	30.3 (25.8–35.3)	22.1 (18.3–26.5)	12.9 (9.7–16.9)	14.3 (11.1–18.2)	13.7 (10.5–17.6)	5.7 (3.8–8.6)	5.5 (3.6–8.2)	5.0 (3.2–7.7)	5.1 (3.3–7.8)
6–10 y ($n = 847$)	—	25.5 (22.0–29.5)	19.6 (16.6–23.0)	17.1 (14.0–20.6)	14.3 (11.6–17.5)	11.1 (8.6–14.3)	6.2 (4.5–8.5)	4.8 (3.4–6.9)	5.0 (3.5–7.1)	4.0 (2.6–6.2)
11–13 y ($n = 584$)	—	28.1 (23.7–32.9)	17.7 (14.2–22.0)	20.4 (16.8–24.7)	15.2 (12.0–19.2)	6.6 (4.4–9.9)	7.0 (4.8–10.1)	4.6 (3.1–6.8)	8.2 (5.9–11.2)	6.9 (4.7–10.0)
≥14 y ($n = 900$)	—	20.2 (17.0–23.7)	18.4 (15.3–22.1)	23.8 (20.1–27.9)	13.4 (10.7–16.6)	4.1 (2.9–5.9)	7.2 (5.2–9.8)	4.9 (3.3–7.3)	3.3 (2.1–5.0)	0.3 (0.2–0.4)
P	—	.0050	.0001	.0000	.0010	.0000	.4646	.4486	.0174	.1296

Common food allergens are those reported with a frequency of $n > 150$.

TABLE 3 Severity of Common Food Allergies Among Affected Children ($N = 3339$)

Reaction History	Proportion, % (95% CI)									
	All Allergens ($N = 3339$)	Tree Nut ($N = 430$)	Peanut ($N = 767$)	Shellfish ($N = 509$)	Soy ($N = 162$)	Fin Fish ($N = 188$)	Wheat ($N = 170$)	Milk ($N = 702$)	Egg ($N = 304$)	Strawberry ($N = 189$)
Severe	38.7 (36.7–40.8)	52.5 (46.7–58.3)	52.4 (47.9–56.7)	46.8 (41.4–52.3)	42.6 (33.1–52.7)	40.6 (32.5–49.3)	38.0 (29.4–47.5)	31.2 (27.1–35.7)	29.5 (23.7–36.1)	19.6 (13.3–28.0)
Mild-to-moderate	61.3 (59.2–63.4)	47.5 (41.7–53.4)	47.7 (43.3–52.1)	53.2 (47.7–58.6)	57.4 (47.3–67.0)	50.4 (50.8–67.5)	62.0 (52.5–70.6)	68.8 (64.3–72.9)	70.5 (63.9–76.3)	80.4 (72.0–86.7)

Common food allergens are those reported with a frequency of $n > 150$.

TABLE 4 Multiple Logistic Regression Models: Adjusted Odds of Food Allergy, Diagnosis of Food Allergy, and Severe Food Allergy

Variable	Food Allergy vs No Food Allergy	Confirmed vs Convincing Food Allergy	Severe vs Mild-to-Moderate Food Allergy
Race/ethnicity vs white, non-Hispanic			
Asian, non-Hispanic	1.4 (1.2–1.7)	0.7 (0.4–0.9)	0.7 (0.4–1.0)
Black, non-Hispanic	1.8 (1.6–2.1)	0.8 (0.6–1.0)	1.1 (0.8–1.4)
Hispanic	0.9 (0.8–1.1)	0.8 (0.6–1.0)	0.9 (0.7–1.2)
Multiple/other, non-Hispanic	1.1 (0.9–1.4)	1.2 (0.8–1.8)	1.1 (0.7–1.7)
Gender			
Male vs female	0.9 (0.9–1.1)	1.1 (0.9–1.3)	1.3 (1.0–1.5)
Age vs 0–2 y			
3–5	1.5 (1.3–1.8)	1.4 (1.0–1.9)	1.6 (1.1–2.4)
6–10	1.2 (1.1–1.4)	1.2 (0.9–1.)	1.6 (1.2–2.3)
11–13	1.3 (1.1–1.5)	1.1 (0.8–1.6)	1.9 (1.4–2.8)
14–17	1.4 (1.2–1.6)	1.2 (0.9–1.7)	2.1 (1.5–3.0)
Household income, $			
<50 000 vs ≥50 000	0.5 (0.4–0.7)	0.5 (0.4–0.6)	0.8 (0.6–0.9)
Geographic region vs Midwest			
Northeast	1.3 (1.2–1.5)	1.3 (1.0–1.7)	1.1 (0.9–1.5)
South	1.5 (1.3–1.7)	1.1 (0.9–1.4)	1.1 (0.8–1.4)
West	1.3 (1.1–1.5)	1.0 (0.7–1.3)	1.0 (0.7–1.3)
Report of multiple food allergies			
Yes vs no	—	3.1 (2.6–3.8)	3.2 (2.7–4.0)

Each estimate is adjusted for all variables listed in the table.

gests that food allergy affects more children than recently reported.

Allergen-specific prevalence in this study fell within the range of past estimates for milk,[18] shellfish,[18] tree nut,[11] wheat,[11] and soy allergy among children.[11] However, estimates of peanut and fin fish allergy were somewhat higher than previously reported.

Peanut allergy was found to affect 2.0% of children. This estimate is close to that reported by Hourihane et al[19] in the United Kingdom (1.8%) but double that confirmed by Ben-Shoshan et al[20] in Canada (1.0%). Interestingly, in the study by Ben-Shoshan et al, peanut allergy was probable among 1.7% of children.

Fin fish allergy was found to affect 0.5% of children. Ben-Shoshan et al[20] found that 0.18% of children had a probable fin fish allergy but none of them had a formal diagnosis. Among adults and children, oral food challenges suggest a prevalence of 0.3%.[11] When interpreting these variations in prevalence, it is important to consider that those with a probable allergy may be truly allergic absent a formal diagnosis.

To our knowledge, prevalence of severe childhood food allergy for a representative sample of US children has not been previously estimated. The lack of data on the severity of childhood food allergy has made it difficult to articulate best practices. Our study found that >38.7% of food-allergic children had a history of severe food-induced reactions. Severe reactions were most common among children with a tree nut, peanut, shellfish, soy, and fin fish allergy, ranging from >50% of tree nut and peanut-allergic children to >40% of children with fin fish allergy.

Current literature suggests that adolescents are at greater risk for severe food allergy than children of any other age.[21] Consistent with past reports, this study found that odds of severe food allergy progressively increased with age, peaking at more than twofold higher odds of severe reaction history among children aged 14 to 17 years versus those aged 0 to 2 years. Odds were most pronounced among children with versus without multiple food allergies—the former had a more than threefold higher odds of severe food-induced reactions. Although this finding seems somewhat intuitive, to our knowledge it has not been previously reported.

The identification of significant differences in odds of food allergy and diagnosed food allergy suggests that disparities may exist in both the etiology and management of disease. Age and geographic region were significantly associated with having a food allergy but not with odds of having a confirmed versus convincing food allergy. This finding suggests that these associations are not the result of varying clinical practices by age or region. Rather, they may be indicative of underlying causes of disease, such as pathophysiologic differences in the development of food allergy by age. Indeed, food allergy prevalence was highest among children 3 to 5 years at 9.2%. The role of geographic region in etiology is less clear and warrants further investigation.

Unlike age and geographic region, findings suggest that differences in prevalence by race and income may represent socially constructed disparities. For example, black and Asian children had significantly higher odds of food allergy compared with white children but had significantly lower odds of having the allergy diagnosed. In short, these children were more likely to have food allergy but less likely to receive a formal diagnosis. Interestingly, the odds of food allergy among Hispanic children were lower compared with white children in both models, although only to a degree of statistical significance in the confirmed versus convincing model. It is possible that Hispanic children are protected

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against food allergy in a manner not yet identified.

Limitations to this study need to be highlighted. Reaction history and diagnosis of food allergy were based solely on participant report, which is subject to recall bias. Furthermore, data on the reproducibility of reaction symptoms were not collected and the survey was not validated to ensure accuracy of diagnosis. However, the prevalence of a number of specific allergies is consistent with that reported by other studies, lending credibility to the definition of food allergy used in this study.

CONCLUSIONS

Findings suggest that the impact of food allergy in the United States may be greater than previously reported. The prevalence of childhood food allergy was estimated at 8.0%, which is considerably higher than many recent reports. Furthermore, 38.7% of food-allergic children had a history of severe food-induced reactions. Data also suggest that disparities exist in childhood food allergy and its clinical diagnosis. These findings provide critical epidemiologic information to guide strategies for the prevention of food-induced reactions and for the diagnosis and management of childhood food allergy.

APPENDIX METHODS

The data in this study were collected by Knowledge Networks using an online survey that used a combination of the Knowledge Networks KnowledgePanel sample and an opt-in sample. Although the KnowledgePanel sample is probabilistic and nationally representative, it was not large enough for the purposes of this study. To obtain enough participants, Knowledge Networks combined their KnowledgePanel sample with an opt-in sample and then used weights to calibrate the overall sample. After excluding subjects with missing data for the outcomes and demographic characteristics, 6892 subjects from the KnowledgePanel and 31 588 subjects from the opt-in panel were included in the analyses.

KnowledgePanel Methods

Knowledge Networks created the KnowledgePanel by randomly recruiting subjects using sampling methods that included both RDD and address-based sampling. After recruitment, subjects who did not have e-mail access were provided with the necessary equipment and services to access online content. By providing online access, subjects that might otherwise be excluded from participating in online surveys were included in the sample. For the RDD sample, Knowledge Networks used a sampling frame of US residential telephone landlines. Areas with a high concentration of black and Hispanic households were oversampled, and sampling was done without replacement. Households with a mailing address that matches their telephone number receive a letter indicating they have been selected to participate in the panel and that they will receive a phone call. Subjects are then recruited by telephone; trained interviewers attempt to contact and recruit potential subjects. Households without computers and/or access to the Internet are offered a computer and free Internet access in exchange for completing weekly surveys. Households with computers are offered incentive points that can be redeemed for cash. To address the increasing number of households without landlines, Knowledge Networks added address-based recruitment in 2009.

Survey Administration

Households with children younger than 18 years were randomly selected for this survey. Members who were selected for the survey received an e-mail with a link, and then received an automatic e-mail reminder if they did not respond. Panel members have access to a personalized online list of surveys that need to be completed. Usually, panel members are assigned no more than 1 survey per week. Ongoing incentive programs, including raffles and sweepstakes, are used to retain member panels, and additional incentives may be offered for longer surveys.

Weighting

The data in this study were weighted using a series of weights that adjusted for the sampling design and various sources of sampling and nonsampling error. The weights included a base weight, a panel demographic post-stratification weight, a Spanish language base weight, a child adjustment in the base weight, and a study-specific poststratification weight. Details for how the weights were created are discussed below.

The first weight for the KnowledgePanel is the base weight. The base weight addresses several sources of deviation from an equal probability of selection. The first is the undersampling of telephone numbers that were not matched to a valid mailing. The KnowledgePanel sample is partially based on a sample of RDD-generated phone numbers. After the sample of phone numbers is obtained, they are matched to mailing addresses. Approximately 30% to 40% of these numbers will not have a matching address, and these are undersampled to increase the efficiency of recruiting. The second aspect of the base weight addresses households that have multiple landlines. KnowledgePanel collects data about the number of landlines in a household and then weights the selection probability for these households. The third issue that the weight adjusts for is some minor oversampling of cer-

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tain cities when the sample was started. In addition to oversampling from these cities, the weight also adjusts for potential oversampling of the 4 largest states and states located in the central region of the country. Because some households are located in areas in which Knowledge Networks was unable to provide Internetaccess, the base weight also includes an adjustment to address the undersampling of these areas. Finally, the base weight adjusts for oversampling of black and Hispanic telephone numbers, and incorporates panel members from the address-based sample described above.

The second weight is the Spanish Language Base Weight. Starting in 2008, Knowledge Networks started recruiting households that were Spanish-language dominant. The recruitment interviews in these households were conducted in Spanish. To recruit Spanish-language dominant households, 11 regions were screened using both RDD methods as well as lists of Hispanic surnames. The weight includes 3 adjustments. The first adjusts for the number of telephone landlines in a household. The second adjusts for balancing the RDD and listed surname samples. The final adjustment uses Pew Hispanic Center surveys and census regions to adjust for the degree of Spanish language spoken at home.

Because the sample included only 1 child in every household, the base weight was adjusted for the number of children within each household. The number of children was collapsed into 3 categories (1 child, 2 children, and $\geq$3 children), and the starting weights were then adjusted.

After the base weights were calculated, the panel demographic post-stratification weights were applied. This weight is designed to address the effects of nonresponse and noncoverage bias in the panel membership. The adjustment is based on recent data from the Current Population Survey for demographic characteristics and from the 2006 Pew Hispanic Center Survey to adjust for Spanish language usage. Because the survey data do not address Internet availability, the benchmark for this adjustment is based on KnowledgePanel recruitment data. The variables included in the post-stratification weights were gender, age, ethnicity, race, education, census region, metropolitan area, income, and parent language spoken at home.

Finally, after the survey was fielded, poststratification weights were applied to address survey nonresponse and noncoverage. These weights were based on the same data and variables as the demographic weights. The post-stratification weighting adjustment was completed through iterative proportional fitting.

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Dr Gupta had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. The funders played no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; or preparation, review, or approval of the manuscript.

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Original Investigation | Allergy

Prevalence and Severity of Food Allergies Among US Adults

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Abstract

IMPORTANCE Food allergy is a costly, potentially life-threatening condition. Although studies have examined the prevalence of childhood food allergy, little is known about prevalence, severity, or health care utilization related to food allergies among US adults.

OBJECTIVE To provide nationally representative estimates of the distribution, severity, and factors associated with adult food allergies.

DESIGN, SETTING, AND PARTICIPANTS In this cross-sectional survey study of US adults, surveys were administered via the internet and telephone from October 9, 2015, to September 18, 2016. Participants were first recruited from NORC at the University of Chicago's probability-based AmeriSpeak panel, and additional participants were recruited from the non–probability-based Survey Sampling International (SSI) panel.

EXPOSURES Demographic and allergic participant characteristics.

MAIN OUTCOMES AND MEASURES Self-reported food allergies were the main outcome and were considered convincing if reported symptoms to specific allergens were consistent with IgE-mediated reactions. Diagnosis history to specific allergens and food allergy–related health care use were also primary outcomes. Estimates were based on this nationally representative sample using small-area estimation and iterative proportional fitting methods. To increase precision, AmeriSpeak data were augmented by calibration-weighted, non–probability-based responses from SSI.

RESULTS Surveys were completed by 40 443 adults (mean [SD] age, 46.6 [20.2] years), with a survey completion rate of 51.2% observed among AmeriSpeak panelists (n = 7210) and 5.5% among SSI panelists (n = 33 233). Estimated convincing food allergy prevalence among US adults was 10.8% (95% CI, 10.4%-11.1%), although 19.0% (95% CI, 18.5%-19.5%) of adults self-reported a food allergy. The most common allergies were shellfish (2.9%; 95% CI, 2.7%-3.1%), milk (1.9%; 95% CI, 1.8%-2.1%), peanut (1.8%; 95% CI, 1.7%-1.9%), tree nut (1.2%; 95% CI, 1.1%-1.3%), and fin fish (0.9%; 95% CI, 0.8%-1.0%). Among food-allergic adults, 51.1% (95% CI, 49.3%-52.9%) experienced a severe food allergy reaction, 45.3% (95% CI, 43.6%-47.1%) were allergic to multiple foods, and 48.0% (95% CI, 46.2%-49.7%) developed food allergies as an adult. Regarding health care utilization, 24.0% (95% CI, 22.6%-25.4%) reported a current epinephrine prescription, and 38.3% (95% CI, 36.7%-40.0%) reported at least 1 food allergy–related lifetime emergency department visit.

CONCLUSIONS AND RELEVANCE These data suggest that at least 10.8% (>26 million) of US adults are food allergic, whereas nearly 19% of adults believe that they have a food allergy. Consequently, these findings suggest that it is crucial that adults with suspected food allergy receive appropriate confirmatory testing and counseling to ensure food is not unnecessarily avoided and quality of life is not unduly impaired.

Key Points

Question What are the prevalence and severity of food allergy in US adults?

Findings In a population-based survey study of 40 443 US adults, an estimated 10.8% were food allergic at the time of the survey, whereas nearly 19% of adults believed that they were food allergic. Nearly half of food-allergic adults had at least 1 adult-onset food allergy, and 38% reported at least 1 food allergy–related emergency department visit in their lifetime.

Meaning The findings suggest that food allergies are common and severe among US adults, often starting in adulthood.

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

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Introduction

Food allergy is a costly,[1] potentially life-threatening[2] health condition that can adversely affect patients' well-being.[3,4] Although population-based studies[5,6] have examined the prevalence of food allergy among children, less is known about the population-level burden of food allergy among adults in the United States. The few population-based studies[7,8] to date that examined adult food allergy have focused on a limited number of specific allergens (eg, peanut) or allergen groups (eg, tree nut, seafood) or have been secondary analyses of federal health surveys, which were not designed to comprehensively characterize food allergy prevalence and severity among US adults. For example, neither the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey[9] nor the US Food and Drug Administration's (FDA's) Food Safety Survey[10] collects information about specific allergic reaction symptoms critical for differential diagnosis of food allergy (eg, food intolerances, oral allergy syndrome). Nevertheless, food allergy prevalence estimates from these recent national surveys exceed 9% of US adults, suggesting that food allergy may affect more US adults than previously acknowledged.

Although some children with food allergy develop natural tolerance, others retain their food allergy as they enter adulthood.[11,12] Adults can also develop new food allergies,[13] and evidence suggests that certain food allergies (eg, shellfish and fin fish) may be more likely than others to develop during adulthood.[8,13] Moreover, studies[14-16] suggest that rates of food allergy–related emergency department (ED) visits may be increasing among children and young adults.

Much remains to be learned about the population-level consequences of adult food allergy in the United States, including the relative frequency and timing of adult- vs childhood-onset food allergy, allergen type, severity, and key sociodemographic and clinical factors of each of these food allergy characteristics. This study aimed to provide comprehensive, nationally representative estimates of the distribution, severity, and factors associated with adult food allergy in the United States.

Methods

Surveys were administered by NORC at the University of Chicago from October 9, 2015, to September 18, 2016, to a sample of US households through a dual-sampling approach using NORC's nationally representative AmeriSpeak panel and the Survey Sampling International (SSI) non–probability-based sample (eMethods in the Supplement). Written informed consent was obtained from all participants during enrollment into the AmeriSpeak panel and SSI web samples. Identical surveys were administered to both samples. All data were deidentified. The NORC Institutional Review Board and Northwestern University Institutional Review Board approved all study activities. The study followed the American Association for Public Opinion Research (AAPOR) reporting guideline.

Survey Development and Design

The surveys extended our national child food allergy survey, administered in 2009 to 2010, which was developed by pediatricians, allergists, health services researchers, and survey methodologists. Expert panel review and key informant cognitive interviews (N = 40) were conducted on the original survey using the approach described previously.[17] Although core constructs from the 2009-2010 survey were retained, additional questions were added to the present instrument to assess emerging research issues that related to the cause and management of adult food allergy. The revised instrument was pretested on 345 interviewees to ensure clarity, relevance, validity, and reliable functioning of all questions and response options. Interviewee data and feedback were reviewed and incorporated into the final 2015-2016 surveys, which were administered via the internet or telephone. All write-in responses were hand coded and reviewed by an expert panel to ensure accuracy of final data. Participants who did not answer the initial question about whether they have

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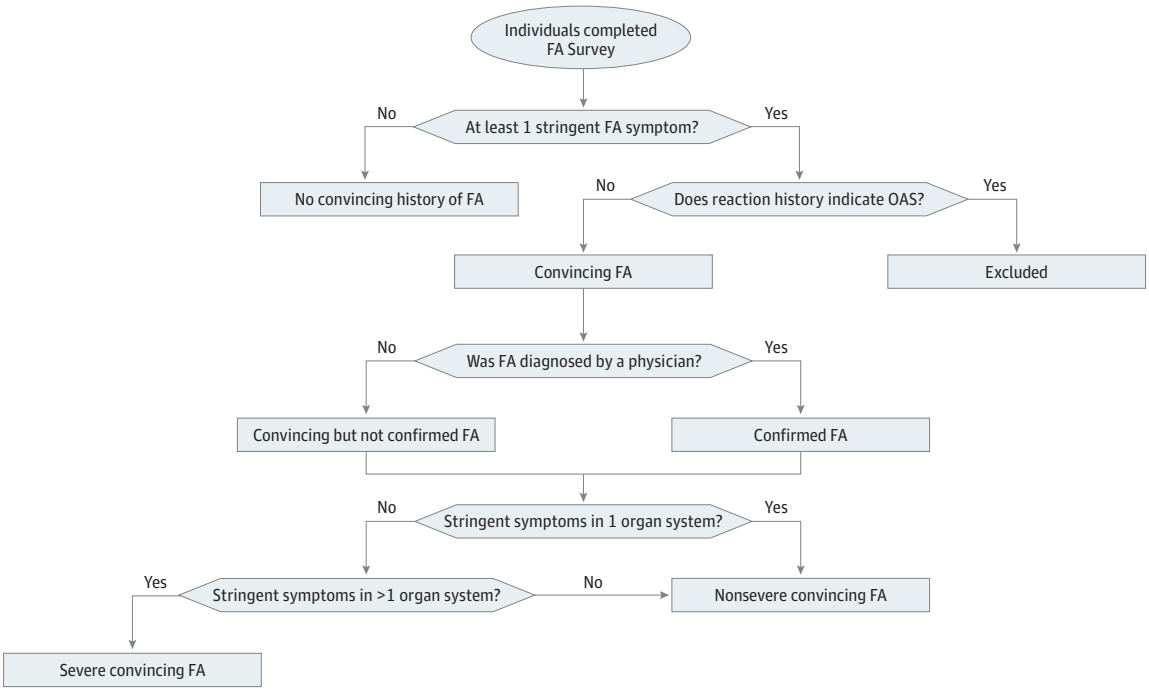
ever had a food allergy were considered to have provided incomplete responses and were not included in any analyses.

Outcome Measures

The primary outcome measures for the study were the prevalence and severity of overall and food-specific convincing adult food allergy. Food allergies were considered to be convincing if the most severe reaction reported to that food included at least 1 symptom on the stringent symptom list developed by our expert panel (eFigure in the Supplement). Reported allergies with reaction symptoms characteristic of oral allergy syndrome or food intolerances were excluded and not considered to be convincing according to the food allergy categorization flowchart summarized in **Figure 1**, even if such allergies were reported as diagnosed by a physician. Only convincing food allergies for which a physician's diagnosis was reported were considered to be physician diagnosed for the purposes of our study. For each convincing allergy, a severe reaction history was indicated by reporting 1 or more stringent symptoms across 2 or more of the following organ systems: skin or oral mucosa, gastrointestinal tract, cardiovascular, and respiratory tract.

If multiple food allergies were reported, each reported food allergy was evaluated separately using the food allergy categorization flowchart. For example, if a respondent reported a nut allergy with a reaction history limited to oral symptoms indicative of oral allergy syndrome as well as a shellfish allergy with a reaction history that included throat tightening, vomiting, and hives, the respondent would be considered to have only a single, severe shellfish allergy and the nut allergy would be excluded. Lifetime physician-diagnosed atopic comorbidities were also assessed using the question, "Have you ever been diagnosed by a doctor with any of the following chronic conditions? Please select all that apply." Response options included asthma, eczema/atopic dermatitis, hay fever/

Figure 1. Convincing, Physician-Diagnosed, and Severe Food Allergy (FA) Categorization Flow Diagram



Stringent symptoms by organ system include skin or oral mucosa (hives, swelling [except lip or tongue], lip or tongue swelling, difficulty swallowing, throat tightening), respiratory tract (chest tightening, trouble breathing, wheezing), gastrointestinal tract (vomiting), and cardiovascular (chest pain, rapid heartbeat, fainting, low blood pressure). Gastrointestinal symptoms commonly associated with intolerance (eg, diarrhea, cramps) were not considered to be stringent symptoms. The following allergies were considered for exclusion as probable oral allergy syndrome (OAS) based on symptom report: fruit, vegetable, peanut, tree nut, wheat, soy, barley, rice, seed, spice, shellfish, and fin fish.

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allergic rhinitis/seasonal allergies, insect sting allergy, latex allergy, medication allergy, and urticaria/chronic hives.

Study Participants and Survey Weighting

Eligible study participants included adults (≥18 years of age) able to complete surveys in English or Spanish who were residing in a US household. As in the 2009-2010 survey, this study relied on a nationally representative household panel to support population-level inference.[5] Study participants were first recruited from NORC at the University of Chicago's probability-based AmeriSpeak panel, where a survey completion rate of 51.2% was observed (7218 responses from 14 095 invitees). The weighted cumulative AAPOR response rate for the AmeriSpeak sample was 8.8%. This rate is a function of the 18.3% rate of originally sampled households successfully recruited into the AmeriSpeak panel when it was established, the 93.8% rate of successfully recruited households who were also successfully retained into the panel so that they were potentially eligible for participation in the present study, and the aforementioned 51.2% completion rate among successfully recruited and retained AmeriSpeak panelists who were approached for this particular study. Each AmeriSpeak respondent was assigned a base, nonresponse-adjusted sampling weight, which was then ranked to external population totals associated with age, sex, educational level, race/ethnicity, housing tenure, telephone status, and census division using iterative proportional fitting to improve external validity. To increase precision of estimates when data were scarce, such as for the prevalence of rare allergies within specific age groups, and ensure sufficient sample size among key subpopulations, prevalence estimates calculated from population-weighted AmeriSpeak responses were augmented by calibration-weighted, non–probability-based responses obtained through the SSI Dynamix platform.[18] SSI is a leading survey research organization with a diverse and large web-based panel of potential participants, who were sampled for the present study using methods designed to minimize self-selection bias. State-of-the-art small-area estimation methods were used, which leverage similarity and borrow strength across all available information in both samples to minimize the bias and variance of resulting estimates to a greater degree than independent analysis of either sample permitted.[19] These methods are frequently used by census bureaus and national survey research organizations because of their efficiency and effectiveness.[20,21] The final, combined sample weight was derived by applying an optimal composition factor that minimizes the mean square error associated with food allergy prevalence estimates. In total, surveys were completed by 40 443 US adults, each of whom received $5 on survey completion.

Statistical Analysis

Complex survey weighted proportions and 95% CIs were calculated to estimate prevalence using the svy: tabulate command using the "ci" and "per" options in Stata statistical software, version 14 (StataCorp).[22] Relative proportions of demographic characteristics were compared using weighted Pearson χ^2 statistics, which were corrected for the complex survey design with the second-order correction of Rao and Scott[23] and converted into *F* statistics. Covariate-adjusted complex survey weighted logistic regression models compared relative prevalence and other assessed food allergy outcomes by participant characteristics. Two-sided hypothesis tests were used, with 2-sided $P < .05$ considered to be statistically significant.

Results

Demographics, Food Allergy Prevalence, and Childhood vs Adult-Onset Allergies

Surveys were completed by 40 443 adults (7210 from the AmeriSpeak panel and 33 233 from the SSI panel; mean [SD] age, 46.6 [20.2] years). As anticipated, the observed completion rate was higher among the probability-based AmeriSpeak panel (51.2% of invited adults) compared with the non–probability-based SSI panel (5.5% of invited adults). The weighted distributions of respondents

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by age, sex, and race/ethnicity (eTable 1 in the Supplement) were consistent with 2016 estimates from the US Census Bureau's Current Population Survey.[24]

Overall, 10.8% (95% CI, 10.4%-11.1%) of US adults were estimated to have 1 or more current convincing food allergies. However, an estimated 19.0% (95% CI, 18.5%-19.5%) of US adults reported at least 1 convincing or nonconvincing FA. (**Table 1**). Among all adults with convincing food allergy, 48.0% (95% CI, 46.2%-49.7%) reported developing at least 1 of their convincing food allergies as an adult, whereas 26.9% (95% CI, 25.3%-28.6%) developed convincing food allergy only during adulthood and 52.0% (95% CI, 50.3%-53.8%) developed convincing food allergy only before 18 years of age.

Table 1. Estimated Current FA Prevalence Rates Among US Adults

Variable	Prevalence of Current FA, % (95% CI)	*P* Value	Prevalence of Adult-Onset Current FA, % (95% CI)	*P* Value
Overall	10.8 (10.4-11.1)	NA	5.2 (4.9-5.4)	NA
Race/ethnicity				
Asian, non-Hispanic	11.4 (9.8-13.3)	<.001	4.8 (3.8-6.1)	<.001
Black, non-Hispanic	11.2 (10.2-12.3)		5.1 (4.4-5.9)	
White, non-Hispanic	10.1 (9.7-10.6)		5.2 (4.9-5.5)	
Hispanic	11.6 (10.5-12.8)		4.6 (3.9-5.4)	
Multiple or other	15.9 (13.6-18.6)		7.2 (5.8-9.0)	
Sex				
Male	7.5 (7.0-7.9)	<.001	3.0 (2.7-3.3)	<.001
Female	13.8 (13.3-14.4)		7.2 (6.8-7.7)	
Age, y				
18-29	11.3 (10.5-12.2)	.002	2.7 (2.4-3.2)	<.001
30-39	12.7 (11.8-13.7)		5.5 (4.8-6.1)	
40-49	10.0 (9.2-10.9)		5.1 (5.0-5.7)	
50-59	11.9 (11.0-12.8)		6.8 (6.1-7.6)	
≥60	8.8 (8.2-9.4)		5.9 (5.4-6.4)	
Household income, US$				
<25 000	10.6 (9.8-11.5)	.002	4.9 (4.4-5.5)	.57
25 000-49 999	10.9 (10.2-11.6)		5.5 (5.0-6.1)	
50 000-99 999	11.6 (11.0-12.3)		5.6 (5.1-6.1)	
100 000-149 000	10.5 (9.6-11.5)		5.0 (4.3-5.7)	
≥150 000	8.8 (7.7-10.0)		4.0 (3.3-5.7)	
Born in the United States				
Yes	10.8 (10.5-11.2)	.37	5.1 (4.9-5.4)	.06
No	10.2 (8.9-11.6)		5.5 (4.6-6.7)	
Census region				
West	11.5 (10.7-12.3)	.07	5.4 (4.9-6.0)	.43
Midwest	10.3 (9.6-11.0)		4.9 (4.4-5.4)	
South	10.4 (9.9-11.0)		5.0 (4.7-5.5)	
Northeast	11.2 (10.3-12.2)		5.5 (4.8-6.3)	
Physician-diagnosed comorbid conditions				
Asthma	20.9 (19.5-22.3)	<.001	9.9 (9.0-10.9)	.77
Atopic dermatitis or eczema	19.2 (17.4-21.1)	<.001	9.0 (7.8-10.4)	.66
Environmental allergies	17.2 (16.3-18.2)	<.001	10.0 (9.3-10.8)	<.001
Insect sting allergy	22.9 (20.5-25.6)	<.001	13.4 (11.5-15.6)	<.001
Latex allergy	28.8 (25.5-32.3)	<.001	18.4 (15.6-21.5)	<.001
Medication allergy	18.5 (17.3-19.8)	<.001	11.3 (10.4-12.4)	<.001
Urticaria or chronic hives	27.8 (22.9-33.3)	<.001	18.8 (14.6-23.8)	<.001
Other chronic conditions	12.7 (11.4-14.2)	.003	7.5 (6.5-8.7)	<.001

Abbreviations: FA, food allergy; NA, not applicable.

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The 5 most common convincing food allergies reported among adults were shellfish (2.9%; 95% CI, 2.7%-3.1%), peanut (1.8%; 95% CI, 1.7%-1.9%), milk (1.9%; 95% CI, 1.8%-2.1%), tree nut (1.2%; 95% CI, 1.1%-1.3%), and fin fish (0.9%; 95% CI, 0.8%-1.0%) (**Table 2**). Multiple convincing food allergies were reported by 45.3% (95% CI, 43.6%-47.1%) of convincingly food-allergic adults (**Table 3**). Roughly half of adults with convincing food allergies reported having a physician-diagnosed convincing food allergy (47.5%; 95% CI, 45.8%-49.3%). Individuals with peanut allergy reported the highest rate of physician diagnosis (72.5% [95% CI, 68.9%-75.8%] of convincing peanut allergies).

Food Allergy Severity and Health Care Use

Among adults with 1 or more convincing food allergies, 51.1% (95% CI, 49.3%-52.9%) reported experiencing at least 1 severe food-allergic reaction (Table 3). A history of severe reactions was most commonly observed among participants with convincing peanut (67.8%; 95% CI, 64.2%-71.1%) and tree nut (61.3%; 95% CI, 56.6%-65.8%) allergies. Among adults with 1 or more convincing food allergies, 24.0% (95% CI, 22.6%-25.4%) reported a current epinephrine prescription and 38.3% (95% CI, 36.7%-40.0%) reported 1 or more lifetime food allergy–related ED visits. A total of 8.6% (95% CI, 7.7%-9.6%) of convincingly food-allergic adults reported 1 or more food allergy–related ED visit within the past year.

Factors Associated With Food Allergies and Related Conditions

Adjusted associations from multiple logistic regression models estimating odds of convincing food allergy and food allergy characteristics are presented in eTable 2 in the Supplement. Significant differences in convincing food allergy prevalence were observed by race/ethnicity, with higher rates among groups other than white compared with white adults. Rates of convincing food allergy were higher among females (13.8%; 95% CI, 13.3%-14.4%) compared with males (7.5%; 95% CI, 7.0%-7.9%). Compared with younger adults, individuals aged 30 to 39 years had elevated rates of

Table 2. Overall and Age-Specific Prevalence of Specific Food Allergies Among All US Adults

	Prevalence, % (95% CI)					
Specific Food Allergy	All Ages	18-29 y	30-39 y	40-49 y	50-59 y	≥60 y
Any food allergy	10.8 (10.4-11.1)	11.3 (10.5-12.2)	12.7 (11.8-13.7)	10.0 (9.2-10.9)	11.9 (11.0-12.8)	8.8 (8.2-9.4)
Peanut	1.8 (1.7-1.9)	2.5 (2.2-2.8)	2.9 (2.5-3.3)	1.8 (1.5-2.1)	1.4 (1.1-1.7)	0.8 (0.7-1.0)
Tree nut	1.2 (1.1-1.3)	1.6 (1.3-1.9)	1.7 (1.4-2.1)	1.1 (0.9-1.4)	1.2 (0.9-1.5)	0.6 (0.4-0.7)
Walnut	0.6 (0.6-0.7)	0.8 (0.7-1.1)	0.9 (0.7-1.3)	0.6 (0.5-0.8)	0.7 (0.5-0.9)	0.3 (0.2-0.4)
Almond	0.7 (0.6-0.8)	0.9 (0.7-1.2)	1.0 (0.7-1.3)	0.7 (0.6-1.0)	0.7 (0.5-0.9)	0.3 (0.2-0.4)
Hazelnut	0.6 (0.5-0.7)	0.7 (0.5-0.9)	0.9 (0.6-1.2)	0.6 (0.4-0.8)	0.6 (0.4-0.8)	0.3 (0.2-0.4)
Pecan	0.5 (0.5-0.6)	0.6 (0.5-0.8)	0.8 (0.5-1.1)	0.6 (0.5-0.8)	0.5 (0.4-0.8)	0.5 (0.4-0.8)
Cashew	0.5 (0.5-0.6)	0.8 (0.6-1.0)	0.8 (0.6-1.1)	0.5 (0.4-0.7)	0.5 (0.3-0.7)	0.2 (0.1-0.3)
Pistachio	0.4 (0.3-0.5)	0.6 (0.4-0.8)	0.6 (0.4-0.8)	0.5 (0.3-0.6)	0.4 (0.3-0.6)	0.1 (0.1-0.2)
Other tree nut	0.2 (0.1-0.2)	0.1 (0.1-0.2)	0.1 (0.0-0.2)	0.3 (0.2-0.6)	0.2 (0.1-0.5)	0.1 (0.1-0.2)
Milk	1.9 (1.8-2.1)	2.4 (2.0-2.9)	2.3 (1.9-2.8)	2.0 (1.6-2.4)	1.9 (1.6-2.2)	1.9 (1.6-2.2)
Shellfish	2.9 (2.7-3.1)	2.8 (2.4-3.2)	3.6 (3.1-4.2)	2.5 (2.2-3.0)	3.3 (2.8-3.8)	2.6 (2.2-3.0)
Shrimp	1.9 (1.8-2.1)	1.8 (1.5-2.1)	2.5 (2.1-3.0)	1.8 (1.4-2.1)	2.2 (1.8-2.6)	1.6 (1.3-1.9)
Lobster	1.3 (1.2-1.4)	1.2 (1.0-1.5)	1.6 (1.3-2.0)	1.3 (1.0-1.5)	1.4 (1.1-1.7)	1.1 (0.9-1.3)
Crab	1.3 (1.2-1.5)	1.2 (1.0-1.5)	1.6 (1.3-2.0)	1.3 (1.0-1.6)	1.6 (1.3-2.0)	1.1 (0.9-1.4)
Mollusk	1.6 (1.4-1.7)	1.6 (1.3-2.0)	2.0 (1.7-2.5)	1.3 (1.1-1.7)	1.7 (1.4-2.0)	1.2 (1.0-1.5)
Other shellfish	0.3 (0.2-0.3)	0.3 (0.1-0.5)	0.1 (0.1-0.2)	0.3 (0.2-0.4)	0.3 (0.2-0.5)	0.3 (0.2-0.4)
Egg	0.8 (0.7-0.9)	1.1 (0.7-1.5)	1.1 (0.9-1.3)	0.7 (0.5-0.9)	0.8 (0.6-1.1)	0.5 (0.3-0.7)
Fin fish	0.9 (0.8-1.0)	1.1 (0.9-1.4)	1.0 (0.8-1.2)	0.8 (0.6-1.1)	1.0 (0.7-1.3)	0.6 (0.4-0.7)
Wheat	0.8 (0.7-0.9)	1.0 (0.7-1.3)	1.0 (0.8-1.3)	0.8 (0.6-1.0)	0.7 (0.5-0.9)	0.6 (0.4-0.8)
Soy	0.6 (0.5-0.7)	0.7 (0.5-0.9)	0.8 (0.6-1.0)	0.6 (0.5-0.8)	0.7 (0.5-0.9)	0.4 (0.3-0.6)
Sesame	0.2 (0.2-0.3)	0.3 (0.2-0.4)	0.3 (0.2-0.5)	0.2 (0.1-0.4)	0.3 (0.2-0.5)	0.1 (0.0-0.2)

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convincing food allergy (12.7%; 95% CI, 11.8%-13.7%), whereas rates were lower for those 60 years or older (8.8%; 95% CI, 8.2%-9.4%). In adjusted models, each assessed chronic atopic comorbidity, including asthma, eczema, allergic rhinitis, urticaria, and latex allergy, was significantly associated with increased odds of convincing food allergy (**Figure 2**).

Adults were more likely to have a physician-diagnosed convincing food allergy if they earned $25 000 or more annually compared with those earning less than $25 000. Having multiple convincing food allergies, a current epinephrine prescription, a history of 1 or more lifetime food allergy–related ED visits, a severe reaction history, comorbid allergic rhinitis, or latex allergies were each associated with increased odds of having 1 or more physician-diagnosed convincing food allergy. When examining factors related to a severe food allergy reaction history, convincingly food-allergic adults older than 50 years had significantly decreased risk of severe food allergy compared with younger adults, whereas black adults (odds ratio [OR], 1.4; 95% CI, 1.1-1.7) and adults with comorbid asthma (OR, 1.4; 95% CI,1.1-1.6) or allergic rhinitis (OR, 1.3; 95% CI, 1.1-1.5) were at increased risk for severe food allergy.

Factors Associated With Epinephrine Prescription and ED Visits

eTable 3 in the Supplement reports factors associated with having a current epinephrine prescription, reporting 1 or more lifetime food allergy–related ED visits, and reporting 1 or more food allergy–related ED visits within the past year. Adults reporting 1 or more lifetime ED visits (OR, 3.2; 95% CI, 2.6-3.9) or severe food allergy (OR, 1.5; 95% CI, 1.2-1.8) had elevated odds of having a current epinephrine prescription, as did adults with peanut (OR, 2.4; 95% CI, 1.9-3.1), tree nut (OR, 3.3; 95%

Table 3. Allergen-Specific FA Characteristics and Health Care Utilization Among Adults With Convincing FA

	Prevalence, % (95% CI)[a]						
Specific FA	Severe Reaction	Adult-Onset FA	Multiple FAs	Physician Diagnosed	Current Epinephrine Prescription	Lifetime History of FA-Related ED Visits	Past 12-mo History of FA-Related ED Visits
All allergens	51.1 (49.3-52.9)	48.0 (46.2-49.7)	45.3 (43.6-47.1)	47.5 (45.8-49.3)	24.0 (22.6-25.4)	38.3 (36.7-40.0)	8.6 (7.7-9.6)
Peanut	67.8 (64.2-71.1)	17.5 (14.8-20.7)	67.8 (64.1-71.3)	72.5 (68.9-75.8)	53.8 (49.9-57.6)	62.3 (58.6-65.9)	19.8 (17.1-22.9)
Tree nut	61.3 (56.6-65.8)	34.6 (30.1-39.4)	90.4 (87.5-92.6)	61.4 (56.6-65.9)	51.5 (46.7-56.2)	54.3 (49.5-59.0)	19.2 (15.6-23.5)
Walnut	51.1 (44.6-57.6)	26.6 (20.8-33.2)	95.1 (92.2-97.0)	53.3 (46.7-59.7)	51.0 (44.5-57.5)	57.0 (50.5-63.4)	18.7 (13.5-25.4)
Almond	57.2 (50.8-63.3)	26.7 (21.4-32.8)	95.7 (92.8-97.5)	63.0 (56.6-69.0)	55.3 (48.7-61.8)	60.7 (54.5-66.7)	24.5 (19.1-30.9)
Hazelnut	55.1 (47.8-62.2)	25.9 (19.8-33.0)	96.2 (92.2-98.2)	58.0 (50.8-64.9)	54.0 (46.6-61.3)	60.6 (53.4-67.3)	19.7 (14.0-26.9)
Pecan	51.4 (44.0-58.6)	29.5 (22.7-37.4)	100	53.2 (45.8-60.4)	56.3 (48.7-63.6)	56.3 (48.9-63.5)	20.1 (14.4-27.3)
Cashew	50.6 (43.6-57.5)	27.7 (21.3-35.2)	96.3 (93.1-98.0)	57.1 (50.2-63.8)	59.3 (52.1-66.1)	58.4 (51.5-65.0)	21.4 (15.7-28.4)
Pistachio	49.6 (41.5-57.7)	28.1 (21.7-35.6)	97.0 (93.9-98.6)	57.9 (49.9-65.5)	56.8 (48.2-65.0)	63.4 (55.7-70.5)	20.9 (14.3-29.6)
Other tree nut	59.7 (44.6-73.1)	30.9 (19.0-46.1)	80.8 (65.7-90.3)	43.0 (29.1-58.1)	52.7 (37.8-67.1)	43.9 (29.7-59.1)	4.5 (1.6-11.7)
Milk	39.3 (35.2-43.5)	22.7 (19.6-26.3)	60.1 (55.9-64.2)	47.1 (43.0-51.3)	24.0 (20.9-27.5)	47.0 (42.8-51.1)	12.0 (9.9-14.4)
Shellfish	56.8 (53.4-60.1)	48.2 (44.8-51.6)	69.9 (66.5-73.2)	42.1 (39.0-45.4)	27.4 (24.7-30.3)	45.3 (42.0-48.7)	11.1 (9.0-13.5)
Shrimp	56.6 (52.6-60.5)	37.2 (33.3-41.3)	76.1 (72.1-79.7)	42.6 (38.8-46.5)	29.8 (26.5-33.4)	47.7 (43.8-51.7)	10.6 (8.6-13.0)
Lobster	48.3 (43.5-53.1)	40.5 (35.8-45.5)	94.1 (91.3-96.1)	35.9 (31.5-40.5)	32.8 (28.6-37.4)	53.0 (48.2-57.8)	12.5 (9.6-16.1)
Crab	48.9 (44.2-53.5)	40.0 (35.4-44.7)	89.7 (86.1-92.4)	35.1 (30.9-39.5)	32.8 (28.7-37.2)	51.9 (47.2-56.6)	11.3 (8.6-14.7)
Mollusk	47.0 (42.4-51.6)	39.2 (34.7-43.8)	81.0 (76.5-84.8)	33.1 (29.2-37.2)	30.3 (26.4-34.5)	50.8 (46.2-55.4)	12.4 (9.3-16.4)
Other shellfish	60.1 (49.6-69.7)	39.2 (29.3-50.0)	89.8 (80.2-95.1)	28.8 (19.9-39.7)	35.9 (25.9-47.4)	50.9 (40.0-61.6)	10.7 (4.6-22.7)
Egg	39.4 (32.8-46.5)	29.0 (23.2-35.6)	65.6 (58.3-72.1)	52.1 (45.1-59.0)	34.0 (28.5-40.0)	55.0 (47.8-61.9)	22.4 (17.6-28.0)
Fin fish	56.5 (51.0-61.7)	39.9 (34.7-45.4)	89.8 (86.2-92.5)	40.9 (35.7-46.3)	37.2 (32.1-42.6)	60.1 (54.7-65.3)	19.9 (15.9-24.7)
Wheat	42.6 (36.2-49.3)	52.6 (46.1-59.0)	68.3 (61.8-74.1)	55.5 (48.9-61.9)	24.6 (20.0-29.9)	43.6 (37.3-50.1)	14.9 (11.1-19.8)
Soy	45.4 (38.9-52.2)	45.4 (38.8-52.2)	81.2 (75.4-85.9)	48.5 (41.9-55.2)	37.3 (31.4-43.6)	48.3 (41.7-55.1)	18.2 (13.6-23.9)
Sesame	39.7 (30.3-49.9)	25.7 (18.1-35.1)	80.3 (67.5-88.9)	37.7 (28.7-47.6)	61.6 (51.3-70.9)	66.2 (54.6-76.2)	31.5 (23.1-41.5)

Abbreviations: ED, emergency department; FA, food allergy.

[a] All columns represent frequency with a denominator of all those with convincing FA to each specified food.

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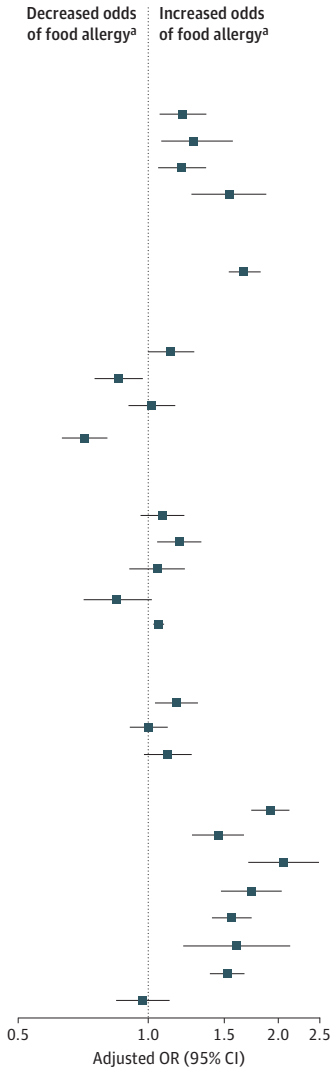
CI, 2.0-5.3), sesame (OR, 3.0; 95% CI, 1.4-6.2), or soy allergy (OR, 1.5; 95% CI, 1.0-2.1) or a comorbid insect sting allergy (OR, 2.0; 95% CI, 1.4-2.9). Adults 50 years or older also had significantly reduced odds of a current epinephrine prescription. Current epinephrine prescription rates varied considerably by food allergy type, with the highest rates observed among adults with sesame (61.6%), peanut (53.8%), or tree nut allergy (51.5%). With respect to lifetime ED visits, adults with multiple food allergies (OR, 1.2; 95% CI, 1.0-1.5), severe food allergy (OR, 1.9; 95% CI, 1.6-2.3), childhood-onset food allergy only (OR, 1.7; 95% CI, 1.4-2.0), a current epinephrine prescription (OR, 3.2; 95% CI, 2.6-3.9), or comorbid asthma (OR, 1.3; 95% CI, 1.0-1.5) had significantly elevated odds of 1 or more food allergy–related ED visits, as did Hispanics and adults earning less than $25 000 per year.

Discussion

The present population-weighted data revealed that an estimated 10.8% of US adults had at least 1 current food allergy during the study period (corresponding to >26 million US adults), whereas 19.0% of adults believed that they were food allergic. These data suggest that there are currently at least 13 million food-allergic adults who have experienced at least 1 severe food-allergic reaction, at least 10

Figure 2. Factors Associated With Current Food Allergy

Factor	Adjusted OR (95% CI)
Race/ethnicity	
White, non-Hispanic[b]	1 [Reference]
Black, non-Hispanic	1.20 (1.06-1.36)
Asian, non-Hispanic	1.28 (1.06-1.54)
Hispanic	1.20 (1.06-1.36)
Multiple/other	1.54 (1.26-1.88)
Sex	
Male[b]	1 [Reference]
Female	1.67 (1.54-1.82)
Age, y	
18-29[b]	1 [Reference]
30-39	1.13 (1.00-1.28)
40-49	0.85 (0.75-0.97)
50-59	1.02 (0.90-1.16)
≥60	0.71 (0.63-0.80)
Income, US$	
<25 000[b]	1 [Reference]
25 000-49 000	1.08 (0.96-1.21)
50 000-99 000	1.18 (1.05-1.33)
100 000-149 000	1.05 (0.90-1.22)
≥150 000	0.85 (0.71-1.02)
Education[c]	1.06 (1.03-1.09)
Census region	
Midwest[b]	1 [Reference]
West	1.16 (1.04-1.30)
South	1.00 (0.91-1.11)
Northeast	1.11 (0.98-1.26)
Comorbidity[d]	
Asthma	1.92 (1.73-2.12)
Eczema	1.45 (1.26-1.67)
Latex allergy	2.06 (1.70-2.48)
Sting/venom allergy	1.73 (1.47-2.04)
Medication allergy	1.56 (1.40-1.74)
Urticaria	1.60 (1.20-2.13)
Allergic rhinitis	1.52 (1.39-1.67)
Other	0.97 (0.84-1.12)



Each square represents the odds ratio (OR) point estimate for each corresponding variable or sample characteristic, adjusting for all other variables in the logistic regression model. Each horizontal line represents the 95% CI. Percentages of all adults in each subgroup and adults with current food allergies in each subgroup are given in eTable 1 in the Supplement.

[a] Compared with the reference group.

[b] Reference group.

[c] Educational attainment was modeled as a continuous variable with the following 7 categories: less than high school, high school, some college, associates, bachelors, masters, and professional or doctorate.

[d] The reference group for each comorbid condition is the absence of that condition.

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million adults who have received food allergy treatment in the ED, and at least 12 million adults with adult-onset food allergy.

This overall estimate of adult food allergy prevalence falls between the 10% estimated from 2007-2010 National Health and Nutrition Examination Survey data by McGowan and Keet[9] and estimates reported by Verrill et al[10] from 2010 FDA Food Safety Survey data, who reported an overall adult food allergy prevalence of 13% and physician-diagnosed food allergy prevalence of 6.5%. However, neither of these previous surveys collected data on reaction symptoms that could be used to identify adults reporting food allergies that are unlikely to be IgE mediated. Given that the most prevalent allergies observed were shellfish and peanut, which prior pediatric work suggests are infrequently outgrown,[25] this finding suggests that the population-level burden of food allergy is likely to increase in the future, absent widespread implementation of effective prevention efforts and/or therapies. Of interest, the current data suggest that shellfish allergy may be a particularly enduring allergy among adults. For example, estimated shellfish allergy prevalence was 2.8% among individuals aged 18 to 29 years and 2.6% among those 60 years or older, a lower rate of decrease across the life span than observed for other food allergies. These relatively high rates of shellfish allergy across the life span, including adult-onset shellfish allergies, require further investigation. Whether these high rates are attributable to different underlying pathophysiological mechanisms among shellfish-allergic patients, greater awareness of shellfish allergy, and/or additional factors remains to be seen and is the subject of ongoing research. Shellfish has long been acknowledged as a persistent allergy,[8,26,27] although adult cohort studies are needed to more definitively establish its natural history.

Among US adults, our data revealed that the burden of shellfish allergy was greatest, affecting an estimated 7.2 million US adults. Milk (affecting an estimated 4.7 million adults), peanut (4.5 million), tree nut (3.0 million), fin fish (2.2 million), egg (2.0 million), wheat (2.0 million), soy (1.5 million), and sesame (0.5 million) were the next most common food allergies.

As summarized in a recent review,[28] racial/ethnic disparities in allergic diseases, such as asthma[29] and eczema,[30] are well established, and data suggest that the burden of child food allergy may also be greater among the population of races/ethnicities other than white, non-Hispanic.[17] However, much less is known about such disparities in adult food allergy. The current data showed that food allergy rates were significantly higher among adults other than white, even after adjustment for income, educational level, numerous physician-diagnosed atopic conditions, and other covariates. These findings are consistent with findings from our previous population-based study[8,17] of child food allergy prevalence, which also found elevated rates of food allergy in non-Hispanic black and Asian children. Although previous examinations of food allergy disparities have largely contrasted sensitization and estimated prevalence rates between non-Hispanic black and white populations,[31,32] the present findings suggest that the scope of future work examining food allergy disparities should be expanded to further investigate racial/ethnic differences among Hispanic adults. In the current study, Hispanic adults were estimated to have comparable rates of food allergy to non-Hispanic black adults, as well as the highest rates of food allergy–related ED visits among all racial groups, despite reporting epinephrine prescription rates comparable to those of white adults.

Clinical food allergy management guidelines recommend intramuscular epinephrine as first-line treatment for food-induced anaphylaxis.[33] All patients diagnosed with a food allergy should be prescribed epinephrine because of the inability to accurately and reliably estimate the severity of future allergic reactions.[34,35] Our data suggest that approximately one-quarter of adults with food allergy possess a current epinephrine prescription, with higher rates among adults reporting a history of severe reactions and lifetime food allergy–related ED visits. These overall rates of epinephrine prescription are comparable to the 23% of peanut- and tree nut–allergic adults reporting an epinephrine prescription in a 2002 prevalence study.[36] However, further analyses suggest that a substantial proportion of adults with food allergy who may be at elevated risk of anaphylaxis do not report having a current epinephrine prescription. For instance, among adults with 1 or more severe,

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physician-diagnosed food allergies who reported at least 1 food allergy–related ED visit in the past year, only 65% reported a current epinephrine prescription. These low rates of epinephrine possession are particularly notable given that nearly 40% of food-allergic adults reported at least 1 lifetime food allergy–related ED visit and more than half reported a history of 1 or more severe food-allergic reactions.

The high rate of severe reactions in our study compared with previous literature[17] is consistent with findings from multiple studies[37-39] showing an association of increased age with more severe allergic reaction symptoms. However, it is also possible that the higher proportion of adults reporting severe reactions is a function of adults' greater cumulative lifetime risk. This idea is supported by the slightly reduced rates of severe reactions and ED visits observed among adults reporting adult-onset food allergy in the present study. More specifically, the significantly elevated odds of severe food allergy observed among adults with comorbid allergic rhinitis extends findings from a large case series where a marked increase in food-induced severe pharyngeal edema was observed among peanut- and tree nut–allergic patients with comorbid allergic rhinitis.[40] Although less than 10% of food-allergic adults reported a food allergy–related ED visit within the past year, this figure increased to 32% among sesame-allergic adults, who also reported the highest epinephrine possession rates in the cohort (62% vs 24% overall). Patients with comorbid asthma were also at increased risk of food allergy–related ED visits, which is consistent with previous work that found an association of asthma with increased anaphylaxis risk.[41]

Adult-onset food allergies are an important emerging health problem. A recent analysis[13] of electronic health record data collected from a network of Chicago-area clinics concluded that although shellfish, tree nut, and fin fish allergies were the most common adult-onset food allergies, it appears to be possible to develop adult-onset food allergies to all major food allergen groups. In the current study, adult-onset allergies were observed to every assessed food. After wheat, the most common adult-onset allergies in our sample were shellfish, soy, tree nut, and fin fish, which were the top 4 allergies identified by Kamdar et al.[13] Furthermore, the observed rates of adult-onset shellfish and fin fish allergy in our sample are not dissimilar to the rates of 60% and 40%, respectively, observed by Sicherer et al[8] more than a decade ago. The most common childhood-onset allergy was peanut, which underlines the importance of early-life primary prevention efforts, such as the targeted early introduction practices advocated by the recent Addendum Guidelines for the Prevention of Peanut Allergy in the United States.[42]

In light of the considerable economic[1] and quality of life[3] consequences associated with allergen avoidance and other food allergy management behaviors, individuals with a suspected food allergy should receive appropriate confirmatory testing and counseling to counter unnecessary avoidance of allergenic food. Greater patient education efforts regarding key differences between food intolerances and allergies also may be warranted.[43] Furthermore, the results of our study suggest that adults need to be encouraged to see their physicians to receive proper diagnosis, epinephrine prescription, and counseling for their food allergy. Given the increasing evidence for the preventive benefits of early allergen exposure during infancy and potential treatment options, adults should be made aware of these new practices to potentially prevent food allergies in their children or consider treatments in the near future.

Limitations

Although double-blinded, placebo-controlled oral food challenges remain the criterion standard for food allergy diagnosis, such methods were not used to confirm self-reported food allergy in the present study because of their expense and impracticality with such a large nationally representative sample and concerns about nonparticipation bias. However, similar to past work,[7] to strengthen the rigor of our self-report questionnaire, stringent criteria were established in collaboration with an expert panel to exclude food allergies for which corresponding symptom report was not consistent with an IgE-mediated food allergy. Nevertheless, given the self-report paradigm used in the present study, bias remains a concern.

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Conclusions

These data suggest that at least 1 in 10 US adults are food allergic. However, they also suggest that nearly 1 in 5 adults believe themselves to be food allergic, whereas only 1 in 20 are estimated to have a physician-diagnosed food allergy. Overall, approximately half of all food-allergic adults developed at least 1 adult-onset allergy, suggesting that adult-onset allergy is common in the United States among adults of all ages, to a wide variety of allergens, and among adults with and without additional, childhood-onset allergies.

ARTICLE INFORMATION

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Author Contributions: Dr Gupta had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Gupta, Warren, Smith, Jiang, Blumenstock, Nadeau.

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Supervision: Gupta, Smith, Nadeau.

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SUPPLEMENT.

eMethods. Dual-Sample Complex Survey Sampling and Weighting Methodology

eFigure. List of Allergic Reaction Symptoms Highlighting Stringent Symptoms Indicative of Convincing Food Allergy

eTable 1. Demographic Distribution of Sample, Food-Allergic Adults, Adult- and Childhood-Onset Allergies [Frequency % (95% CI)]

eTable 2. Demographic and Allergic Characteristics Associated With Convincing, Physician-Diagnosed, Adult-Onset, Severe, and Multiple Food Allergies, Adjusted Odds Ratio (95% CI)

eTable 3. Demographic and Allergic Characteristics Associated With Epinephrine Prescription, Lifetime ED Visits, Last Year ED Visits, Adjusted Odds Ratio (95% CI)

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Attachment 8 – FDA 2023 CFP Issue on Allergen Cross Contact - Reference #8 Sharma et al

8. Sharma, G., Ma. Y. and Luccioli. (2022). P3-08 Food Allergen and Gluten Associated Recalls of FDA Regulated Foods from October 2012 to September 2019. In: International Association of Food Protection; July 31- August 3. Pittsburgh, PA. https://www.foodprotection.org/upl/downloads/meeting/archive/63052f3cd9f5354e6afef.pdf

P3-08 Food Allergen and Gluten Associated Recalls of FDA-Regulated Foods from October 2012 to September 2019

Girdhari Sharma, Yinqing Ma and Stefano Luccioli *U.S. Food and Drug Administration, College Park, MD*

Introduction: Food allergens remain a major food safety hazard responsible for a high number of recalls every year.

Purpose: To determine the trend of food allergen and gluten (FA/G) recalls over a 7-year period and study associated root causes.

Methods: Recalls related to FA/G during fiscal year 2013-2019 were queried in the FDA's recall database. Wheat related recalls were categorized as gluten recall if they involved gluten-free products. Recall information was analyzed to study recall Class, number and type of allergens involved, associated food categories based on FDA Product Codes, and root cause.

Results: 1,705 recalls related to FA/G were identified with 1,471 unique recalls (including non-major food allergen and gluten recalls) analyzed after removing 234 downstream or related events. Among 1,471 recalls, 49.3% were Class I, 47.3% were Class II and 3.4% were Class III. Over the study period, the percentage of Class I recalls generally decreased while that of Class II recalls increased. FA/G recalls involved one (N=1,171; 79.6%), two (N=193; 13.1%) or multiple (N=107; 7.3%) allergens/gluten. Milk was the leading allergen identified in 531 recalls (36.1%), followed by soy (N=319; 21.7%) and tree nuts (N=305; 20.7%). Gluten caused 34 recalls (2.3%). For recalls involving one allergen/gluten, the majority (>60%) of recalls associated with egg, Crustacean shellfish, peanut and milk resulted in Class I recalls, whereas those associated with soy, wheat, gluten, fish and non-major food allergens resulted in Class II recalls. Among FA/G recalls that involved one product category (N=1,427), Bakery Products/Dough/Bakery Mixes/Icings (N=370; 25.9%) ranked first, followed by Chocolate/Cocoa Products (N=123; 8.6%) and Multiple Food Dinners/Gravies/Sauces/Specialties (N=117; 8.2%). Labeling associated errors were the leading cause of FA/G recalls.

Significance: Recall trend analysis and root cause evaluation can identify major areas of concern and potential corrective actions that can be implemented by the industry to reduce future FA/G recalls.

Please consider the following website as a resource: **FARE Responds to Companies Intentionally Adding Sesame Flour as FASTER Act Goes into Effect:**

https://www.foodallergy.org/resources/fare-responds-companies-intentionally-adding-sesame-flour-faster-act-goes-effect

Allergic Living

Bread Suppliers ‘Adding Sesame’ as Seed Becomes Top Allergen

By: **Wendy Mondello** in **Food Allergy**, **Food Allergy News**, **Soy & Seed**

Published: **December 20, 2022**

A growing number of U.S. commercial bakeries are intentionally adding sesame to some breads and baked goods, then labeling sesame as an ingredient.

These additions just barely precede a new law coming into effect that makes sesame the ninth top allergen in the United States. The new practice is eliciting frustration and concern in the food allergy community.

The FASTER Act is meant to make food safer for Americans who are allergic to sesame. Under the law, which takes effect January 1, 2023, the FDA requires sesame to be clearly labeled on food packaging in plain language.

But news that baking industry companies and restaurants, such as Chick-fil-A and Pan-O-Gold, are instead adding a small amount of sesame to their products, in light of the new requirements, are “horrendous,” says Jason Linde of the nonprofit FARE. He says these businesses “chose to turn their backs on the approximately 1.6 million Americans with sesame allergy.”

Photo: Getty

“We are disappointed and frustrated that previously trusted companies would rather add small amounts of sesame flour to their bakery products than comply with the intent of the FASTER Act, clean their lines, and safely feed members of our community,” said Linde, FARE’s senior vice president, government and community affairs.

Allergic Living reached out to several restaurant chains and baking suppliers to learn more about sudden sesame flour additions. We’ve discovered the practice is widespread and growing. As well, we reached out to the FDA, which enforces food allergy labeling.

“While a practice of adding sesame and then declaring it on the label is not violative, it would make it more difficult for sesame allergic consumers to find foods that are safe for them to consume,” an FDA spokesperson said in an email. This is “a result the FDA does not support,” the spokesperson said.

Adding Sesame: What Chick-fil-A Says

Chick-fil-A alerted customers on its website that the new law led to a recipe change, so its white bun and multigrain brioche now include sesame as an ingredient. (One flat bread and one wrap have always contained it, the company states.)

A Chick-fil-A spokesperson says the fast-food chain learned from its bread suppliers of the change to include sesame in recipes. This occurred because the suppliers could not guarantee their production lines are sesame-free.

“Food safety and quality are our top priorities. We take great care in adhering to stringent food safety procedures,” the spokesperson told Allergic Living. “Chick-fil-A sources bread from multiple suppliers across the country and due to the shared production lines in our supplier facilities and use of shared cooking and preparation areas, we cannot ensure that our menu items are sesame-free.”

Flowers Foods, which includes brands Nature’s Own, Canyon Bakehouse, Wonder, Sunbeam and Merita, is among those adding sesame flour (less than 2%). It has announced that all buns, rolls and hoagies will now have sesame. All loaves will include a “may contain” warning on packaging due to possible cross-contact. An exception is the brand Dave’s Killer Bread, which has sesame as an actual ingredient in its breads and bagels.

Canyon Bakehouse‘s breads, buns, bagels and English muffins from will continue to be sesame-free, according to a FARE ingredient alert.

Cross-contact with allergens during manufacturing can be a risk for severe reactions for people with food allergies, says Kenneth Mendez, president and CEO of the Asthma and Allergy Foundation of America (AAFA).

“However, instead of making changes to reduce this cross-contact risk, we are hearing reports about some companies intentionally adding sesame flour,” Mendez said. “We are concerned and disappointed that some companies are undermining the purpose of the FASTER Act.”

Impact on School Cafeteria Lunch

FARE and AAFA worked for years to lobby for and create the new food allergy legislation, along with the American Academy of Allergy Asthma & Immunology (AAAAI). FASTER (short for Food Allergy Safety, Treatment, Education, and Research) was signed into law on April 23, 2021. The act gave companies 18 months to comply with the requirements regarding sesame.

FARE's Linde says that grace period was plenty of time to make the changes to ensure baked goods that do not contain sesame are free of cross-contact, or to appropriately label on packaging. "They knew the law was coming, yet they still decided to take this short cut," he says.

The addition of sesame flour to products at restaurants and in retail will deprive many in the food allergy community of choices, he added.

Pan-O-Gold Baking Company, a supplier to retailers and schools primarily in the Midwest, has said it plans to add sesame flour to its bread and dough recipes, according to a petition on Change.org. The petition is an effort to change the strategy by the company, which supplies brands such as Country Hearth, Lakeland and Papa Pita.

It is especially problematic that suppliers to schools are adding sesame because students in the cafeteria might not be aware, Linde says. A student with a sesame allergy, who has always safely eaten a hamburger from the school cafeteria, could now potentially be exposed to sesame in the bun, he notes.

Bakers and Wendy's on Adding Sesame

Pan-O-Gold did not respond to Allergic Living's request for comment. It is one of more than 300 members of the American Bakers Association, the trade organization. We asked the association to comment on the sesame additions and whether there is an issue with sesame and cleaning production lines. Robb MacKie, the association's president and CEO replied, but simply addressed transparency.

"Baking companies are working with their customers, including restaurants, to transparently disclose any allergen labeling changes to help ensure consumer safety," said MacKie. Plus, he reminded allergic consumers to read labels carefully.

Those with sesame allergy should be aware: Olive Garden recently began adding sesame flour to its famous breadsticks. One news report says the company confirmed the addition relates to the new law and cross-contact risk.

Fast-food restaurant Wendy's also has menu items (French toast sticks, and premium and value buns) that now contain sesame flour, according to a statement a Wendy's spokesperson sent to Allergic Living. The company advises checking the brand's mobile app for up-to-date ingredient information for the evolving menu.

"We take food safety and allergen matters very seriously. Like others in the restaurant industry, Wendy's nutrition and allergen information was updated recently to include sesame, where applicable, in advance of the January 1, 2023 effective date of the Food Allergy Safety, Treatment, Education, and Research Act," Wendy's said.

Linde says that fast-food giants such as Wendy's and Chick-fil-A have purchasing power. He contends they could use that to tell the baking partners that they must keep sesame out of their products. "You lost the opportunity to do the right thing," he says. "It's frustrating and it hurts."

But Chick-fil-A's spokesperson counters that this is an industry-wide issue, and there are no sesame-free bread suppliers that could consistently supply Chick-fil-A's bread volumes.

Bright Spot: Package Labeling

Linde is thankful, though, that Chick-fil-A communicated the recipe change, so that food-allergic customers are aware of the presence of sesame.

Customers with a sesame allergy may prefer to order the chain's gluten-free bun, which does not contain a sesame ingredient. Bread products on the breakfast menu, including the tortilla, English muffin, mini yeast rolls and biscuit, are also free of sesame ingredients, the Chick-fil-A spokesperson says.

The move to add sesame flour in light of the FASTER Act is specific to bakers. Linde says food allergy families have been expressing concern and outrage to his nonprofit organization. "There is frustration. There was real hope and promise in the FASTER Act," he says.

According to Linde, there was no indication that companies might take this type of action during negotiations with industry members and lawmakers about the law.

Food allergy advocate Stacey Saiontz's 15-year-old son Jared is allergic to the seed. She finds it disappointing that more products will become off-limits due to companies adding sesame flour. "Sadly, this means that brands that had been safe for us are no longer safe," she says.

However, Saiontz is glad to avoid spending hours calling companies to find out if sesame is in many packaged foods. "We are still very excited that sesame will be labeled," Saiontz says.

The clear information on labels for products like salad dressings, crackers, granola bars, and sauces will still make this law a success for the allergy community, Linde says.

How to Proceed with Sesame Allergy

As of January 1, packaged food labels are required to clearly state if sesame is an ingredient. But the FASTER Act does not require products with a long shelf life that were distributed before 2023 to list sesame on the label.

During the transition period, the FDA recommends consumers proceed with caution and check with the manufacturer identified on the food product if uncertain whether a food product contains sesame.

Linde recommends being cautious with label reading for the first three to six months.

“It is critically important for food allergy consumers to continue to read every label every time and to inquire at restaurants and fast-food chains. Formerly safe foods may now contain sesame allergen,” says AAFA’s Mendez.

AAFA is eager to work with industry members, lawyers, the FDA and the food allergy community to improve allergen labeling and prevent “potentially harmful manufacturing practices,” Mendez says.

“We believe there is a workable solution with improved, regulated, and evidence-based precautionary allergy labeling that would ensure the safety of people with food allergy while eliminating manufacturers need to purposefully add a known allergen to reduce liability,” Mendez says.

FARE is raising concerns with the FDA about sesame flour being added to products in light of the new legislation, Linde says. However, potential legislative fixes, such as saying companies can’t add an allergen to products to comply, will take time, he says.

Related Reading:
FASTER Act Signed, Making Sesame Labeling the Law
Study Finds Sesame Allergy a Significant Health Risk
Is Someone with Peanut Allergy Likely to Develop Sesame Allergy?

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U.S.News & WORLD REPORT NEWS

Tough New Labeling Law for Sesame Prompts Companies to Add It to Their Products

By HealthDay

Dec. 22, 2022

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By Cara Murez [illegible]oster HealthDay Reporters

(HEALTHDAY)

THURSDAY, Dec. 22, 2022 (HealthDay News) -- Call it a good idea that seems to have backfired: A tough new labeling law that requires even the smallest amount of sesame be listed on food products has instead spurred some companies to add it to their products.

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The new federal law goes into effect on Jan. 1, adding sesame to the list of major allergens that must appear on food labels when they are present in the product. Allergens that have appeared on labels since 2004 are milk, eggs, fish, shellfish, tree nuts, peanuts, wheat and soybeans, the *Associated Press* reported.

Food allergen labeling advocates have sought to add sesame to the list of major allergens for years.

But the new requirements are so strict that it costs less to add sesame to food products than to try to keep it out of those aren't meant to contain it, the *AP* reported.

"It was really exciting as a policy advocate and a mom to get these labels," Naomi Seiler, a consultant with the Asthma and Allergy Foundation of America whose 9-year-old daughter, Zoe, is allergic to sesame, told the *AP*. "Instead, companies are intentionally adding the allergen to food."

To follow the law, companies must label foods that contain sesame or follow safety measures to keep it from getting into foods through shared equipment and supplies.

"It's as if we've suddenly asked bakers to go to the beach and remove all the sand," Nathan Mirdamadi, a consultant with Commercial Food Sanitation, which advises the industry about food safety, told the *AP.*

Some foods that contain sesame aren't surprising. It appears on top of hamburger buns, for example. Yet, it also is a hidden ingredient in items like sauces, dips, salad dressings, spices, ice cream and protein bars.

"Sesame is in so many things that people don't really understand," said Dr. Ruchi Gupta, director of the Center for Food Allergy & Asthma Research at Northwestern University. Gupta told the *AP* that the move to add sesame to products is "so disappointing."

"In families that do have a sesame allergy, it is truly challenging," she said.

Among the companies adding sesame to foods that didn't contain it before are Olive Garden restaurants, fast food eateries Wendy's and Chick-fil-A and United States Bakery's Franz products.

This isn't illegal, but it does run counter to the goals of the new law, the *AP* reported.

The U.S. Food and Drug Administration has said it "does not support" these changes, the *AP* added.

"It would make it more difficult for sesame-allergic customers to find foods that are safe for them to consume," the FDA statement said.

Cases of sesame allergy have been growing and now number more than 1.6 million people in the United States. In Canada, Europe, Australia and New Zealand, sesame has appeared on food labels for years, the *AP* reported.

More information

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Food Allergy Knowledge and Attitudes of Restaurant Managers and Staff: An EHS-Net Study

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Abstract

Dining outside of the home can be difficult for persons with food allergies who must rely on restaurant staff to properly prepare allergen-free meals. The purpose of this study was to understand and identify factors associated with food allergy knowledge and attitudes among restaurant managers, food workers, and servers. This study was conducted by the Environmental Health Specialists Network (EHS-Net), a collaborative forum of federal, state, and local environmental health specialists working to understand the environmental factors associated with food safety issues. EHS-Net personnel collected data from 278 randomly selected restaurants through interviews with restaurant managers, food workers, and servers. Results indicated that managers, food workers, and servers were generally knowledgeable and had positive attitudes about accommodating customers' food allergies. However, we identified important gaps, such as more than 10% of managers and staff believed that a person with a food allergy can safely consume a small amount of that allergen. Managers and staff also had lower confidence in their restaurant's ability to properly respond to a food allergy emergency. The knowledge and attitudes of all groups were higher at restaurants that had a specific person to answer food allergy questions and requests or a plan for answering questions from food allergic customers. However, food allergy training was not associated with knowledge in any of the groups but was associated with manager and server attitudes. Based on these findings, we encourage restaurants to be proactive by training staff about food allergies and creating plans and procedures to reduce the risk of a customer having a food allergic reaction.

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Keywords

Food allergies; Food allergy attitudes; Food allergy knowledge; Food safety; Restaurants

Food allergies are a growing public health and food safety concern affecting an estimated 15 million U.S. residents, including 1 in every 13 children (8). A food allergic reaction occurs when the immune system overreacts to the proteins in food (2). Currently, the only way to prevent a food allergic reaction is strict avoidance of the allergen (15). Eight foods are responsible for approximately 90% of all food allergic reactions in the United States: milk, eggs, fish, shellfish, wheat, tree nuts, peanuts, and soybeans (8). Symptoms of an allergic reaction range from mild skin rashes to severe, potentially life-threatening anaphylactic reactions (10). In the case of anaphylactic reactions, administration of epinephrine within minutes is crucial to survival (15). Food-related anaphylaxis is responsible for approximately 30,000 emergency room visits, 2,000 hospitalizations, and 150 deaths each year in the United States (13).

A significant number of food allergic reactions occur in restaurants. A survey at the 2007 Food Allergy & Anaphylaxis Network conference (14) found that 34% of the 294 respondents had experienced at least one food allergic reaction in a restaurant, and of those, 36% had experienced at least three reactions. Another study revealed that nearly half of fatal food allergic reactions over a 13-year period were caused by food from a restaurant or other food service establishment (15). An investigation of peanut and tree nut allergic reactions in restaurants or other food service establishments found that in 45% of these cases, the food allergic customers had alerted the restaurant to their allergy in advance (9). The same investigation revealed that in 78% of the episodes, someone in the establishment knew that the food contained the allergen as an ingredient.

Managers, food workers, and servers all play unique and crucial roles in preventing food allergic reactions in their restaurants. Managers can provide food allergy training for staff and develop plans for serving food allergic customers. Food workers can become educated about allergens and methods to ensure allergen-free food preparation. Servers can accurately describe menu items to the customer and alert the manager and kitchen staff to requests for allergen-free meals. Miscommunication between any of these groups can result in an unsafe meal being served (3). Benefits to restaurants that consistently provide safe meals to food allergic customers include preventing harm to their clientele, avoiding lawsuits, and gaining the loyal patronage of the food allergic community.

A key to preventing food allergic reactions in restaurants is understanding manager, food worker, and server food allergy knowledge, attitudes, and practices. Several studies have been conducted to examine these topics collectively (1, 3, 5, 6, 11, 12). However, the measures used in these studies have been limited with regard to food allergy attitudes and practices. All studies either included a regional or convenience sample (1, 6, 11) or were conducted outside of the United States (3, 5, 11, 12); thus, the generalizability of their results must be considered.

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In 2014, the Centers for Disease Control and Prevention's (CDC) Environmental Health Specialists Network (EHS-Net) conducted a study on restaurant manager and staff (food workers and servers) food allergy knowledge, attitudes, and practices. Our measures of knowledge, attitudes, and practices were comprehensive and were primarily based on the Food Allergy Research and Education guidance document "Welcoming Guests with Food Allergies" (7). EHS-Net also collected data in six demographically diverse sites, providing good geographic coverage of the United States (Northeast, South, Midwest, West). The goals of this study were threefold: (i) describe restaurant manager and staff food allergy knowledge, attitudes, and practices; (ii) compare knowledge, attitudes, and practices among managers and staff; and (iii) identify factors associated with food allergy knowledge, attitudes, and practices. This article primarily focuses on knowledge and attitudes. Complete practice data will be published at a later date.

MATERIALS AND METHODS

EHS-Net is a network of environmental health specialists and epidemiologists who conduct research designed to identify and understand environmental factors associated with foodborne illness outbreaks and other food safety issues. EHS-Net is a collaborative project of the CDC, the U.S. Food and Drug Administration, the U.S. Department of Agriculture, and state and local health departments. At the time this study was conducted, six state and local health departments were funded by CDC to participate in EHS-Net. The state and local health departments (EHS-Net sites) were in California, Minnesota, New York, New York City, Rhode Island, and Tennessee.

Sample

For this study, we used a random sample from a nonrandomly selected cluster (i.e., site). In each site, EHS-Net personnel chose an area, based on convenience (reasonable travel distance), in their jurisdiction to recruit restaurants for study participation through telephone calls. SAS version 9.3 (SAS Institute, Cary, NC) was used to select a random sample of restaurants from population lists of restaurants in those areas. Data collectors (EHS-Net personnel) collected data in approximately 50 randomly selected restaurants per site. For this study, restaurants were defined as facilities that prepare and serve food or beverages to customers and are not institutions, food carts, mobile food units, temporary food stands, supermarkets, restaurants in supermarkets, or caterers. Only restaurants with English-speaking managers were included in the study.

Data collection

Data were collected from January 2014 through February 2015. The institutional review boards of the participating EHS-Net site health departments approved the study protocol. We did not collect any data that could identify individual restaurants, managers, food workers, or servers. All data collectors participated in training designed to increase data collection accuracy and consistency. Data collectors solicited restaurant participation by contacting randomly selected restaurants within a specified geographic location via telephone using a standardized recruiting script.

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After obtaining permission from the restaurant manager, data collectors conducted an on-site interview with a manager (worker with authority over the kitchen), food worker (worker who primarily prepares or cooks food), and server (worker who primarily takes orders or serves food to customers). To increase participation and cooperation, data collectors asked the manager to choose the food worker and server to be interviewed. Manager interviews lasted approximately 20 min and were focused on characteristics of the restaurant (e.g., chain versus independent ownership and number of meals served in a typical day) and the manager (e.g., years of experience in current restaurant and whether they had been food safety certified). Food worker and server interviews lasted approximately 12 min each and were focused on food worker and server characteristics (e.g., highest level of education and whether they had received food allergy training in their current restaurant).

Interviewers asked 19 questions to assess manager, food worker, and server food allergy knowledge (e.g., identifying major food allergens and knowing what to do when a customer has a bad food allergic reaction). Five questions (e.g., should servers be knowledgeable about food allergies and should restaurants try to meet food allergic customers' special requests) were scored on a Likert scale to assess staff food allergy attitudes. Another 13 to 22 questions (e.g., whether the restaurant has a plan for answering questions from food allergic customers and whether the restaurant has a specific person on duty to handle food allergy questions and requests) were used to assess food allergy practices. Data collectors also observed the restaurant and examined its menu to assess additional restaurant characteristics (e.g., highest priced food item and number of critical violations on the restaurant's last inspection) and food allergy documentation (e.g., whether the menu mentioned anything about allergens and whether documentation about allergens was available in the kitchen area).

Data analysis

We initially created knowledge and attitude scores for each participant group (i.e., manager, food worker, and server). For the knowledge score, we summed the number of correct answers (out of 19) and used each group's median score to dichotomize the participants as having more or less knowledge.

For the attitude score, we assigned point values to each response as follows: strongly disagree = 1, disagree = 2, unsure = 3, agree = 4, and strongly agree = 5. We then averaged each participant's response to the five attitude questions. We used each group's median score to divide participants into those having relatively positive or less positive attitudes.

We used one-way analyses of variance (ANOVAs) to test whether groups were significantly different ($P \leq 0.05$) in knowledge and attitude scores. We then conducted univariate descriptive analyses of restaurant, manager, food worker, and server characteristics; food allergy knowledge, attitudes, and practices; and food allergy documentation. Some continuous variables were recoded to provide approximately even groups to facilitate interpretation. For example, managers' experience was split into <4 years (52.0%) and ≥4 years (48.0%). We next conducted a series of simple logistic regressions to examine associations between potential explanatory variables (restaurant, manager, food worker, and server characteristics; food preparation and service practices; and allergen documentation)

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and each outcome variable (knowledge and attitude scores) for managers, food workers, and servers (data not shown). We then created multiple logistic regression models for each group and outcome using a forward selection criterion (entrance criterion of $P \leq 0.10$) to further explore the relationship between 20 potential explanatory variables and the outcomes. We choose $P \leq 0.10$ to allow for more inclusiveness, given the relative exploratory nature of these analyses. We used SAS version 9.3 for all analyses.

RESULTS

Restaurant characteristics

Of the 1,307 restaurants contacted for participation in the study, 852 fit the study definition, and 278 (32.6%) of those agreed to participate (Table 1). Manager interview data indicated that 60.1% of the participating restaurants were independently owned. Data collectors classified 56.9% of the restaurants as either quick service (e.g., fast food), fast casual service, or takeout only. Manager interview data indicated that 54.3% of the restaurants had complex food preparation processes (i.e., preparation that includes holding food beyond same day service or some combination of holding, cooling, reheating, and freezing). Additionally, 64.1% had American (nonethnic) menus, 29.7% served more than 300 meals in a typical day, 50.5% had three or more managers, 50.7% employed more than 10 workers, 25.5% had a food item priced more than $20, and 23.0% were cited for more than one critical violation on the last inspection.

Manager, food worker, and server characteristics

Interview data from the 277 managers indicated that 66.4% were male, 81.2% spoke English as their primary language, 61.0% had some college education or more, 48.0% had been working at the restaurant for at least 4 years, and 80.8% had been food safety certified (Table 1). Less than half (44.7%) of managers had received training on food allergies while working at their current restaurant, and 27.8% did not recall serving any meals to food allergic customers in the past month.

Interview data from the 211 food workers indicated that 67.3% were male, 77.7% spoke English as their primary language, 37.0% had some college education or more, and 50.7% had been working at the restaurant for at least 2 years (Table 1). Less than half (44.1%) had received food allergy training while working at their current restaurant, and 21.0% did not recall preparing any meals for food allergic customers in the past month.

Interview data from the 156 servers indicated that 72.9% were female, 85.9% spoke English as their primary language, 50.0% had some college education or more, and 52.6% had been working at the restaurant for at least 2 years (Table 1). Only 33.5% had received training on food allergies while working at their current restaurant, and 12.6% did not recall serving any meals to food allergic customers in the past month.

Practices and observations

According to manager interview data, 70.8% percent of the restaurants had a plan for answering questions from food allergic customers (Table 2). Approximately half (53.3%) of

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the restaurants typically had a specific person on duty to handle food allergy questions and requests. Data collectors found that 22.0% of menus mentioned allergens. In 55% of these menus, the allergen information was a note for the customer to inform the restaurant whether they or someone with them had a food allergy. Food allergen documentation was available in the front of the restaurant (areas accessible to customers or the dining area) and the kitchen area in 23.1 and 36.3% of restaurants, respectively.

Manager, food worker, and server knowledge

Overall, managers correctly identified peanuts (95.0%), milk and dairy (91.0%), shellfish (92.4%), and eggs (81.6%) as major allergens (Table 3). Managers also recognized that trouble breathing (97.1%), hives or rash (98.2%), and swelling of tongue and throat (97.5%) are symptoms of an allergic reaction to food. Nearly all managers knew to call 911 (99.3%) when a customer has a bad food allergic reaction, such as trouble breathing. Managers (95.0%) knew that a person who eats food they are allergic to can die, and 92.8% of managers correctly said that taking a food allergen out of a meal after the meal had been prepared is not a way to make it safe for a food allergic customer. However, more than 1 in 10 managers (11.9%) incorrectly believed that a person allergic to a specific food ingredient can safely eat small amounts of that food.

Food workers also correctly identified peanuts (95.3%), milk and dairy (88.2%), shellfish (90.5%), and eggs (77.7%) as major allergens (Table 3). Food workers recognized trouble breathing (96.7%), hives or rash (97.2%), and swelling of tongue and throat (95.7%) as symptoms of an allergic reaction to food. Nearly all workers knew to call 911 (98.1%) when a customer has a bad food allergic reaction, such as trouble breathing. Food workers (94.8%) knew that a person who eats food they are allergic to can die, and 91.5% of food workers correctly said that taking a food allergen out of a meal after the meal has been prepared is not a way to make it safe for a food allergic customer. However, more than 1 in 10 food workers (11.8%) incorrectly believed that a person allergic to a specific food ingredient can safely eat small amounts of that food.

Servers correctly identified peanuts (95.5%), milk and dairy (93.0%), shellfish (94.2%), and eggs (72.4%) as major allergens (Table 3). Servers also recognized trouble breathing (99.4%), hives or rash (100%), and swelling of tongue and throat (100%) as symptoms of an allergic reaction to food. All servers knew to call 911 (100%) when a customer has a bad food allergic reaction, such as trouble breathing. Servers (97.4%) knew that a person who eats food they are allergic to can die, and 93.0% of servers correctly said that taking a food allergen out of a meal after the meal has been prepared is not a way to make it safe for a food allergic customer. However, more than 1 in 10 servers (11.5%) incorrectly believed that someone allergic to a specific food ingredient can safely eat small amounts of that food.

Comparisons of manager, food worker, and server knowledge scores

All three groups had similar knowledge scores (Table 4). Median knowledge scores were 13 for managers (mean = 13.7, SD = 2.0, $n = 277$), 12 for food workers (mean = 13.0, SD = 2.5, $n = 211$), and 13 for servers (mean = 13.5, SD = 2.2, $n = 156$).

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The overall ANOVA model suggested significant differences between groups ($F_{2,641} = 7.45$, $P < 0.001$). Post hoc tests revealed that managers (mean = 13.75, SD = 2.01, $n = 277$) had significantly higher knowledge scores than did food workers (mean = 12.96, SD = 2.50, $n = 211$). Servers had a mean score of 13.46 (SD=2.21, n=156), and their scores were not significantly different from those of managers or workers.

Multiple logistic regression of manager, food worker, and server knowledge

A multiple logistic regression analysis identified two characteristics that were significantly associated with manager food allergy knowledge (Table 5). Managers in restaurants that served more than 10 meals to allergic customers in the past month had greater odds of having a higher food allergy knowledge score than did managers in restaurants that served 10 or fewer such meals. Managers in restaurants that had a specific person to answer food allergy questions and requests had greater odds of having a higher food allergy knowledge score than did those managers in restaurants without such a person.

A multiple logistic regression analysis identified four characteristics that were significantly associated with food worker food allergy knowledge (Table 5). Food workers in restaurants with a plan for answering questions from food allergic customers had greater odds of having a higher food allergy knowledge score than did workers in restaurants with no such plan. Female food workers had greater odds of having a higher food allergy knowledge score than did male food workers. Food workers with at least 2 years of experience in the restaurant had greater odds of having a higher food allergy knowledge score than did food workers with less experience. Food workers in restaurants in which the highest priced food item was between $10 and $20 had greater odds of having a higher food allergy knowledge score than did those workers in restaurants in which the highest priced food item was less than $10.

A multiple logistic regression analysis identified three characteristics that were significantly associated with server food allergy knowledge (Table 5). Servers in restaurants with a specific person to answer food allergy questions and requests had greater odds of having a higher food allergy knowledge score. Servers in full service restaurants had greater odds of having a higher food allergy knowledge score than did servers in quick service restaurants. Servers in restaurants that served more than 300 meals in a typical day had greater odds of having a higher food allergy knowledge score than did servers in restaurants that served 300 meals or less.

Manager, food worker, and server attitudes

Managers (97.5%) agreed or strongly agreed that servers should be knowledgeable about food allergies (Table 6). Nearly all managers (99.6%) agreed or strongly agreed that kitchen staff should be knowledgeable about food allergies. Managers (91.3%) agreed or strongly agreed that restaurants should try to meet food allergic customers' special requests. Most managers (87.4%) also agreed or strongly agreed that their restaurant could easily meet food allergic customers' special requests. However, fewer managers (70.7%) agreed or strongly agreed that the staff in their restaurant would know what to do if a customer had a bad food allergic reaction.

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All food workers (100%) agreed or strongly agreed that servers should be knowledgeable about food allergies (Table 6). Food workers (99.5%) agreed or strongly agreed that kitchen staff should be knowledgeable about food allergies. Food workers (97.1%) also agreed or strongly agreed that restaurants should try to meet food allergic customers' special requests. Most food workers (92.9%) agreed or strongly agreed that their restaurant could easily meet food allergic customers' special requests. However, only 74.4% of food workers agreed or strongly agreed that the staff in this restaurant would know what to do if a customer had a bad food allergic reaction.

All servers (100%) agreed or strongly agreed that servers should be knowledgeable about food allergies (Table 6). Servers (100%) also unanimously agreed or strongly agreed that kitchen staff should be knowledgeable about food allergies. Nearly all servers (98.1%) agreed or strongly agreed that restaurants should try to meet food allergic customers' special requests. Most servers (93.0%) agreed or strongly agreed that their restaurant could easily meet food allergic customers' special requests. However, only three-quarters of servers (75.7%) agreed or strongly agreed that the staff in their restaurant would know what to do if a customer had a bad food allergic reaction.

Comparisons of manager, food worker, and server attitude scores

The three participant groups had approximately equivalent median attitude scores: 4.2 for managers (mean=4.3, SD=0.5, n=277), 4.2 for food workers (mean = 4.4, SD = 0.4, n = 207), and 4.4 for servers (mean = 4.5, SD=0.4, n=155) (Table 4). Knowledge and attitude scores were not significantly correlated in any of the respondent groups: managers, $r = 0.06$, $P = 0.317$, $n = 277$; food workers, $r = -0.03$, $P = 0.684$, $n = 207$; and servers, $r = 0.04$, $P = 0.653$, $n = 155$.

The overall ANOVA model suggested significant differences between groups ($F_{2,636} = 6.31$, $P = 0.002$). Post hoc tests revealed that servers (mean=4.46, SD=0.41, n= 155) had significantly higher attitude scores than did managers (mean=4.30, SD=0.50, n=277). Food workers had a mean score of 4.39 (SD = 0.44, n = 211), and their scores were not significantly different from those of managers or servers.

Multiple logistic regression of manager, worker, and server attitudes

A multiple logistic regression analysis identified six characteristics that were significantly associated with manager food allergy attitudes (Table 7). Managers in restaurants that served more than 10 meals to food allergic customers in the past month had greater odds of having a higher food allergy attitude score than did managers in restaurants that served 10 meals or fewer. Managers in restaurants with plans for answering questions from food allergic customers had greater odds of having a higher food allergy attitude score. Managers in restaurants with a specific person to answer food allergy questions and requests had greater odds of having a higher food allergy attitude score than did managers in restaurants without such a person. Managers in restaurants that had allergen information on the menu were less likely to have a higher food allergy attitude score than did managers in restaurants without this information. Managers with at least 4 years of experience in the restaurant were also less likely to have a higher food allergy attitude score than were managers with less experience.

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Managers who had received food allergy training at their restaurant had greater odds of having a higher food allergy attitude score than did managers with no food allergy training.

A multiple logistic regression analysis identified four characteristics that were significantly associated with food worker food allergy attitudes (Table 7). Food workers in restaurants with a plan for answering questions from food allergic customers were more likely to have a higher food allergy attitude score than were workers in restaurants without such a plan. Food workers with at least some college education had greater odds of having a higher food allergy attitude score than did workers with less education. Food workers in restaurants that employed fewer than five workers for every manager were more likely to have a higher food allergy attitude score than were those workers in restaurants with five workers or more for every manager. Food workers in chain restaurants had greater odds of having a higher food allergy attitude score than did workers in independent restaurants.

A multiple logistic regression analysis identified four characteristics that were significantly associated with server food allergy attitudes (Table 7). Servers with at least some college education were more likely to have a higher food allergy attitude score than were servers with less education. Servers who had received food allergy training at the restaurant had greater odds of having a higher food allergy attitude score than did servers with no food allergy training. Servers in restaurants with a plan for answering questions from food allergic customers were more likely to have a higher food allergy attitude score than were servers in restaurants with no such plan. Servers with at least 2 years of experience in the restaurant had greater odds of having a higher food allergy attitude score than did servers with less experience.

DISCUSSION

The overarching goal of this study was to describe food allergy knowledge, attitudes, and practices in restaurants. This multisite study revealed that restaurant managers and staff are knowledgeable and have positive attitudes concerning accommodations for food allergic customers. One positive finding was that nearly all restaurant staff could correctly identify symptoms of an allergic reaction and knew to call emergency medical services (i.e., 911) in these situations. Most managers and staff thought it was important for food workers and servers to be knowledgeable about food allergies and that their restaurant could easily meet food allergic customers' special requests. However, we identified important gaps in knowledge and attitudes. For example, restaurant staff members were less likely to recognize eggs as a major allergen, and conversely, some foods such as strawberries were incorrectly believed to be major allergens. Another troubling finding was that more than 10% of managers and staff believe that someone with a food allergy can safely consume a small amount of that allergen. These findings for food workers are particularly troubling, because their main job responsibilities include food preparation. Accurate knowledge is critical to preventing an allergic reaction. Managers and staff also had lower confidence in their restaurants' ability to properly respond to a food allergy emergency. This finding suggests that restaurant plans and trainings may not adequately prepare staff for these emergencies. Because the incidence of food allergies continues to increase, it is important for restaurants to be prepared for potential anaphylaxis emergencies.

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Identifying areas of concern is only the first step in preventing food allergic reactions in restaurants. Our additional analyses quantified the associations between restaurant, manager, and staff characteristics, practices, and observations and their food allergy knowledge and attitudes. Understanding these relationships is critical to creating effective interventions.

We found that several individual characteristics were significantly associated with food allergy knowledge and attitudes, e.g., education, work experience, and sex. Food worker knowledge level was higher among female workers and those with more experience working in their current restaurant. These findings suggest that it is important for restaurants to engage less experienced workers in food allergy trainings. Work experience and education were also significantly related to attitudes for managers, food workers, and servers. Managers with less experience had positive attitudes. In this case, experience might be a proxy for age. Anecdotal information from our data collectors suggests that younger managers were more receptive to accommodating food allergens than were older managers. In contrast, servers with more experience had positive attitudes. The contradiction between these findings is not readily explainable. Both food workers and servers with higher levels of education had positive attitudes.

Our findings also revealed a number of restaurant characteristics associated with food allergy knowledge and attitudes. Food workers in restaurants with higher priced food and servers in full service restaurants were more knowledgeable about food allergies. These characteristics might be indicative of restaurants with more resources to hire and retain staff who are more knowledgeable in general. Servers who served more meals per day also were more knowledgeable, perhaps because they recited the ingredients in meals to customers more frequently. Food workers in chain restaurants and those in restaurants with a lower worker-to-manager ratio also had positive food allergy attitudes.

Several allergy-specific practices were consistently related to knowledge and attitudes for managers, food workers, and servers. Serving more meals to food allergic customers was positively related to manager knowledge and attitudes but not to food worker and server knowledge and attitudes. Although staff are all involved in the process of serving food allergic customers, managers have more of the burden to ensure a meal is allergen free, especially if they are designated as the specific person in the restaurant to handle food allergy questions and requests. Having a plan for answering questions from food allergic customers or having a specific person to answer food allergy questions and requests was positively related to food allergen knowledge and attitudes for all staff groups. Both of these practices are recommended by the Food Allergy Research and Education group (8) as part of a restaurant’s food allergy management plan. Research concerning the direction of the relationship between restaurant practices and food allergy knowledge and attitudes should be explored.

Food allergy training was associated with positive manager and server attitudes but not with knowledge in any staff group. These findings suggest that food allergy trainings influence attitudes but either do not impart enough food allergy knowledge or do not result in retention of that knowledge. Relevant material for these trainings can include information on major food allergens, menu items containing food allergens, symptoms of an allergic reaction,

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interacting with food allergic customers, preparing for a food allergic reaction, and preventing cross-contact with allergens. Food allergy training can also be provided to new employees, and existing staff can be retrained periodically. Further research could explore which training techniques are most effective and result in long-term retention of important food allergy information.

Counterintuitively, the presence of allergen information on the menu was associated with less positive attitudes for managers. In 55% of these menus, the allergen information was a note for the customer to inform the restaurant if they or someone with them had a food allergy. In at least one of the data collection sites, legislation requires restaurants to state in the menu that customers should notify the server of any food allergies. Such legislation may produce situations in which even managers with less positive food allergy attitudes still include such notices on their menus. As more states and cities adopt food allergy laws, the extent to which these laws affect restaurants' food allergy practices can be evaluated. In any case, alerting customers to menu items containing allergens or encouraging these customers to notify staff regarding their allergies might help prevent allergic reactions. Only 22% of restaurant menus mentioned anything about allergens; we encourage more restaurants to include information about allergens on their menus.

This study had several limitations. Because we included only English-speaking managers, food workers, and servers in the study, the findings might not generalize to non-English speakers. Similarly, because the interviewed food workers and servers were chosen by managers rather than randomly, the food worker and server data might not be representative of these groups as a whole. This study also had a low participation rate (32.6%). The low response rate might have resulted in an overrepresentation of better and safer restaurants in the sample. In reporting results of a food allergen survey that also had a low response rate (4), the authors suggested that a lack of participation might reflect "a general discomfort in responding to an inquiry regarding food allergies." In comparison to other food safety topics, food allergies have emerged more recently, and managers might not feel as comfortable participating in research. Almost all participants in the present study had very favorable food allergy attitudes. This range restriction limited our ability to investigate the relationship between explanatory variables and attitudes. We also were not able to make causal inferences about the relationships between explanatory and outcome variables. For example, knowledgeable managers may attract and retain more customers with food allergies, or an increase in customers with food allergies may compel staff to acquire additional knowledge about allergens. We cannot determine whether serving more customers with food allergies leads to higher knowledge levels. Thus, although our data suggest significant relationships between several restaurant, manager, and staff characteristics and food allergy knowledge and attitudes, more research is needed to determine the causal nature of those relationships.

Overall, these findings suggest that managers, food workers, and servers are knowledgeable and have positive attitudes about accommodating customers with food allergies. We encourage restaurants to develop plans and designate a specific person to handle food allergy requests. Such practices were consistently associated with better knowledge and more

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positive attitudes. Food allergy training is also recommended for new and existing managers and staff.

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TABLE 1

Descriptive data on restaurant, manager, and staff characteristics

Parameter	*n*	%
Restaurant characteristics[a]		
Restaurant type (*N* = 276)		
Chain	110	39.9
Independent	166	60.1
Service type (*N* = 276)[b]		
Full service casual or fine dining	119	43.1
Quick service, fast casual service, or takeout only	157	56.9
Establishment type (*N* = 278)[b]		
Prep serve or cook serve	127	45.7
Complex	151	54.3
Menu type (*N* = 276)		
American	177	64.1
Non-American	99	35.9
No. of meals served in a typical day (*N* = 266)		
1–100	95	35.7
101–300	92	34.6
>300	79	29.7
No. of managers or persons in charge that work in this restaurant (*N* = 277)		
<3	137	49.5
≥3	140	50.5
No. of workers other than managers that work in this restaurant (*N* = 272)		
≤10	134	49.3
>10	138	50.7
Highest priced food item on the menu (*N* = 267)[b]		
<$10	95	35.6
$10–$20	104	38.9
>$20	68	25.5
No. of critical violations received after the last inspection (*N* = 278)[b]		
0	134	48.2
1	80	28.8
>1	64	23.0
Manager characteristics[a]		
Sex (*N* = 277)		
Male	184	66.4
Female	93	33.6

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Parameter	*n*	%
Primary language spoken (*N* = 277)		
English	225	81.2
Other	52	18.8
Highest level of education (*N* = 277)		
High school diploma or less	108	39.0
Some college or more	169	61.0
Experience as a manager in this restaurant (*N* = 277)		
<4 yr	144	52.0
≥4 yr	133	48.0
Ever been food safety certified (*N* = 276)		
Yes	223	80.8
No	53	19.2
Received training on food allergies while working at this restaurant (*N* = 275)		
Yes	123	44.7
No	152	55.3
No. of meals served to food allergic customers in the past month (*N* = 263)		
0	73	27.8
1–10	115	43.7
>10	75	28.5
Food worker characteristics[C]		
Sex (*N* = 211)		
Male	142	67.3
Female	69	32.7
Primary language spoken (*N* = 211)		
English	164	77.7
Other	47	22.3
Highest level of education (*N* = 211)		
High school diploma or less	133	63.0
Some college or more	78	37.0
Experience in this restaurant (*N* = 207)		
<2 yr	102	49.3
≥2 yr	105	50.7
Received training on food allergies while working at this restaurant (*N* = 209)		
Yes	86	41.1
No	123	58.9
No. of meals prepared for food allergic customers per month (*N* = 195)		
0	41	21.0
1–10	105	53.9
>10	49	25.1

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Parameter	*n*	%
Server characteristics[d]		
Sex (*N* = 155)		
Male	42	27.1
Female	113	72.9
Primary language spoken (*N* = 156)		
English	134	85.9
Other	22	14.1
Highest level of education (*N* = 156)		
High school diploma or less	78	50.0
Some college or more	78	50.0
Experience in this restaurant (*N* = 156)		
<2 yr	74	47.4
≥2 yr	82	52.6
Received training on food allergies while working at this restaurant (*N* = 155)		
Yes	52	33.5
No	103	66.5
No. of meals served to food allergic customers per month (*N* = 151)		
0	19	12.6
1–10	97	64.2
>10	35	23.2

[a] Data were obtained from manager interviews, unless otherwise noted.

[b] Data were obtained from data collector observations.

[c] Data were obtained from food worker interviews.

[d] Data were obtained from server interviews.

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TABLE 2

Descriptive data on food allergy practices and restaurant environment observations

Parameter	*n*	%
Practices[a]		
Restaurant has plan for answering questions from food allergic customers (*N* = 267)		
Yes	189	70.8
No	78	29.2
Specific person typically on duty to handle food allergy questions and requests (*N* = 276)		
Yes	147	53.3
No	129	46.7
Observations[b]		
Menu shows anything about allergens (*N* = 273)		
Yes	60	22.0
No	213	78.0
Documentation in the front of the house (areas accessible to customers) or dining area about allergens (*N* = 277)		
Yes	64	23.1
No	213	76.9
Documentation about allergens in the kitchen area (*N* = 278)		
Yes	101	36.3
No	177	63.7

[a]Data were obtained from manager interviews.

[b]Data were obtained from data collector observations.

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TABLE 3

Descriptive data on restaurant manager and staff food allergy knowledge[a]

	Manager (*N* = 277)		Food worker (*N* = 211)		Server (*N* = 156)	
Question	***n***	**%**	***n***	**%**	***n***	**%**
Of the following foods, which do you think are major allergens?						
Peanuts (*correct*)	263	95.0	201	95.3	149	95.5
Tomatoes	53	19.1	47	22.3	37	23.7
Milk or dairy (*correct*)	252	91.0	186	88.2	145	93.0
Strawberries	88	31.8	68	32.2	47	30.1
Shellfish (*correct*)	256	92.4	191	90.5	147	94.2
Eggs (*correct*)	226	81.6	164	77.7	113	72.4
Chocolate	64	23.1	59	28.0	27	17.3
Which of the following are symptoms of an allergic reaction to food?						
Trouble breathing (*correct*)	269	97.1	204	96.7	155	99.4
Hives or rash (*correct*)	272	98.2	205	97.2	156	100
Headache	154	55.6	109	51.7	72	46.2
Swelling of tongue and throat (*correct*)	270	97.5	202	95.7	156	100
Fever	166	59.9	122	57.8	102	65.4
Which of the following should you do if a customer is having a bad food allergic reaction, such as trouble breathing?						
Suggest that the customer drink water	67	24.2	59	28.0	41	26.3
Call 911 (*correct*)	275	99.3	207	98.1	156	100
Ask the customer if they have medicine they could take	250	90.3	193	91.5	145	93.0
Suggest that the customer throw up	42	15.2	28	13.3	9	5.8
Someone with a food allergy can safely eat small amounts of the food they are allergic to.						
Yes	33	11.9	25	11.8	18	11.5
No (*correct*)	225	81.2	159	75.4	122	78.2
Unsure or skipped	19	6.9	27	12.8	16	10.3
Someone with a food allergy can die from eating the food they are allergic to.						
Yes (*correct*)	263	95.0	200	94.8	152	97.4

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	Manager (N = 277)		Food worker (N = 211)		Server (N = 156)	
Question	***n***	**%**	***n***	**%**	***n***	**%**
No	7	2.5	6	2.8	2	1.3
Unsure or skipped	7	2.5	5	2.4	2	1.3
Taking a food allergen out of a meal after it has been made is one way to make it safe for a food allergic customer.						
Yes	17	6.1	12	5.7	6	3.8
No (*correct*)	257	92.8	193	91.5	145	93.0
Unsure or skipped	3	1.1	6	2.8	5	3.2

[a] Responses are shown in the order they were asked. *n*, the number of managers and workers that affirmatively answered the question.

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TABLE 4

Comparisons of food allergy knowledge and attitude scores by group

Group	Mean difference	95% confidence interval
Knowledge scores[a]		
Manager vs food worker	0.785	(0.28, 1.29)[b]
Manager vs server	0.292	(−0.26, 0.84)
Server vs food worker	0.493	(−0.08, 1.07)
Attitude scores[c]		
Manager vs food worker	−0.087	(−0.19, 0.02)
Manager vs server	−0.157	(−0.27, −0.04)[b]
Server vs food worker	0.069	(−0.05, 0.19)

[a] Fisher's one-way ANOVA ($F_{2,641} = 7.45$, $P < 0.001$).

[b] $P \leq 0.05$.

[c] Equal variance not assumed. Welch's one-way ANOVA ($F_{2,636} = 6.31$, $P = 0.002$).

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TABLE 5

Multiple logistic regression analysis of characteristics associated with restaurant managers, food workers, and servers scoring in the top 50% of food allergy knowledge scores[a]

Characteristic	OR (90% CI)	*P*
Manager scored in top 50%[b]		
No. of meals served to allergic customers in the past month		0.003
1–10 vs 0	1.48 (0.89, 2.48)	0.208
>10 vs 1–10	2.33 (1.35, 4.04)	0.011
>10 vs 0	3.45 (1.87, 6.36)	0.001
Specific person to answer food allergy questions and requests		
Yes vs no	1.71 (1.09, 2.70)	0.052
Food worker scored in top 50%[c]		
Restaurant plan for answering questions from food allergic customers		
Yes vs no	4.23 (2.20, 8.12)	<0.001
Sex		
Female vs male	3.63 (1.81, 7.26)	0.002
Experience in this restaurant		
≥2 vs <2 yr	2.60 (1.43, 4.72)	0.009
Highest priced food item on the menu		0.071
$10–$20 vs <$10	2.72 (1.33, 5.56)	0.022
>$20 vs $10–$20	0.68 (0.32, 1.42)	0.389
>$20 vs <$10	1.84 (0.80, 4.24)	0.228
Server scored in top 50%[d]		
Specific person to answer food allergy questions and requests		
Yes vs no	2.49 (1.33, 4.66)	0.017
Service type		
Full service vs quick service	2.71 (1.40, 5.24)	0.013
No. of meals served in a typical day		0.077
101–300 vs 1–100	1.03 (0.51, 2.05)	0.953
>300 vs 101–300	2.54 (1.20, 5.38)	0.042
>300 vs 1–100	2.60 (1.19, 5.69)	0.045

[a]Overall models were created using a forward selection criterion of $P < 0.10$. Variables are presented in order of steps at which they entered the model. OR, odds ratio; CI, confidence interval. OR > 1 indicates that the odds of the outcome (knowledge score in top 50%) were greater for the first mentioned category (e.g., 1 to 10) than for the second mentioned category (e.g., 0).

[b]$\chi^2 = 17.18$, df = 3, $P < 0.001$, $N = 262$.

[c]$\chi^2 = 30.50$, df = 5, $P < 0.001$, $N = 192$.

[d]$\chi^2 = 16.97$, df = 4, $P = 0.002$, $N = 149$.

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TABLE 6

Descriptive data on restaurant manager and staff food allergy attitudes[a]

	Manager (*N* = 277)		Food worker (*N* = 211)		Server (*N* = 156)	
Statement	***n***	**%**	***n***	**%**	***n***	**%**
Servers should be knowledgeable about food allergies						
Strongly agree	173	62.5	137	64.9	113	72.4
Agree	97	35.0	74	35.1	43	27.6
Unsure	0	0	0	0	0	0
Disagree	7	2.5	0	0	0	0
Strongly disagree	0	0	0	0	0	0
Kitchen staff should be knowledgeable about food allergies						
Strongly agree	194	70.0	147	69.7	125	80.1
Agree	82	29.6	63	29.8	31	19.9
Unsure	0	0	1	0.5	0	0
Disagree	1	0.4	0	0	0	0
Strongly disagree	0	0	0	0	0	0
Restaurants should try to meet food allergic customers' special requests						
Strongly agree	133	48.0	106	50.2	88	56.4
Agree	120	43.3	99	46.9	65	41.7
Unsure	7	2.6	0	0	2	1.3
Disagree	15	5.4	4	1.9	1	0.6
Strongly disagree	2	0.7	2	1.0	0	0
This restaurant can easily meet food allergic customers' special requests						
Strongly agree	113	40.8	82	38.9	74	47.5
Agree	129	46.6	114	54.0	71	45.5
Unsure	9	3.2	4	1.9	1	0.6
Disagree	26	9.4	10	4.7	10	6.4

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Statement	Manager (N = 277)		Food worker (N = 211)		Server (N = 156)	
	n	%	*n*	%	*n*	%
Strongly disagree	0	0	1	0.5	0	0
The staff in this restaurant know what to do if a customer has a bad food allergic reaction						
Strongly agree	66	23.8	51	24.2	36	23.1
Agree	130	46.9	106	50.2	82	52.6
Unsure	27	9.8	29	13.7	22	14.1
Disagree	49	17.7	25	11.9	16	10.2
Strongly disagree	5	1.8	0	0	0	0

[a] Strongly disagree = 1; disagree = 2; unsure = 3; agree = 4; strongly agree = 5.

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TABLE 7

Multiple logistic regression analysis of characteristics associated with restaurant managers, food workers, and servers scoring in the top 50% of food allergy attitude scores[a]

Characteristic	OR (90% CI)	*P*
Manager scored in top 50%[b]		
No. of meals served to allergic customers in past month		<0.001
1–10 vs 0	1.29 (0.73, 2.28)	0.467
>10 vs 1–10	3.72 (2.00, 6.92)	0.001
>10 vs 0	4.80 (2.35, 9.77)	<0.001
Restaurant plan for answering questions from food allergic customers		
Yes vs no	2.77 (1.59, 4.81)	0.003
Specific person to answer food allergy questions and requests		
Yes vs no	1.71 (1.02, 2.85)	0.085
Allergen information on menu		
Yes vs no	0.42 (0.22, 0.79)	0.023
Experience in this restaurant		
≥4 vs <4 yr	0.57 (0.35, 0.94)	0.061
Received food allergy training at this restaurant		
Yes vs no	1.71 (1.00, 2.92)	0.099
Food worker scored in top 50%[c]		
Restaurant plan for answering questions from food allergic customers		
Yes vs no	2.43 (1.33, 4.43)	0.015
Highest level of education		
Some college or more vs high school diploma or less	3.35 (1.83, 6.14)	0.001
Worker:manager ratio		
<5:1 vs ≥5:1	2.44 (1.37, 4.35)	0.011
Restaurant type		
Chain vs independent	2.04 (1.13, 3.70)	0.048
Server scored in top 50%[d]		
Highest level of education		
Some college or more vs high school diploma or less	3.33 (1.80, 6.17)	0.001
Received food allergy training at this restaurant		
Yes vs no	2.60 (1.32, 5.08)	0.020
Restaurant plan for answering questions from food allergic customers		
Yes vs no	2.43 (1.16, 5.12)	0.050
Experience in this restaurant		
≥2 vs <2 yr	1.89 (1.01, 3.52)	0.093

[a]Overall models were created using a forward selection criterion of $P < 0.10$. Variables are presented in order of steps at which they entered the model. OR, odds ratio; CI, confidence interval. OR > 1 indicates that the odds of the outcome (attitude score in top 50%) were greater for the first mentioned category (e.g., 1 to 10) than for the second mentioned category (e.g., 0).

[b]$\chi^2 = 52.00$, df = 7, $P < 0.001$, $N = 248$.

[c] χ^2 = 27.86, df = 4, $P < 0.001$, $N = 196$.

[d] χ^2 = 24.43, df = 4, $P < 0.001$, $N = 149$.

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Original Article

Characteristics of Food Allergic Reactions in United States Restaurants

Roxanne C. Oriel, MD[a], Omar Waqar, MD[a], Hemant P. Sharma, MD, MHS[b,c], Thomas B. Casale, MD[d,e], and Julie Wang, MD[a] *New York, NY; Washington, DC; Tampa, FL; and Mclean, VA*

What is already known about this topic? Food allergic reactions occur while dining out. Prior studies have shown that restaurant patrons fail to communicate allergies to restaurant staff and restaurant staff lack fundamental food allergy knowledge that could help decrease allergic reactions.

What does this article add to our knowledge? Peanut, tree nuts, and milk are the most commonly implicated foods in restaurant allergic reactions, with tree nuts the most common cause of epinephrine use. More than 1 in 4 reactions result in epinephrine use.

How does this study impact current management guidelines? Data presented here of the circumstances surrounding food allergic reactions will help counsel food allergic patients and advance advocacy efforts for mandatory declaration of allergenic ingredients on menus and food allergy training of restaurant staff.

BACKGROUND: Food allergic reactions of varying severity occur in restaurants. Studies to date have shown that there are gaps in knowledge of and communication between restaurant staff and food allergic individuals.
OBJECTIVE: We sought to characterize allergic reactions in restaurants to better inform the restaurant industry, food allergic individual, and allergist so that mitigation strategies can be implemented.
METHODS: Data collected over a 2-year period from 2822 individuals in the Food Allergy Research & Education registry were analyzed using descriptive statistics.
RESULTS: Dining out accounted for the second most common location for a food allergic reaction, after one's home, and many were severe with 28.0% requiring 1 dose and 6.2% requiring 2 doses of epinephrine. Cafes, fast food establishments, and Asian restaurants were frequently implicated sites. Peanut, tree nuts, and milk were the most common inciting allergens, and tree nuts resulted in the most common use of epinephrine. Of the allergic reactions, 53.9% occurred despite conveyance of food allergy to restaurant staff, 26.6% occurred when allergens were declared on the menu, and 13.7% occurred when allergens were declared on the menu and restaurant staff were informed of a food allergy.
CONCLUSIONS: Allergic reactions in restaurants are common and can be severe. Findings presented here underscore the need for restaurant staff training and mandatory declaration of allergenic ingredients in meals. This updated knowledge will help support advocacy efforts and inform patients, allergists, and the restaurant industry on best practices for dining out to improve the quality of life for food allergic individuals. © 2020 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2021;9:1675-82)

Key words: *Food allergy; Restaurant; Dining out; Allergic reaction; Accidental ingestion*

Severe and sometimes fatal food allergic reactions occur in restaurants.[1-8] Despite this, there are few policies in the United States mandating formalized training of restaurant staff on food allergic issues.[9-12] Moreover, declaration of allergenic ingredients in meals is not compulsory in food-serving establishments. Compounding the problem, studies have also consistently shown that many food allergic individuals do not inform restaurant staff of their food allergy.[4,6,7,13]

In a study using interviews of restaurant employees, conducted by the Centers for Disease Control and Prevention Environmental Health Specialists Network (EHS-Net), less than half of restaurant managers, food workers (ie, those who prepare or cook food), and servers (ie, those who take orders or serve food to patrons) received food allergy training.[9] When food allergy training did occur, the topics covered included discussion of

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Abbreviations used
AAAAI- American Academy of Allergy, Asthma & Immunology
EHS-Net- Environmental Health Specialists Network
FARE- Food Allergy Research & Education
ICU- Intensive care unit

major food allergens, cross-contamination, and actions to be taken if a customer has a food allergy. However, restaurant managers, food workers, and servers were trained on each of these topics only to a varying degree. Key food allergy issues inconsistently addressed included review of menu items with allergens, symptoms consistent with an allergic reaction, and restaurant action plan should an allergic reaction occur.[9] EHS-Net investigators also found that in this group interviewed, more than 10% of managers and restaurant staff presumed that a food allergic individual could safely consume a small amount of their allergen.[10] Currently, the Food and Drug Administration Food Code 2017 advises, not requires, that the person-in-charge of the restaurant establishment (ie, manager) ensure that employees are properly trained in food allergy awareness in order for them to safely perform duties related to food allergies. It should be noted that not all states implement the Food Code.[14] At the time of this publication, there is still no federal legislation mandating food allergy training for restaurant staff.

Many food allergic individuals do not dine out because of the risk of an allergic reaction.[5] In 2001, using data from the United States Peanut and Tree nut Allergy Registry, investigators found that 13.7% of registry participants reported an allergic reaction to peanut or tree nuts in restaurants.[15] In a survey conducted in 2007 at the Food Allergy & Anaphylaxis Network conference, 34% of survey respondents reported at least 1 food allergic reaction in a restaurant, with 36% of those respondents reporting at least 3 reactions in restaurants.[5] In addition to inadequate food allergy knowledge by restaurant staff, other studies have outlined additional reasons for these allergic reactions including the presumption by patrons of food served being safe if there was no obvious use of allergen (eg, hidden ingredient in sauce) as well as patrons not notifying restaurant staff of their allergy.[4,6,7,13]

The present study sought to characterize food allergic reactions in restaurants to better inform the food allergic individual, physician providing counseling on dining out, and restaurant industry.

METHODS

The primary data source for this study was Food Allergy Research & Education's (FARE) Patient Registry, a national online repository of data collected from participants with food allergy. Data collection is ongoing through the Invitae survey platform. Potential participants were informed about the Registry using FARE's e-mail list of over 200,000 food allergy–interested consumers. In addition, the Registry was advertised through social media posts, FARE websites, and local food allergy support groups. Allergists at 33 clinical research centers across the United States were provided with information to promote the Registry to their patients. Online informed consent was obtained before data entry by the individuals with food allergy and family members of children with food allergies. Deidentified self- and parental-reported data from September 2017 to September 2019 from the voluntary Registry were reviewed. Demographics, location of the most recent allergic reaction, type of food-serving establishment, implicated food, and treatment received were analyzed using descriptive statistics. The χ^2 test or Fisher's exact test was used to compare categorical variables between groups. Analyses of contingency tables were accomplished using the method of adjusted standardized residuals described by Beasley and Schumacker.[16] A result was considered statistically significant at the $P < .05$ level of significance. Analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC) and R version 3.6 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Allergic reactions to food were reported for 2822 individuals from the United States over the 2-year period examined (1579 children <18 years, 40% female; 1243 adults, 82% female). For both children and adults, dining out was the second most common location for these reported allergic reactions (n = 597, 21%), the most common location being one's home (n = 1231, 44%). Demographics of survey respondents reporting reactions while dining out are shown in Tables I and II. School accounted for 6% of allergic reactions in children, and the workplace comprised 11% of reactions in adults (Figure 1). The distribution of location where allergic reactions occurred differed significantly between the pediatric and adult groups ($P < .0001$). Adult allergic reactions occurred more frequently while dining out (31% vs 13%) and less frequently at home (35% vs 51%) compared with pediatric allergic reactions. Cafes (15%), fast food restaurants (10%), ice cream parlors (7%), and Asian restaurants (7%) were the most frequently identified food-serving establishments where children experienced an allergic reaction (Figure 2A). Cafes (18%), fast food restaurants (10%), Asian restaurants (10%), and bars (7%) were the most often cited locations for allergic reactions in adults (Figure 2B). The distribution of type of food-serving establishment in which allergic reactions occurred differed significantly between the pediatric and adult groups ($P < .0001$).

The most common food allergens that caused an allergic reaction for both children and adults while dining out were peanut, tree nuts, and milk (Figure 3). Egg (15%), shellfish (5%), and sesame (3%) were also noted to be triggers in children, whereas shellfish (11%), wheat (9%), and egg (5%) were identified as triggers in adults (Figure 3). The distribution of culprit food allergens associated with allergic reactions differed significantly between the pediatric and adult groups ($P < .0001$). Adult allergic reactions occurred more frequently with wheat (9% vs 2%) and less frequently with eggs (5% vs 15%), compared with pediatric allergic reactions.

In 53.9% of cases, an allergic reaction occurred despite informing restaurant staff of their food allergy. A list of ingredients (5.0%), allergens (9.2%), and/or precautionary statement (3.5%) was included on the menu in a minority of cases. In 26.6% of cases, a reaction occurred in the setting of ingredients, allergens, or a precautionary statement declared on the menu. In instances when staff were informed and menu information was available, 13.7% of individuals still had an allergic reaction. Instances of "hidden" food allergens accounted for 16.9% of reactions. A total of 9.7% of respondents had not been previously exposed to the culprit allergen.

In children and adults who dined out, the majority of allergic symptoms occurred within 30 minutes of ingestion of their meal. H1 antihistamines were used in 74.4% of dining out allergic

TABLE I. Demographics of survey respondents who had food-induced allergic reactions at restaurants: demographics of children and adults

	Age 0-5	Age 6-11	Age 12-17	Age 18-25	Age 26-40	Age 41-59	Age 60-80	Age 80+
Sex								
Male	17 (50.0)	48 (66.7)	55 (53.4)	19 (23.2)	18 (16.1)	16 (12.4)	16 (26.2)	1 (25.0)
Female	17 (50.0)	24 (33.3)	48 (46.6)	63 (76.8)	94 (83.9)	113 (87.6)	45 (73.8)	3 (75.0)
Total	34	72	103	82	112	129	61	4
Average age (y)	4.1	9.2	15.1	21.8	32.9	50.0	67.0	90.1
Race								
American Indian or Alaska Native	1 (2.9)	2 (2.8)	2 (1.9)	0 (0.0)	2 (1.8)	2 (1.6)	1 (1.6)	0 (0.0)
Asian	5 (14.7)	8 (11.1)	10 (9.7)	8 (9.8)	8 (7.1)	7 (5.4)	2 (3.3)	0 (0.0)
Black	0 (0.0)	6 (8.3)	7 (6.8)	3 (3.7)	5 (4.5)	9 (7.0)	1 (1.6)	0 (0.0)
White	32 (94.1)	69 (95.8)	96 (93.2)	79 (96.3)	104 (92.9)	120 (93.0)	56 (91.8)	4 (100.0)
Native Hawaiian or Other Pacific Islander	2 (5.9)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
Unknown	1 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)
Ethnicity								
Hispanic or Latino	4 (11.8)	4 (5.6)	5 (4.9)	4 (4.9)	8 (7.1)	7 (5.4)	1 (1.6)	0 (0.0)
Non-Hispanic or Latino	24 (70.6)	55 (76.4)	72 (69.9)	59 (72.0)	78 (69.6)	82 (63.6)	36 (59.0)	3 (75.0)
Unknown	6 (17.6)	13 (18.1)	26 (25.2)	19 (23.2)	26 (23.2)	40 (31.0)	24 (39.3)	1 (25.0)

Data are presented as n (%).

TABLE II. Demographics of survey respondents who had food-induced allergic reactions at restaurants: geographical distribution of survey respondents

	Northeast (n)	%	Southeast (n)	%	Southwest (n)	%	Midwest (n)	%	West (n)	%	Unknown (n)	%
Children	54	25.8	45	21.5	15	7.2	56	26.8	34	16.3	5	2.4
Adults	96	24.7	90	23.2	32	8.2	93	24.0	62	16.0	15	3.9
All	150	25.1	135	22.6	47	7.9	149	25.0	96	16.1	20	3.4

reactions. In some instances, reactions were severe requiring epinephrine (28.0%), with adults accounting for 61% of those reactions. Biphasic reactions, defined as a second wave of symptoms after initial symptoms disappear, were reported in 14.4% of cases. Epinephrine use (n = 166) prompted seeking medical attention in 88.0% of cases (n = 146), 9.6% sought help from family and/or friends (n = 16), and 2.4% (n = 4) did not seek help after use. Those food allergic individuals who sought medical help from various sources included the following: 911 or emergency medical services (36.7%, n = 61), urgent care (3.6%, n = 6), emergency department (66.3%, n = 110), general practitioner (8.4%, n = 14), and allergist (7.2%, n = 12). After epinephrine use, survey respondents reported hospitalization in 16.3% (n = 27) and intensive care unit (ICU) admission in 4.2% (n = 7). In 6.2% of cases (n = 37), 2 doses of epinephrine were used. Of those cases, 29.7% (n = 11) were hospitalized and 18.9% (n = 7) were admitted to the ICU. No deaths were reported.

Overall, food allergic individuals were admitted to the hospital in 6.2% of cases and 1.8% were admitted to the ICU. The mean ages for children who required 2 doses of epinephrine, hospitalization, and ICU care were 11, 14, and 8 years, respectively; for adults, the averages were 28, 29, and 56 years, respectively. Additional details of those who experienced severe allergic reactions in restaurants are shown in Table III. Reaction outcomes did not differ in terms of age, gender, race, or ethnicity. Characteristics of those who were in the ICU are detailed in Table IV. When noted by the survey respondent, the most common food allergens that necessitated 1 or 2 doses of epinephrine were peanut, tree nuts, and milk, with tree nuts being the most common cause of epinephrine use in restaurant establishments (Table V). There was no significant difference in food triggers in relation to epinephrine requirement. Of the 3 children who required ICU care, 2 reported milk as the culprit allergen and 1 reported egg. Of the 7 adults who required the ICU for management of their allergic reaction, 3 were from tree nuts, 2 from milk, 1 from shellfish, and 1 reported alcohol. Regarding pediatric cases that required non-ICU hospitalization (n = 16), peanut was the most common trigger, followed by tree nuts and milk. For hospitalized adults (n = 25), when identified, shellfish, peanut, and tree nuts were the most common triggers. Table VI details the food allergens that led to hospitalizations or ICU care.

DISCUSSION

Although dining out at restaurants contributes substantially to the morbidity including anxiety of food allergic individuals, formal procedures in restaurants aimed at preventing and managing allergic reactions and governmental oversight in the form of legislation are lacking.

After one's home, restaurants are the second most common location for food allergic reactions and those reactions can be severe. The most common types of establishments for food allergic reactions were cafes and fast food restaurants. In children, dining out accounted for 13% of allergic reactions, more than double the number of reactions that occur in school (6%), possibly because there are voluntary guidelines in place set forth by the federal government to aid in mitigating allergic reactions

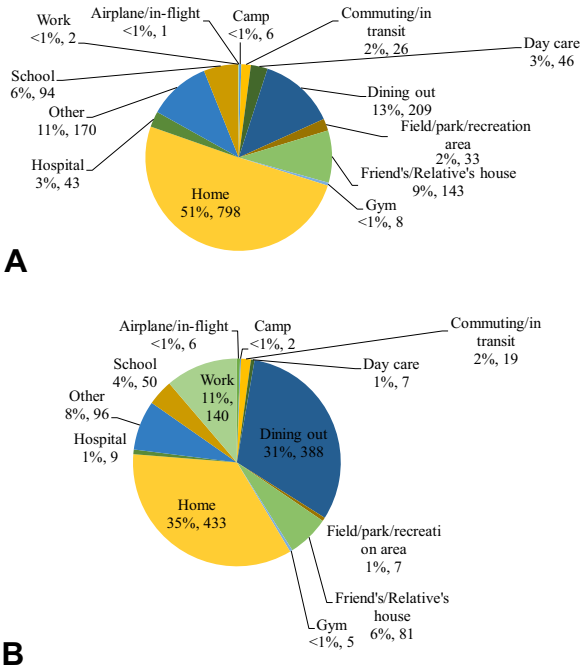

FIGURE 1. Most recent location for an allergic reaction reported as percentage, number of subjects. (**A**), Children <18 years (n = 1579). (**B**) Adults ≥18 years (n = 1243). Other refers to unsure or no response.

in school.[17] There are no guidelines or legislative measures in place for the restaurant industry despite accounting for 13% and 31% of food allergic reactions in children and adults, respectively.

Although the majority of food allergic reactions were treated with antihistamines, more than 1 of 4 reactions that occurred in food-serving establishments resulted in the use of epinephrine. In 2.4% of cases, after using their epinephrine autoinjector, food allergic individuals did not seek additional medical assistance. These findings reinforce the importance of counseling food allergic individuals to carry their epinephrine autoinjectors at all times and reviewing the emergency action plan at regular intervals. Moreover, it further emphasizes the need for guidelines for the restaurant industry on preventing and managing food allergic reactions. Although a workgroup report was recently published by the American Academy of Allergy, Asthma & Immunology (AAAAI) to help guide the restaurant industry, legislative action requiring training of restaurant staff on food allergic topics (eg, most common food allergens, cleaning methods for removal of allergens, cross-contact, hidden ingredients, symptoms of an allergic reaction, appropriate treatment) and labeling of menu items containing top allergens remains critical.[18]

Individuals with allergies to milk, peanut, or tree nuts are at the highest risk for allergic reactions in restaurants and at the highest risk for severe reactions requiring epinephrine. Nearly half of those needing 2 epinephrine doses needed a higher level of care (ie, hospitalization, ICU admission), potentially indicating more severe reactions. This finding highlights the importance of raising awareness of allergic reactions occurring in restaurants and promoting efforts to reduce these reactions.

Increased public awareness of peanut allergy and lower awareness of tree nut allergies by restaurant staff may be the reason for our finding that tree nuts instead accounted for the most common cause of epinephrine use while dining out. Other possibilities include that individuals were unaware of their tree nut allergy or use of different nuts in a dish that the family or restaurant staff may not associate with specific dishes (eg, pesto made with walnuts or cashews instead of pine nuts). Another possibility is that individuals were unaware of their tree nut allergy. Peanut was also not implicated in severe allergic reactions that required ICU care in both children and adults. Instead, peanut was the most commonly reported allergen for pediatric cases hospitalized, not requiring ICU care.

Factors such as food allergic individuals not informing restaurant staff of an allergy and absence of information on menus regarding allergens contribute to the considerable number of allergic reactions in food-serving establishments. The possibility of communication breakdowns (eg, language barrier, perceptual difference, distraction/noise in a busy restaurant) between patron, server, and kitchen staff may contribute to why allergic reactions still occur despite informing staff and allergenic ingredient information provided on the menu.[18] Cross-contact with allergens during preparation and serving is another consideration. In this study, only 53.9% of food allergic patrons who had an allergic reaction while dining out informed restaurant staff of their allergy. This lack of communication between restaurant staff and food allergic individual has been consistently reported in the literature.[4,6,7,13,19] Prior studies demonstrate that food allergic individuals rely on visual identification of their allergen in a dish or are embarrassed to disclose their allergy.[4,20] Allergists should stress the importance of informing restaurant staff of their food allergy because visualization alone is not a reliable way to decrease allergic reactions as allergens can be hidden. Food allergic individuals not informing restaurant staff of a food allergy can be prevented by the server proactively inquiring whether or not any individual at the table has any dietary restrictions. Although this is occurring with increasing frequency in restaurants in the United States, it should be a routine question asked when patrons are ordering their food. The combination of allergists emphasizing the importance of disclosing allergy information and restaurants incorporating a question about dietary restrictions as part of routine practice will facilitate transfer of this important information and help decrease the number of food allergic reactions that occur while dining out. It should be underscored, however, that even when restaurant staff are informed of a food allergy and allergen information is present on the menu, we found that more than 1 in 10 will still have an allergic reaction. Undoubtedly, more than improved communication by the restaurant patron and staff is necessary to reduce the occurrence of food allergic reactions in restaurants. Continued education for patients, caregivers, and restaurant staff is necessary to decrease the incidence of allergic reactions further.

There are limitations to our study. First, allergic reactions were self- or parent-reported, which is subject to recall bias. Second, allergic reactions in restaurants were less frequently reported by individuals from the southwestern and western regions of the United States, likely due to a lower number of overall registry participants from these states. Because this registry is dependent on awareness of the registry, people choosing to participate in this study, and it is a survey promoted by FARE, our study is also

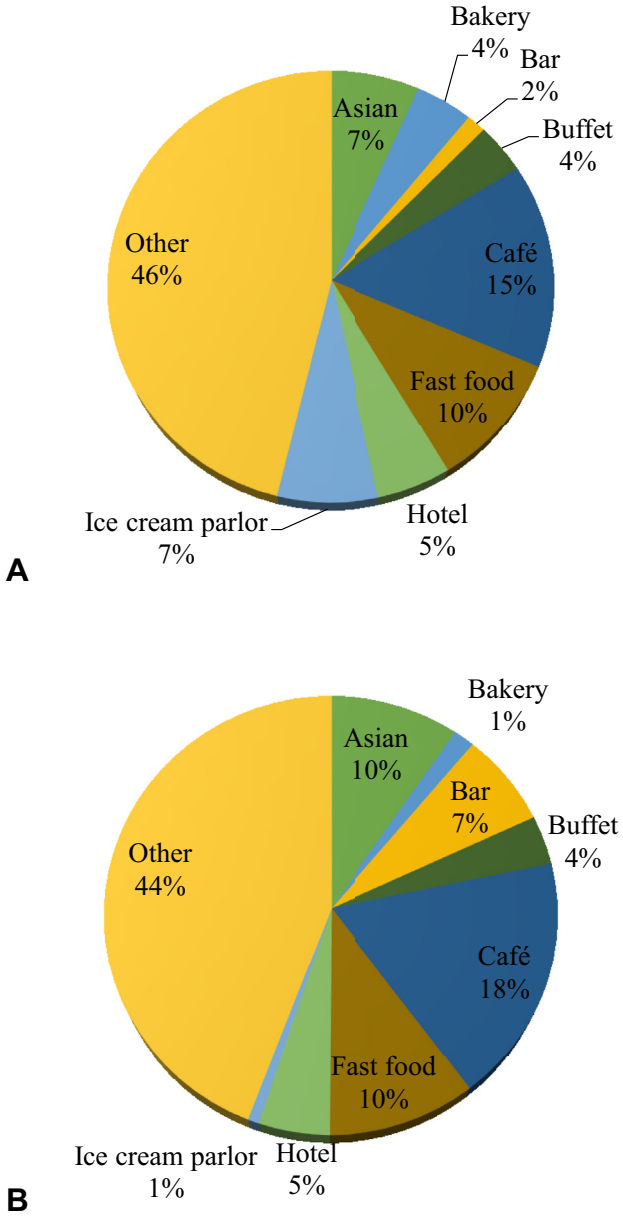

FIGURE 2. Type of food-serving establishment in which an allergic reaction occurred. (**A**), Children <18 years. (**B**), Adults ≥18 years.

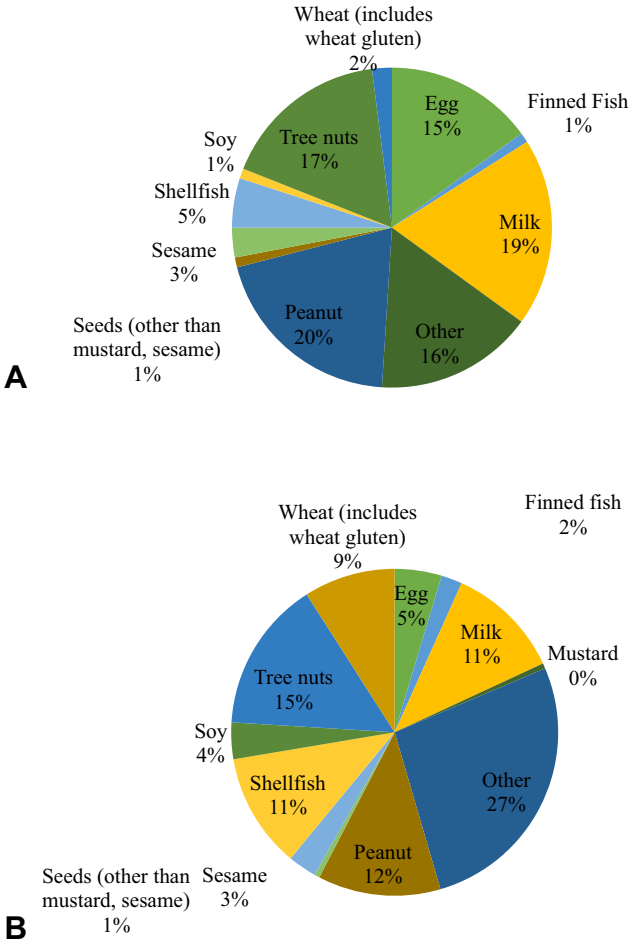

FIGURE 3. Culprit food allergens while dining out. (**A**), Children <18 years. Other refers to fruits, vegetables, herbs or spices, or unspecified by the survey respondent. (**B**), Adults ≥18 years. Other refers to fruits, vegetables, herbs or spices, cereals, and grains other than wheat, beans, legumes, or pulses other than soy, meats, non-food items, or unspecified by the survey respondent.

subject to participation bias and may not be representative of the general population of individuals with food allergies. As a consequence, it is difficult to know the exact reason for observed geographical differences. Third, the majority of adult respondents were female, and all respondents were disproportionately white, non-Hispanic, or Latino. Fourth, the percentage of biphasic reactions might be an overestimate because there was limited information provided to the survey participant regarding the definition of a biphasic reaction. Two subjects were excluded from the analysis because of reporting a biphasic reaction less than 1 hour after the disappearance of initial symptoms. Fifth, "other" was a possible option for many fields in the registry and accounted for a substantial number of responses by survey respondents. In some cases, "other" did not allow for a typeable, free-text response. In other cases, the answers did not fit in any other category (examples include allergist's office, grocery store, place of worship, or hotel as the site of an allergic reaction). Sixth, the registry did not have a field for takeout or delivery items from a restaurant as an option for the location of an allergic reaction. Some reactions may have been incorrectly categorized as reactions occurring at home. The number of allergic reactions in restaurants due to errors in restaurant-prepared food that is subsequently delivered or carried out is absent. Therefore, data shown here are likely an underestimate. In our current era of massive online ordering with delivery and takeout options, we must also consider mandatory declaration of allergenic ingredients in online meal options and mechanisms for patrons to declare their food allergies that ensure visualization by restaurant staff.

In summary, mitigation strategies that can be employed by the food allergic individual to decrease the occurrence of food allergic reactions while dining out include choosing restaurants that declare allergenic ingredients on their menu as this was shown to be more effective than informing restaurant staff of their allergy. Dining at a restaurant with allergenic ingredients declared in

TABLE III. Characteristics of severe food allergic reactions while dining out

	No epinephrine		Two doses of epinephrine used		Hospitalized		Intensive care unit	
Characteristic	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Children <18 y of age								
Sex								
Male	72	55.39	9	81.80	11	68.75	3	100
Female	58	44.61	2	18.20	5	31.25	0	0
Total	130		11		16		3	
Average age (y)	11		11		14		8	
Race								
American Indian or Alaska Native	4	3.08	0	0	0	0	1	33.30
Asian	15	11.54	0	0	2	12.50	0	0
Black	11	8.46	0	0	1	6.25	0	0
White	120	92.31	11	100	14	87.50	3	100
Native Hawaiian or Other Pacific Islander	3	2.31	0	0	0	0	0	0
Unknown	0	0	0	0	1	6.25	0	0
Ethnicity								
Hispanic or Latino	10	7.69	1	9.10	1	6.25	0	0
Non-Hispanic or Latino	95	73.08	8	72.70	11	68.75	3	100
Unknown	25	19.23	2	18.20	4	25	0	0
Adults >18 y of age								
Sex								
Male	39	14.83	3	11.50	8	32.00	2	28.60
Female	224	85.17	23	88.50	17	68.00	5	71.40
Total	263		26		25		7	
Average age (y)	43		28		29		56	
Race								
American Indian or Alaska Native	4	1.52	0	0	0	0	0	0
Asian	17	6.46	3	11.50	3	12.00	0	0
Black	14	5.32	1	3.80	0	0	1	14.30
White	240	91.25	25	96.20	24	96.00	7	100
Native Hawaiian or Other Pacific Islander	1	0.38	0	0	0	0	0	0
Unknown	1	0.38	0	0	0	0	0	0
Ethnicity								
Hispanic or Latino	16	6.08	1	3.80	1	4.00	0	0
Non-Hispanic or Latino	163	61.98	23	88.50	18	72.00	5	71.40
Unknown	84	31.94	2	7.70	6	24.00	2	28.60

In some cases, percentages are >100% due to those individuals of mixed race.

TABLE IV. Details of food allergic individuals in the intensive care unit

Patient	Age (y)	Sex	Allergen	Prior history	Food	Type of establishment	Two or more doses of epinephrine	Biphasic reaction
1	8	M	Egg*	Yes	–	Fast food	N, IV only	N
2	59	F	Tree nuts	Yes	Bread or salad	Other	Y	Unsure
3	56	M	Tree nuts†	Yes	Sandwich	Café	N, IV only	N
4	19	M	Milk*,†	Yes	Cheese	Fast food	Y	Y
5	15	M	Milk†	Yes	Pizza	Other	Y‡	N
6	36	F	Tree nuts (pine nut)	No	Pesto in Italian wrap	Bar	Y, late‡	N
7	60	F	Shellfish*,†	Yes	Oyster sauce	Asian	N, IV only	Y
8	4	M	Milk†	Yes	Butter	Other	Y	Y
9	61	F	Other	No	Alcohol	Other	Y	Y
10	28	F	Milk†	Yes	Cheese	Other	Y	Y

*List of ingredients, allergens, or a precautionary statement on menu.
†Staff informed about the allergy.
‡More than 3 doses of epinephrine reported.

TABLE V. Culprit food allergens that required no epinephrine, 1 dose of epinephrine, or 2 doses of epinephrine

	No epinephrine		One dose of epinephrine		Two doses of epinephrine	
Food allergen	**n**	**%**	**n**	**%**	**n**	**%**
Cereals and grains (other than wheat)	1	0.3	0	0.0	0	0.0
Beans, legumes, or pulses (other than soy)	0	0.0	3	3.0	0	0.0
Egg	37	9.4	3	3.0	0	0.0
Finned fish	9	2.3	1	1.0	0	0.0
Fruits	8	2.0	2	2.0	0	0.0
Herbs or spices	11	2.8	2	2.0	0	0.0
Meats	12	3.1	4	4.0	0	0.0
Milk	54	13.7	12	12.1	5	20.0
Mustard	1	0.3	1	1.0	0	0.0
Other	52	13.2	10	10.1	3	12.0
Peanut	48	12.2	15	15.2	6	24.0
Seeds (other than mustard, sesame)	2	0.5	1	1.0	0	0.0
Sesame	10	2.5	4	4.0	1	4.0
Shellfish	39	9.9	9	9.1	2	8.0
Soy	14	3.6	2	2.0	1	4.0
Tree nuts	48	12.2	21	21.2	7	28.0
Vegetables	12	3.1	4	4.0	0	0.0
Wheat (includes wheat gluten)	33	8.4	5	5.1	0	0.0
Non-food items	2	0.5	0	0.0	0	0.0

TABLE VI. Food allergens implicated in hospitalized individuals and those who required ICU care.

Children <18 y of age					Adults >18 y of age			
	Hospitalized		ICU		Hospitalized		ICU	
	n	%	n	%	n	%	n	%
Milk	3	18.75	2	66.67	3	12	2	28.57
Egg	2	12.5	1	33.33	1	4	0	0
Soy	0	0	0	0	1	4	0	0
Wheat	0	0	0	0	2	8	0	0
Peanut	5	31.25	0	0	4	16	0	0
Tree nuts	3	18.75	0	0	4	16	3	42.86
Shellfish	1	6.25	0	0	5	20	1	14.29
Other	2	12.5	0	0	5	20	1	14.29
Total cases	16		3		25		7	

ICU, Intensive care unit.

combination with informing restaurant staff of their allergy was shown to be the most effective means to decrease an allergic reaction. Informing restaurant staff in the absence of allergenic ingredients declared on the menu only prevented allergic reactions less than 50% of the time. Allergists can provide this information, along with information on high-risk restaurant types (ie, cafes, fast-food restaurants, Asian restaurants), to food allergic individuals when counseling patients on dining out. Informing patients that 1 in 4 reactions while dining out require the use of epinephrine underscores the importance of having epinephrine always accessible. Allergists should emphasize, at every visit, the importance of carrying 2 epinephrine autoinjectors at all times. The allergist should also review the emergency action plan at each visit and emphasize that early use of epinephrine leads to improved outcomes.

Studies have shown that most restaurant staff are ill equipped to manage an allergic reaction underscoring the need for prevention of allergic reactions and education of restaurant employees.[9-11] Specific approaches that can be employed by the restaurant industry include mandatory and regularly scheduled training for all restaurant staff—this training should not be limited to restaurant managers. Food allergy issues that should be addressed in the training include: (1) cross-contact issues (eg, small amount of allergen can lead to allergic reactions; designated allergen-free areas and separate cookware for allergic individuals can help decrease risk of cross-contamination), (2) effective methods for removal of allergen (eg, washing of hands with soap and water or commercial wipes, not antibacterial hand sanitizer or water alone), and (3) symptoms concerning for an allergic reaction and appropriate response by restaurant staff. Other means by which restaurants can decrease allergic reactions include establishing a protocol for obtaining and transmitting information about any food allergies (eg, routine question asked when taking order, note on menu stating to inform server of any allergies, direct communication of the food allergy with the chef preparing the food, full disclosure of allergenic ingredients, computerized orders with allergy highlighted). Given the current COVID-19 pandemic, it may be an apt time for the restaurant industry to implement measures such as these as they institute other practices for ensuring patron safety. Servsafe from the National Restaurant Association is an online option for training that can be considered by restaurateurs. More detailed information on strategies that can be employed by allergists, food allergic individuals, and restaurant staff can be found in the recently published Workgroup report from the AAAAI.[18]

To our knowledge, this is the largest study describing food allergic reactions while dining out. The data presented here are an update to the first comprehensive report of food allergic reactions in restaurants, which detailed peanut and tree nut allergic reactions in food-serving establishments.[15] The findings shown here using the Food Allergy Patient Registry from FARE apprise physicians, food allergic individuals, and restaurant staff of circumstances surrounding food allergic reactions while dining out. This current knowledge of food allergic reactions in restaurants is essential to support advocacy efforts relating to food allergen labeling on restaurant menus and mandatory training for restaurant staff. At the time of publication, the following states and cities have legislative policies designed to make dining out safer for food allergic individuals: Maryland, Massachusetts, Michigan, Minnesota, Rhode Island, Virginia, New York City, New York, St. Paul, Minnesota.[21,22] There is a great need to expand this list. These data will also help inform families and clinicians on best practices for dining out at restaurants with the goal of improving the quality of life of food allergic individuals.

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PSC Issue #14 list of supporting attachments

1) See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC14 & PSC15 Plan Review for Food Establishments Guide 2016

Title: Request for the re-creation of the Hand Hygiene committee

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Factors Impacting Food Workers' and Managers' Safe Food Preparation Practices: A Qualitative Study

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SUMMARY

This study collected data on food workers' self-reported food safety practices and beliefs about factors that impacted their ability to prepare food safely. Eleven focus groups were conducted with food service workers and managers in which they discussed their current implementation of seven food preparation practices (handwashing, hot holding, etc.), and the factors they believed impacted their safe implementation of those practices. Some participants reported unsafe food preparation practices, such as inappropriate glove use and not checking the temperatures of cooked, reheated, and cooled foods. Most participants, however, reported safe practices (e.g., washing their hands after preparing raw meat). Participants identified a number of factors that impacted their ability to prepare food safely, including time pressure; structural environments, equipment, and resources; management and coworker emphasis on food safety; worker characteristics; negative consequences for those who do not prepare food safely; food safety education and training; restaurant procedures; and glove and sanitizer use. Results suggest that food safety programs need to address the full range of factors that impact food preparation behaviors.

INTRODUCTION

Epidemiological research has indicated that the majority of reported foodborne illness outbreaks originate in food service establishments *(15, 23)*, and case control studies have shown that eating meals outside the home is a risk factor for obtaining a foodborne illness *(11, 16, 17, 19, 27)*. In addition, research on foodborne illness risk factors has indicated that most outbreaks associated with food service establishments can be attributed to food workers' improper food preparation practices *(1)*, and observation studies have revealed that food workers frequently engage in unsafe food preparation practices *(4, 14, 20)*. These findings indicate that improvement of restaurant workers' food preparation practices is needed to reduce the incidence of foodborne illness. Food worker intervention programs are needed to effect this improvement. However, health researchers have argued that an understanding of current practices and factors affecting those practices is necessary before behavior change efforts can be successful *(7, 10)*.

In an effort to contribute to our understanding of food workers' food preparation behavior, the Environmental Health Specialists Network (EHS-Net) conducted this study on food workers' and managers' food safety practices. EHS-Net is a

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TABLE 1. Recommended food preparation practices discussed by participants[1]

Food Preparation Practice	Recommendation
Handwashing	Food handlers should wash their hands frequently. For example, they should wash their hands after they use the restroom, before preparing food, and after they have handled raw meat or poultry.
Cross contamination prevention	Cross contamination from raw meat and poultry to other types of food should be prevented. Table tops, equipment, and utensils should be washed, rinsed, and sanitized after they have come into contact with raw meat and before they are used for anything else.
Glove use	To minimize hand-food contact, gloves should be worn when handling ready-to-eat food or raw food with your hands.
Determining food doneness	When cooking raw meat or poultry, a thermometer should be used to check that these foods have reached recommended temperatures at the end of the cooking process.
Holding	Hot foods should be held at 140 degrees or above, and cold foods should be held at 41 degrees or below. Additionally, the temperatures of held food should be checked periodically to ensure that the foods are being held at safe temperatures.
Cooling	Hot foods should be cooled from 140 degrees to 70 degrees within two hours and from 70 degrees to 41 degrees within four hours. The temperatures of cooling food should be checked periodically to ensure that the foods are being held at safe temperatures.
Reheating	Reheated food (food that has been previously cooked in the establishment and is being reheated for service) should be reheated to 165 degrees or higher. The temperature of reheated food should be checked at the end of the reheating process to ensure that the food reaches 165 degrees.

[1]Participants were asked to discuss the factors impacting their ability to implement these recommended food preparation practices.

network of epidemiologists and environmental health specialists from the Centers for Disease Control and Prevention (CDC), the US Food and Drug Administration (FDA), the US Department of Agriculture (USDA), and eight state public health agencies (in California, Colorado, Connecticut, Georgia, Minnesota, New York, Oregon, and Tennessee) that focuses on the investigation of environmental antecedents of foodborne illness. In this study, data were collected from food workers on their food safety practices and beliefs about the factors that impact their ability to prepare food safely. Focus groups were used to collect the data because they supply descriptive, qualitative data that can be difficult to acquire through other research methods.

MATERIALS AND METHODS

Eleven focus groups were conducted with food service workers and managers from restaurants in the eight EHS-Net states. Five groups were conducted with English-speaking food workers, four groups were conducted with English-speaking managers, and two groups were conducted in Spanish with workers whose primary language was Spanish. Twenty-six managers and 30 workers participated in the English-speaking focus groups; 14 workers participated in the Spanish-speaking groups. The focus groups were conducted through telephone conference calls, as they have been found to be effective in collecting information from participants who are difficult to recruit or who are scattered geographically *(12, 26),* as the participants of this study were. Evidence suggests that, compared with face-to-face focus groups, telephone focus groups generate as much information and provide more anonymity for participants *(26).*

To obtain participants, recruiters called restaurants randomly selected from purchased business lists to request participation from a kitchen worker or manager. To be eligible for participation, workers had to have worked in a restaurant kitchen for at least three months and managers had to have worked as a kitchen manager for at least three months. Because of initial difficulty in recruiting Spanish-speaking participants, recruitment for Spanish-speaking participants was limited to areas within the EHS-Net states with relatively high proportions of Hispanic populations. Study participants received an incentive of 60 dollars for their participation.

Each focus group consisted of 4 to 8 participants who responded to questions posed by a group moderator. Participants discussed seven food preparation practices—handwashing, prevention of cross contamination, glove use, determining food doneness, hot and cold holding, cooling, and reheating. These practices were chosen for discussion because their improper implementation has been associated with foodborne illness in food service establishments *(1, 9).* In the worker

TABLE 2. Practices described by worker participants

Practice	Number of groups[a]
Handwashing	**7**
Wash hands after visiting restroom	7
Wash hands before preparing food	7
Wash hands before preparing raw meat/poultry	7
Wash hands when changing tasks	7
Wash hands periodically	7
Wash hands before putting on gloves/when changing gloves	4
Wash hands after handling money	4
Wash hands after sneezing/coughing	4
Wash hands after eating/drinking	3
Wash hands after taking a break	3
Wash hands after touching face, hair, or clothes	3
Use sanitizer	5
Cross contamination prevention	**7**
Clean and sanitize work surfaces, utensils, equipment	7
Sanitize (but not clean and rinse) work surfaces, utensils, equipment	3
Use gloves or utensils to prevent bare hand contact	6
Keep raw meat/poultry separate from other foods with separate storage areas	6
Keep raw meat/poultry separate from other foods during preparation with separate work areas/surfaces	5
Wash hands after preparing raw meat/poultry	5
Use stainless steel equipment	2
Work only with raw meat/poultry until task is complete	2
Flip cutting boards after using one side	1
Glove use	**7**
Wear gloves when in the kitchen or preparing food	6
Wear gloves when preparing raw meat/poultry	6
Wear gloves when hands have cuts or scratches	2
Wear gloves when preparing food don't want to touch directly	2
Wash hands with every glove change	5
Change gloves when changing tasks or products	5
Change gloves after preparing raw meat/poultry	3
Change gloves when damaged or dirty	2
Change gloves periodically	2
Do not wear gloves	5
Do not wear gloves when cutting food	2
Use gloves improperly	2

Practice	Number of groups[a]
Determining food doneness	**6**
Use thermometer	6
Use length of time cooking	6
Use appearance of food	3
Use feel of food	3
Use thermometer with certain foods	2
Use thermometer when inexperienced/working with new food	2
Holding	**5**
Use steam tables	4
Use walk-in coolers	4
Use sandwich/preparation tables	3
Use salad bars	2
Check temperatures of held foods	3
Record temperatures in temperature logs	3
Managers check/record temperatures	2
Set shelf life for held food	3
Throw away foods held at improper time/temperature	3
Stir held foods	2
Cover held foods	2
Cooling	**5**
Place cooling food in walk-in coolers	5
Place cooling food in shallow or small pans	4
Use ice baths	4
Use cooling wands/paddles	2
Use blast chiller	1
Check temperatures of cooling food	5
Do not check temperatures of cooling food	5
Record temperatures in temperature logs	2
Follow improper cooling practices	4
Reheating	**3**
Reheat food prior to placing in holding	2
Do not reheat prior to placing in holding	2
Discard foods rather than reheat/Reheat only once	2
Check the temperatures of reheated foods	3
Record temperatures in temperature logs	1
Have only experienced workers reheat	1

The numbers in bold in this column (column entitled 'Number of Groups') represent the number of groups in which participants were asked to discuss the topic (e.g., Handwashing, Glove Use). The non-bolded numbers in this column represent the number of groups in which the practice was mentioned by at least one participant.

groups, participants first discussed their current implementation of these seven practices and then discussed the factors that influenced their ability to engage in these practices according to recommendations. (These recommendations are based on FDA's 2001 Food Code [9] and are presented in Table 1). For example, participants were asked to describe when they washed their hands while at work. After this discussion, the moderator read the recommendations concerning handwashing, and participants were then asked to discuss what made it easier or more difficult for them to wash their hands according to the recommendations. In the manager groups, participants were not asked to discuss their current food preparation practices because of concerns about their willingness to discuss unsafe practices. Thus, managers discussed only factors that influenced their and their workers' ability to implement recommended practices. The focus group questions and recommendations were derived in part from questions developed by Kendall, Melcher, and Paul *(18)*.

Each focus group discussion was taped and transcribed. We systematically reviewed these transcripts and identified and categorized common themes among the responses.

This study was approved by CDC's Institutional Review Board (protocol # 3773).

RESULTS

Described in this section are the themes identified in the workers' discussions of their current food preparation practices and in the workers' and managers' discussions of the factors that influenced their ability to engage in these practices according to recommendations. These themes are also presented in Tables 2 and 3 along with the number of groups that discussed each theme. The findings for all groups (English and Spanish-speaking worker groups and manager groups) are discussed together. The practices of determining food doneness, holding, reheating, and cooling were not discussed in every focus group, either because time constraints prevented a topic from being discussed or because participants were unfamiliar with the practice (e.g., participants did not work in a restaurant that engaged in the practice or did not have responsibilities pertaining to the practice).

Handwashing practices

When asked to describe when they washed their hands at work, some workers in every group said they washed their hands after visiting the restroom, before preparing food in general and raw meat or poultry specifically, and when they changed tasks, work stations, or items they were handling (e.g., changing from handling money to food) (Table 2). Some workers in every group also said they washed their hands periodically, either because their hands felt dirty, or because

TABLE 3. Factors impacting food preparation practices discussed by worker and manager participants

Factors impacting:	Number of groups[1] Workers	Managers	Total
Handwashing	**7**	**4**	**11**
Sink accessibility	5	4	9
Time pressure/high volume of business/staffing	4	4	8
Management emphasis	4	4	8
Negative consequences	5	2	7
Sanitizer use	3	3	6
Glove use	2	3	5
Restaurant procedures	3	2	5
Worker motivation/experience/age	2	2	4
Expectations of reciprocal treatment	3	1	4
Personal preferences	3	0	3
Food safety education and training	1	2	3
Coworker emphasis	2	1	3
Concern with sanitary appearance	1	1	2
Effect on hands	0	2	2
Adequate resources (e.g., soap)	1	0	1
Cross contamination prevention	**7**	**4**	**11**
Multiple, color-coded cutting boards	5	3	8
Glove and utensil use	6	2	8
Sanitizer use	4	2	6
Separation of work areas/tasks	3	3	6
Management emphasis	3	2	5
Food safety education and training	2	2	4
Time pressure/high volume of business/staffing	1	3	4
Pre-cooked or prepared meat	3	1	3
Negative consequences	2	1	3
Coworker emphasis	1	0	1
Language differences	0	1	1
Glove use	**7**	**4**	**11**
Manager emphasis/requirement	5	2	7
Negative consequences	4	2	6
Comfort and fit of gloves	4	2	6
Type of work	2	3	5
Personal preferences	4	1	5
Allergies to glove materials	2	3	5
Concern about sanitary appearance	3	0	2

Factors impacting:	Number of groups[1] Workers	Managers	Total
Glove use (Continued)	**7**	**4**	**11**
Adequate resources (e.g., gloves)	1	1	2
Time pressure/high volume of business/staffing	1	1	2
Worker motivation/experience/age	1	0	1
Coworker emphasis	1	0	1
Use of thermometer for food doneness	**7**	**4**	**11**
Time pressure/high volume of business/staffing	4	3	7
Type of meat	3	3	6
Restaurant procedures	3	2	5
Worker motivation/experience/age	3	1	4
Health regulations and inspections	0	3	3
Thermometer sanitation	2	1	3
Thermometer type	0	2	2
Holding	**5**	**4**	**9**
Equipment/thermometers	3	4	7
Management emphasis	3	2	5
Food safety education and training	2	2	4
Time pressure/high volume of business/staffing	2	2	4
Restaurant procedures	0	3	3
Negative consequences	0	2	2
Worker motivation/experience/age	1	0	1
Space	0	1	1
Hours of operation	0	1	1
Quality of food	0	1	1
Cooling	**5**	**3**	**8**
Time at which cooling occurs	2	2	4
Worker motivation/experience/age	2	0	2
Equipment/thermometers	2	0	2
Management emphasis	0	2	2
Space	0	2	2
Time pressure/high volume of business/staffing	1	0	1
Reheating	**3**	**3**	**6**
Food safety education and training	2	1	3
Thermometers	2	0	2
Time pressure/high volume of business/staffing	0	1	1

[1]The numbers in bold in this column ('Number of Groups') represent the number of groups in which participants were asked to discuss the topic (e.g., Handwashing, Glove Use). The non-bolded numbers in this column represent the number of groups in which the factor was mentioned by at least one participant.

of a restaurant process that required handwashing (e.g., a bell rings every hour signifying that workers must wash their hands). To a lesser extent, workers also said they washed their hands before putting on gloves or when changing their gloves, and after handling money, sneezing or coughing, eating or drinking, taking a break, or touching their face, hair, or clothes. Workers also said they cleaned their hands with bottled hand sanitizer or cloths stored in sanitizer buckets.

Factors impacting handwashing practices

Workers and managers most frequently identified sink accessibility as a factor that impacted the ability to wash hands as recommended (Table 3). Some participants in all groups said that having too few sinks or sinks inconvenient to the work area were barriers to handwashing, particularly when workers were experiencing time pressure. Time pressure, because of high volumes of business or inadequate staffing, was also frequently mentioned as a factor that negatively impacted proper handwashing. Participants indicated that they were not able to take the time to wash their hands when they had a large number of orders to prepare (e.g., "When your place is booming…only thing they're worried about is those customers getting their food").

Participants identified several factors they believed impacted handwashing positively. They said management and coworker emphasis on and attention to proper handwashing was a facilitator of handwashing (e.g., "If I forget to wash my hands, my supervisor speaks up."). Negative consequences for improper handwashing was also discussed as a handwashing facilitator (e.g., workers getting reprimanded or fired; customers getting sick). Other positive factors included restaurant procedures that encouraged handwashing (e.g., a bell rings every hour signifying that workers must wash their hands; logs in which workers were required to record every handwashing); worker motivation and food preparation experience (often associated with age, according to participants); expectations of reciprocal treatment from other food workers (e.g., "If I expect that of somebody else, I expect that of myself"); personal preferences for clean hands; food safety education and training on proper handwashing practices and their importance; concerns about appearing sanitary to customers (particularly in kitchens where workers can be seen by customers); and adequate re-

sources (e.g., soap). A few participants indicated that frequent handwashing sometimes made hands chapped and raw, which they believed could be a barrier to handwashing.

Some participants discussed sanitizer as a facilitator of clean hands. These participants said they sometimes used sanitizer in situations in which they did not feel they had the time to stop and wash their hands. Some workers said the use of sanitizer in place of handwashing was acceptable only in some situations (e.g., acceptable after making a sandwich but not after preparing raw meat). Even though these participants typically discussed sanitizer positively, comments suggested that sanitizer may actually negatively impact handwashing, as some participants seemed to be using sanitizer instead of washing their hands. Similarly, some participants said they used gloves to ensure the cleanliness of their hands. However, other participants expressed concern that glove use was a barrier to handwashing. These participants said that compared to workers who did not use gloves, some workers who used gloves washed their hands less, perhaps because they assumed that they did not need to wash their hands if they wore gloves.

Cross-contamination prevention practices

When asked to describe how they handled raw meat or poultry, participants described several different cross-contamination prevention practices (Table 2). Workers in all groups said they cleaned and/or sanitized their work surfaces, utensils, *and* equipment after preparing raw meat or poultry. Some said they cleaned and sanitized; however, some participants' comments indicated that although they wiped their work surfaces with a sanitizer, they did not clean and rinse those surfaces first (e.g., "Every time you put raw meat on there [your work surface], you should wipe it down with a clean towel [from your sanitizer bucket]").

Workers said they used gloves and utensils to prevent bare hand contact with raw meat and poultry and kept raw meat and poultry separate from other foods or from other types of raw meat and poultry during storage and preparation. Workers mentioned two methods for keeping these foods separate during preparation: separate work areas (e.g., meat is cut in the cooler, vegetables are cut elsewhere); and separate work surfaces, examples of which typically included color-coded cutting boards for use with different kinds of food (e.g., green boards for vegetables, yellow boards for chicken). Workers also said they washed their hands after preparing raw meat or poultry. Some workers reported using stainless steel bowls and work surfaces when working with raw meat or poultry, and a few said that when working with raw meat or poultry, they did nothing else until they completed the task. Finally, a few workers said that after getting one side of the cutting board dirty, they flipped the board over to its other side rather than cleaning it or getting a new one.

Factors impacting cross-contamination prevention practices

When asked what factors impacted their ability to engage in practices to prevent cross contamination from raw meat and poultry to other foods, participants most frequently identified multiple color-coded cutting boards as a positive factor (Table 3). Multiple boards helped ensure that workers could get clean boards when they needed them, as opposed to re-using dirty boards, and color-coded boards helped ensure that workers used different boards for foods that needed to be kept separated. The use of gloves and utensils with raw meat or poultry was also mentioned as a facilitator of cross-contamination prevention. However, as with handwashing, some participants expressed concern that glove use could act as a barrier to cross-contamination prevention because glove wearers may not wash their hands as often as they should. Participants in most groups also said that using sanitizer (e.g., "bleach water") was a facilitator of cross-contamination prevention because it allowed them to sanitize their equipment (e.g., knives, cutting boards) quickly.

Other identified facilitators of cross-contamination prevention included: separation of work areas and tasks, to ensure that raw meat or poultry and other foods are kept apart; management and coworker emphasis on and attention to cross-contamination prevention (e.g., "We look out for each other, and we say things to each other if it's not being done"); food safety education and training on cross-contamination prevention and its importance (e.g., "If they don't know the reason why, they'll keep doing it"); pre-cooked or prepared meat, which allows minimal meat preparation; and negative consequences for lack of cross-contamination prevention (e.g., restaurant receiving violations; employee getting fined). Time pressure and language differences between managers and workers (e.g., "Sometimes it's just really hard to relay the facts") were identified by some participants as barriers to cross-contamination prevention.

Glove use practicess

When asked when they used and changed gloves at work, workers in six groups said they wore gloves when in the kitchen or preparing food and when they worked with raw meat or poultry (Table 2). To a lesser extent, workers also said they wore gloves when they had cuts on their hands and when preparing food that they did not want to touch directly (e.g., food to which they had allergies or would make their hands smell). Some workers said they washed their hands with every glove change, and changed their gloves when they changed tasks or products (e.g., changing from making one sandwich to another), after preparing raw meat or poultry, and when their gloves were damaged or dirty. Several workers made comments that suggested their glove changing was not necessarily based on their food preparation activity; rather, they simply changed their gloves periodically throughout their shift. A few workers said they did not wear gloves at all (some of these said they used tongs or tissue paper when preparing some foods), and several workers said they did not use gloves when cutting food because gloves made the task more difficult. A few workers described unsafe glove practices, such as changing gloves without washing hands and washing hands with gloves on.

Factors impacting glove use practices

Workers and managers identified several factors that positively impacted glove use when handling raw or ready-to-eat food (Table 3). These factors included management and coworker emphasis on and attention to glove use (including glove use requirements and managers wearing gloves appropriately as a model for proper glove use); negative consequences for not wearing gloves (e.g., workers getting suspended from work); personal preferences; allergies to glove materials; concerns about appearing sanitary to customers; adequate resources (e.g., gloves); and worker motivation and experience.

Participants said gloves were often uncomfortable or did not fit well, which they believed negatively impacted glove use. The type of work was also mentioned

as a factor that impacted glove use, as participants believed that gloves made some work more difficult. For example, participants said gloves interfered with cutting foods (because the gloves got in the way of the knife) and checking the doneness of meat with a finger. Time pressure was also mentioned as a barrier to glove use.

Determining food doneness practices

Although some workers in all six groups that discussed determining food doneness practices said they sometimes used thermometers to check the temperatures of some cooked foods, many felt they did not need to use a thermometer because they had learned through experience to determine doneness by how long food cooked, the appearance of the food, and/or the feel of the food (Table 2). Workers were more likely to say they used thermometers with some types of food than with others (e.g., seafood versus steak; larger pieces of meat versus smaller pieces). Comments also suggested that those employees working with new foods, who were inexperienced, or who were training inexperienced workers were more likely to use thermometers.

Factors impacting determining food doneness practices

When asked what factors impacted their use of thermometers to determine the doneness of cooked meat and poultry, workers and managers most frequently mentioned time pressure (Table 3). Participants said taking the temperature of every piece of meat would be too time consuming and possible only with additional staff. Participants also said the type of meat impacted the difficulty of checking temperatures with a thermometer; they believed it was easier and took less time to check the temperatures of some foods (e.g., large pieces of meat) than others (e.g., hamburgers). Restaurant processes such as temperature logs were seen as facilitators of using a thermometer to check temperatures, as were health regulations and inspections, as temperature logs were kept as documentation for health inspections. Worker experience was also identified as a factor that impacted thermometer use—participants said experienced staff did not need to check temperatures because their experience allowed them to use other factors (e.g., appearance and feel of food; length of cooking time) to determine when food was done. One participant said that checking temperatures may be more likely with "fast" thermometers (e.g., infrared thermometers) than with other thermometers. Finally, a few workers said having to sanitize the thermometer between each use was a barrier to temperature checking.

Holding practices

Participants indicated that holding of hot foods occurred in steam tables, and holding of cold foods occurred in walk-in coolers, in sandwich or preparation tables where food is kept in stainless steel inserts in the top of a table and cooled from below, or in salad bars where food items are set in ice that is kept cool from below (Table 2). Most workers said they periodically checked the temperatures of held food, although there was variation in how often temperatures were checked (from "every half-hour to hour" to every shift change). Temperatures were checked with probe thermometers or with thermometers built in to equipment that display the temperature continuously. Several workers said their restaurants used temperature logs to record temperatures of held food every time they were checked. Comments from participants suggested that managers were more likely to check and record temperatures than were workers. Some workers mentioned that they had "shelf lives" for products that were being held (e.g., two or three hours), particularly during busy times when holding lids were likely to be open for long periods of time. Others said they threw away food that had not been held at appropriate temperatures or was held too long. Some workers also indicated that they periodically stirred foods that were being held hot to ensure even temperatures, and kept held foods covered as much as possible.

Factors impacting holding practices

Equipment was the most frequently mentioned factor impacting managers' and workers' ability to hold food at the proper temperatures and to check those temperatures periodically (Table 3). Workers and managers said that equipment problems, such as malfunctioning refrigerator blowers and heating elements, were barriers to proper holding, while properly maintained equipment and special kinds of equipment were facilitators of proper holding. Such equipment included hot-holding equipment that notified workers whenever the temperature drops below a set point and "ice blankets" that are placed on top of cold-held food during busy times when lids were open. Participants also said having an adequate number of thermometers for checking temperatures was important. Other factors believed to positively impact proper holding included: management emphasis on and attention to proper holding (e.g., "[when it's busy], "…the manager has got to remember to come back and grab them [temperatures]"; food safety education and training; restaurant procedures (e.g., temperature logs); negative consequences for improper holding (e.g., being required by health inspector to throw out costly food because it was held improperly); worker motivation and experience; adequate space for all foods that need to be held (e.g., "He's got limited space in his steam table, he will start jockeying things…to put something that he feels is more important to have hot"); and hours of operation that allow restaurants to close between lunch and dinner to check holding temperatures. Identified barriers to proper holding included time pressure and high volumes of business, which cause frequent opening of lids and doors of the holding equipment, and concerns regarding reduced quality of food (e.g., a small amount of hot-held cream soup easily burns).

Cooling practices

Workers in most groups that discussed cooling described the following practices: placing cooling food in walk-in coolers; transferring cooling food to shallow or smaller pans; and using ice baths (Table 2). A few workers indicated that they used cooling wands or paddles to cool food, and one worker indicated that his establishment used a blast chiller to cool food. Some workers said they checked the temperatures of cooling foods and recorded them in a temperature log. However, at least some workers in each group said they did not take the temperatures of cooling foods, and some workers reported other unsafe practices, such as leaving cooling food out on counters and only checking the temperature of cooling food the morning after the food had been placed in a walk-in cooler.

Factors impacting cooling practices

Workers and managers most frequently said the time at which cooling occurs, usually closing, was a barrier to proper cooling, as workers often did not take the time to cool properly (Table 3).

TABLE 4. Factors impacting safe food preparation practices discussed by worker and manager participants

Factor	Hand-washing	Cross contam.	Glove use	Food doneness	Holding	Cooling	Reheating
Time pressure/high volume of business/staffing	√	√	√	√	√	√	√
Structural environment, equipment, resources	√	√	√	√	√	√	√
Management/coworker emphasis	√	√	√		√	√	
Worker characteristics	√		√	√	√	√	
Negative consequences	√	√	√		√		
Education and training	√	√			√		√
Restaurant procedures	√			√	√		
Gloves and sanitizers	√	√					

Note: A check mark indicates that the factor was mentioned by participants in discussions of that practice.

Similarly, a few participants said that time pressure caused by high volumes of business was a barrier to proper cooling. One worker believed that additional staff that could be responsible for cooling during busy times would help alleviate this problem. Facilitators of proper cooling described by participants included worker motivation, availability of thermometers and equipment such as cooling wands, management emphasis on and attention to proper cooling, and adequate space for cooling equipment, (e.g., space for multiple, shallow containers and quick chill equipment).

Reheating practices

Several workers said they reheated food prior to placing it in hot holding, although one participant said workers in his establishment sometimes place food directly on the steam table without first reheating it to the proper temperature on the stove. Some participants indicated that their practice was to discard left-over food rather than reheat it or to reheat left-over food only once. Most, but not all, workers said they checked the temperatures of reheated food (Table 2), and some said they recorded temperatures of reheated food in temperature logs. One worker indicated that inexperienced workers were not responsible for reheating—only he and his manager reheated food.

Factors impacting reheating practices

Workers and managers identified few factors during the discussions on reheating (Table 3). However, participants did say that food safety education and training were important for safe reheating practices, as were thermometers. A few also said time pressure could be a barrier because reheating can be time consuming and workers may take shortcuts.

Consistencies in factors impacting practices

There are a number of consistencies in the factors participants identified as impacting their safe food preparation practices. Eight factors were mentioned in the context of two or more food preparation practices, and these factors are discussed below and presented in Table 4.

- *Time pressure/high volume of business/staffing.* The issue of time pressure was mentioned in the discussions of all seven food preparation practices. Participants said time pressure caused by high volumes of business and/or inadequate staffing made it difficult for them to wash their hands, change their gloves, clean their cutting boards, check the temperatures of cooked and held food, and cool and reheat foods properly.
- *Structural environment, equipment, and resources.* Issues associated with the structural environment of the restaurant kitchen, equipment, and resources arose in the discussions of all seven practices. Participants said accessible sinks and adequate resources, such as soap and gloves, facilitated handwashing and glove use; multiple color-coded cutting boards and separate work areas for different types of food helped prevent cross contamination; and multiple thermometers, well-maintained equipment, and certain kinds of equipment (e.g., blast chillers and infrared thermometers) facilitated temperature control. Not having enough workspace, however, made cooling and holding foods at proper temperatures difficult.
- *Management/coworker emphasis.* Management and coworker emphasis on safe food preparation practices was discussed in relation to five food preparation practices. Participants said having managers and coworkers who emphasized safe food preparation and who paid at-

tention to others' food preparation practices facilitated food safety.

- *Worker characteristics.* Participants identified several characteristics of food workers that positively impacted five practices. These included experience, motivation, age, preferences for clean hands, concerns about appearing sanitary to customers, and expectations of reciprocal treatment from other food workers. A few said allergies to glove materials negatively impacted glove use practices.
- *Negative consequences.* In discussions of four practices, participants said workers were more likely to engage in safe practices when they knew there would be negative consequences if they did not. These negative consequences could be for workers, for the restaurants, or for the restaurants' customers.
- *Education and training.* Participants indicated in the discussions of four practices that they thought food safety education and training was important to safe food preparation. Several participants emphasized that workers should be taught *why* engaging in safe food preparation practices was important, not just how to engage in those practices.
- *Restaurant procedures.* In discussions of three practices, participants' comments suggested that some restaurant procedures facilitated safe food preparation. For example, some restaurants required workers to record handwashing activities and food temperatures in logs.
- *Gloves and sanitizers.* Some participants believed that gloves and sanitizers facilitated food safety because their use helped to prevent cross contamination and keep hands clean. However, comments indicated that use of these sanitary supplements may sometimes have a negative impact on food safety. For example, some participants said they sanitized their cutting boards without first cleaning them and used sanitizer instead of washing their hands, and some participants expressed concern that glove use actually lowered handwashing rates because some workers used gloves incorrectly.

DISCUSSION

Some food workers in this study reported unsafe food preparation practices. A few workers reported unsafe hand hygiene practices, such as not washing their hands when changing gloves and using sanitizers instead of washing their hands. Several workers said they sanitized but did not wash and rinse their equipment after working with raw meat and did not check the temperature of all the meat they cooked because they believed they could determine food doneness through other methods (e.g., appearance and feel of the food). Others said they did not check the temperature of food being reheated or cooled. Most workers, however, reported safe food preparation practices. For example, workers described a variety of situations in which they washed their hands and changed their gloves, and said they cleaned their work surfaces and equipment after preparing raw meat or poultry and checked the temperatures of held food. These findings indicate that our participants were aware of and engaged in multiple food safety practices.

Previous research, however, suggests that food workers (and consumers) report engaging in food safety practices more frequently than they actually engage in those practices *(20, 24, 25)*. This phenomenon is likely the result of the social desirability bias, which is the tendency for people to report greater levels of socially desirable behavior (such as safe food preparation practices) than they actually engage in, or to report their best behavior rather than their typical or worst behavior. Although it is not possible to determine the extent to which our participants over-reported their safe food preparation practices, it is likely that they do not engage in these practices as frequently as they have reported.

Participants in this study identified a number of factors that impacted their ability to engage in safe food preparation practices. Time pressure and structural environments, including equipment and resources, were the two most consistently identified factors. Participants said time pressure had a negative impact on safe food preparation while structural environments, equipment, and resources supportive of food safety (e.g., accessible sinks, sufficient space for food safety procedures, multiple cutting boards, equipment that facilitated food safety, availability of soap and gloves) had a positive impact on safe food preparation. Other factors consistently identified by workers as having positive impacts on safe food preparation included managers and coworkers who emphasized food safety; worker characteristics, such as age, experience, and preferences for clean hands; negative consequences for those who do not handle food safely; food safety education and training; and restaurant procedures that encouraged food safety. Participants also identified glove and sanitizer use as factors influencing safe food preparation practices. Although some participants believed that these sanitary supplements had a positive influence, other participants indicated that these supplements could have a negative influence if used incorrectly.

The few other studies on this topic have reported similar findings. Kendall, Melcher, and Paul's *(18)* and Clayton and Griffith's *(3)* studies with food workers identified several of the same barriers and facilitators reported here, including time shortages, inadequate staffing, education and training, sink accessibility, availability of properly working equipment, and management concern for and attention to food safety.

Many of these factors are heavily influenced by management. For example, although managers may not be able to control the customer "rushes" that often result in time pressure, managers can emphasize the importance of food safety over speed and attempt to ensure that staffing is adequate to meet the demand. Additionally, managers often directly impact whether: workers have the equipment needed to prepare food safely; there are negative consequences for workers for unsafe food preparation practices; food safety training is provided to workers; and restaurant procedures support food safety. The findings reported here suggest that management plays a significant role in the extent to which food workers engage in safe food preparation practices. The findings also support FDA's contention that active managerial control – implementation and supervision of food safety practices by the person-in-charge — is important to food safety *(8)* and suggest that future food safety initiatives should ensure a significant focus on management and active managerial control.

Although the findings presented here suggest that a variety of factors impact safe food preparation practices, many of the current efforts in food safety are fo-

cused primarily on one factor—education. The findings from this study and others *(5, 21)* indicate that education is important for food safety. However, our results also suggest that providing food safety education to food workers is not enough to ensure that they will handle food safely, as a number of factors may impact their ability to implement that education. Other research supports this implication. Several studies have found that even when food workers demonstrate knowledge of safe food preparation practices, they do not always engage in those practices *(2, 3, 14, 20)*. In order to be successful, food safety intervention programs must do more than provide food safety training; they must also address the full range of factors that impact food preparation behaviors. Other researchers have made similar arguments; for example, Clayton and Griffith *(3)* argued that programs designed to increase safe food -preparation practices will be effective only if the resources and management systems are in place to enable and encourage food workers to implement those practices. Ehiri and Morris argued that food safety training would be more effective if it were founded on "principles which take into account employee motivations and other resource and environmental constraints…" *(6)*.

Participants' mixed beliefs concerning the influence of glove use on food safety reflects the ongoing glove use debate among food safety regulators, researchers, and industry representatives. Research indicates that proper glove use can decrease the transfer of pathogens from hands to food *(22)*. However, there is also evidence that glove use may promote poor handwashing practices *(12)*. More research is needed to determine the relationship between glove use, contamination, and handwashing.

The results presented here are qualitative and should not be generalized to a larger population in any statistical sense. However, these results can be useful for guiding future work in food safety. For example, future research might focus on determining which of the factors identified in this study have the greatest impact on food preparation practices.

The findings in this study have implications for food safety programs. Programs may wish to evaluate and modify their food safety activities in light of the findings provided here. For example, they could develop and implement activities that would contribute to a fuller understanding of the factors that impact food safety in food service establishments in their jurisdiction. They could then develop and test strategies designed to address those factors and eventually incorporate successful strategies into their regular food safety activities. Such activities should improve the effectiveness of these food safety programs as well as contribute to our broader understanding of effective food safety strategies.

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Hand Washing Frequencies and Procedures Used in Retail Food Services

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ABSTRACT

Transmission of viruses, bacteria, and parasites to food by way of improperly washed hands is a major contributing factor in the spread of foodborne illnesses. Field observers have assessed compliance with hand washing regulations, yet few studies have included consideration of frequency and methods used by sectors of the food service industry or have included benchmarks for hand washing. Five 3-h observation periods of employee ($n = 80$) hand washing behaviors during menu production, service, and cleaning were conducted in 16 food service operations for a total of 240 h of direct observation. Four operations from each of four sectors of the retail food service industry participated in the study: assisted living for the elderly, childcare, restaurants, and schools. A validated observation form, based on 2005 Food Code guidelines, was used by two trained researchers. Researchers noted when hands should have been washed, when hands were washed, and how hands were washed. Overall compliance with Food Code recommendations for frequency during production, service, and cleaning phases ranged from 5% in restaurants to 33% in assisted living facilities. Procedural compliance rates also were low. Proposed benchmarks for the number of times hand washing should occur by each employee for each sector of food service during each phase of operation are seven times per hour for assisted living, nine times per hour for childcare, 29 times per hour for restaurants, and 11 times per hour for schools. These benchmarks are high, especially for restaurant employees. Implementation would mean lost productivity and potential for dermatitis; thus, active managerial control over work assignments is needed. These benchmarks can be used for training and to guide employee hand washing behaviors.

An estimated 250 to 350 million people in the United States have experienced acute gastroenteritis, and 25 to 30% of the cases are thought to have been foodborne illnesses *(14).* Viruses and bacteria have been identified as the most likely causative agents *(8).* Effective hand washing decreases the transfer of viruses and bacteria. Poor personal hygiene practices, including improper hand washing, have been identified as common causes of foodborne illness *(12),* and observational studies have revealed that hand washing is not done often enough in retail food service *(9, 11, 13).* The Centers for Disease Control and Prevention (CDC) identified hands as one of the most likely means by which enteric viruses are transmitted to foods *(6).* Individuals in charge of retail food services have the responsibility to follow good hand washing practices to ensure the safety of food prepared and served to customers.

Between January 1996 and November 2000, 348 outbreaks caused by Norwalk-like virus were reported to the CDC. Of these outbreaks, 39% occurred in restaurants, 29% in nursing homes and hospitals, 10% in vacation venues, and 9% in other settings *(8).* Although *Caliciviridae* virus infections are difficult to identify, these viruses may be the most common cause of known and probably unknown cases of foodborne illness *(14).*

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It is important to identify causes of foodborne illnesses and to recognize contributing practices in food service establishments because research has indicated that foodborne outbreaks are likely to occur in food service operations *(3, 5, 7, 12).* Poor personal hygiene has been identified as a contributing factor to such outbreaks *(5, 7, 12).* In one study of retail food service establishments from 1988 to 1992, the two practices most commonly reported as contributing to foodborne illness were improper holding or storage temperatures and poor personal hygiene among food handlers *(7).* In two U.S. Food and Drug Administration (FDA) studies *(19, 21),* inadequate hand washing practices by workers were found in all types of retail food services.

Insufficient and inadequate hand washing by employees in retail food services is a well-known contributing factor to foodborne illnesses and is particularly critical when employees are preparing and serving food to vulnerable individuals such as young children and the elderly *(20).* Previous research identified employees' self-reports of hand hygiene behavior as complying with FDA Food Code *(22)* recommendations less than 30% of the time *(10).* In interviews conducted with the person in charge of the food service *(1),* only 52% of those individuals interviewed were able to correctly describe the hand washing procedure identified in the Food Code. Focus groups working with restaurant workers in two Oregon counties found that barriers to proper hand washing included multiple factors: time pressures, inadequate facilities and supplies, lack of account-

ability, and lack of manager and coworker involvement *(17)*.

A few field studies have included observations of employee hand washing practices in the work area, including health care *(4, 15)* and retail food services *(11, 19, 21)*. In the FDA's follow-up report on the occurrence of foodborne illness risk factors in selected institutional, restaurant and retail store facility types *(21)*, researchers found that employee noncompliance with personal hygiene standards in the Food Code remained high. The proportion of employees who were out of compliance with proper and adequate hand washing regulations ranged from 34% for hospital food service employees to 73% for employees at full-service restaurants. Green et al. *(11)* conducted an observational study of the hand washing practices of restaurant food workers in 333 restaurants located in a six-state region. They found 32% compliance with Food Code recommendations, with appropriate methods used only 27% of the time. Significantly higher compliance was observed for hand washing at appropriate times during food preparation tasks than for hand washing after touching parts of the body or when gloves were worn. The researchers concluded that higher compliance associated with food preparation tasks may be due to the understanding by workers of the importance of hand washing when handling food. In another study of the impact of frequent hand washing by nurses, skin irritation and dryness increased significantly when hands were washed with the unmedicated soap available in the hospital *(4)*.

Paez et al. *(16)* pilot tested a structured hand washing observation form for deli-type food service establishments, a type of quick-service restaurant that serves ready-to-eat foods that require time and temperature control. Based on 30 h of direct observation, these researchers proposed benchmarks for employee hand washing of six times per hour during production and 11 times per hour during service. Benchmarking is a process of using established standards of best practice as a reference point for measurement or comparison. Managers and employees could use these benchmarks as a way to determine effectiveness of hand washing practices and to develop protocols to increase hand washing.

The current study is an elaboration on previous work by using the tested form in observations at four types of retail food service operations: assisted living centers, childcare centers, restaurants, and schools that served ready-to-eat foods (e.g., roast beef sandwich with a lettuce leaf). Observations were made during the food preparation, service, and cleaning phases. The purpose of this study was to analyze hand washing practices (frequency and procedures) of food service employees in operations that serve ready-to-eat food to vulnerable individuals and to propose hand washing benchmarks specific to these four sectors of retail food service.

MATERIALS AND METHODS

As part of a larger project investigating cross-contamination in retail food services that offered no-cook foods requiring time and temperature controls and served vulnerable individuals, hand washing practices of employees during production, service, and cleaning phases were observed. The data collection form and research protocol were approved by the Human Subjects Review Committee of the Institutional Review Board at Iowa State University.

Sample selection. A convenience sample of 16 retail food service locations from one midwestern state agreed to participate in the study. The sample consisted of four assisted living facilities for the elderly, four childcare centers, four restaurants, and four school districts serving children from kindergarten through 12th grade.

Data collection instrument. The Hand Washing Observation Form (www.iowahaccp.iastate.edu) was developed, pilot tested, and validated by Paez et al. *(16)* and was modified slightly for use as the data collection tool in this study. The instrument was organized in a table format, with all tasks identified in the 2005 Food Code as requiring hand washing listed in the left column of the page. Based on observations about hand drying methods in previous research *(11, 21)*, an additional task was added: after touching aprons or clothing. The 16 tasks were grouped into four categories: personal hygiene, food preparation, cleaning, and other. Headings for each column included ''should wash hands'' and ''did wash hands'' and eight specific hand washing procedures identified in the 2005 Food Code, such as soap used and hands lathered for 10 to 15 s. Thus, the form allowed researchers to capture hand washing frequency and procedures used by observed employees. Researchers noted occasions when efforts to wash hands occurred and compliance with recommended procedures. The Hand Washing Observation Form also included space for the researcher to record visible demographic information, such as gender of employee. Through informal conversations, other information was gathered from the employees such as number of years worked in food service, status as full-time or part-time employee, and type of food safety training received.

Procedure. Trained observers scheduled five site visits of 3 h each (15 h total) for each of the 16 participating facilities. Thus, 240 h of observation data were collected, during which 80 employees were observed. Managers were aware of the overall purpose of the study (mitigation of cross-contamination), but employees were not informed of the specific focus on hand washing practices and were told that researchers were there for general observations. Employees at each retail food service were observed during production (approximately 6 h), service (approximately 6 h), and cleaning (approximately 3 h), for a total of 15 h at each site. Observations in each type of retail food service totaled 60 h. Typically, one or two employees were observed in each food service operation during the 3-h period, with observations recorded for only one employee at a time.

Data analysis. The Statistical Package for the Social Sciences was used for data analysis (SPSS for Windows, version 14, SPSS, Chicago, Ill.). Frequencies were calculated for each of the 16 tasks in categories of when employees should have washed hands, when employees did wash hands, and the procedure used for hand washing. Frequencies also were calculated for each type of retail food service establishment. Hand washing procedure was determined to be in compliance with the 2005 Food Code recommendations when the following actions were seen for the observed hand washings: soap was used, hands were lathered for at least 10 s, hands were dried with disposable towel or heated air, and faucet handles were not touched with hands after washing.

Benchmarks were calculated for each of the four sectors of retail food service for three phases of the operation: production,

TABLE 1. *Characteristics of operations (*n *= 16) and employees (*n *= 80) observed in four sectors of retail food service: assisted living centers, childcare centers, restaurants, and schools*

Characteristic	Assisted living centers	Childcare centers	Restaurants	Schools
No. of noon meals served (mean ± SD)	93 ± 63	103 ± 74	159 ± 97	337 ± 130
No. of employees in facility	44	15	110	65
Part time	24	9	91	38
Full time	20	6	38	27
No. of employees observed	17	14	22	27
No. of employees with food safety training[a]	8	7	0	15
Gender				
Male	3	4	14	3
Female	14	10	8	24
Years of food service experience per employee (mean ± SD)	9 ± 4	13 ± 8	5 ± 2	13 ± 8

[a] Defined as completion of a food handler's or ServSafe course.

service, and cleaning. The formula used for calculating benchmarks was

Hand washing benchmark per hour per employee
= Total number of times observed employees should have washed their hands
÷ Total number of observed employee work hours

RESULTS

Description of facilities and observed employees. Table 1 shows characteristics of operations and demographics of employees observed in four sectors of retail food service. Within each sector, there was a large variation in the number of meals served; thus, standard deviations were high. Mean (±standard deviation [SD]) number of noon meals served ranged from 93 (±63) in assisted living centers to 337 (±130) in schools. Employees in schools had the most experience working in food service operations (13 ± 8 years), whereas employees in restaurants reported the least experience in food service (5 ± 2 years). Of the total 80 employees observed, 30 had received food safety training through a food handler's or ServSafe course.

Production phase. Table 2 shows observed hand washing frequency and compliance with the 2005 Food Code recommendations during production phases. In assisted living facilities for the elderly, hand washing was observed most frequently for the following tasks during production: before engaging in food preparation (hands were washed 18 of 25 times when they should have been washed), upon entering the food preparation area (washed 8 of 10 times), and after handling soiled equipment, utensils, or dishware (7 of 11 times). There was low compliance with hand washing standards for the following tasks: before donning gloves to work (15 of 53 times), when changing tasks (7 of 46 times), and after eating or drinking (2 of 7 times). When employees entered the food preparation area during production and washed their hands, soap was used and a disposable towel or heated air was used for drying on each of the eight occasions, yet lathering for the recommended 10 to 15 s occurred only twice. Thus, compliance with the 2005 Food Code recommendations for hand washing procedures was only 25%.

During production observations in childcare centers, there were 199 times when employees should have washed hands, and hands were washed on only 60 of these occasions. Tasks with lowest compliance with Food Code frequency recommendations were after eating or drinking (hands actually were washed 1 of 13 times when hands should have been washed) and before donning gloves to work with food (washed 3 of 22 times). Compliance with recommended hand washing procedures was high for some of the steps in the process. When hands were washed, soap was used 59 of the 60 times, and hands were lathered for 10 to 15 s on 44 of the 60 occasions. Hands were dried with a disposable towel or heated air all 60 times, yet the faucet was turned off with the towel only 39 times.

During production in restaurants, hands should have been washed a total of 582 times but actually were washed only 39 times, for a compliance rate of 7% with Food Code recommendations for hand washing frequency. Hands were washed during production most frequently before engaging in food preparation (23 of 32 times). Specific tasks for when hand washing should have occurred but did not were after touching clothing or aprons (0 of 80 times), when changing tasks (3 of 153 times), and before handling different types of food products (3 of 68 observations). On occasions when hands were washed before engaging in food preparation, soap was used 14 of the 23 times but hands were not lathered for the full 10 s and hands were not dried properly on 12 occasions. Thus, there was 0% compliance with Food Code recommendations for hand washing procedures.

During production phase in schools, hands should have been washed a total of 300 times but actually were washed 69 times, a frequency compliance rate of 23%. Soap was used on 62 of the 69 occasions, although lathering was observed only 37 times. Highest compliance with procedure

TABLE 2. *Observed hand washing frequency and compliance with 2005 Food Code recommendations during production in assisted living centers (AL), childcare centers (CC), restaurants (R), and schools (S)*

Task[a]	No. of times hands should have been washed				No. of times hands were washed				% compliance with Food Code frequency				No. of times hands were washed in compliance with Food Code procedure[b]				% compliance with Food Code procedure[b]			
	AL	CC	R	S	AL	CC	R	S	AL	CC	R	S	AL	CC	R	S	AL	CC	R	S
Personal hygiene																				
After touching bare skin	1	12	27	15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
After touching clothing	0	5	80	11	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
After coughing, sneezing	0	2	0	0	0	1	0	0	0	50	0	0	0	1	0	0	0	100	0	0
After using handkerchief	3	1	0	1	0	1	0	1	0	100	0	100	0	1	0	0	0	100	0	0
After eating, drinking	7	13	23	14	2	1	1	3	29	8	4	21	0	0	0	3	0	0	0	100
Food preparation																				
Before engaging in food preparation	29	21	32	14	18	11	23	6	62	52	72	43	3	8	0	1	17	73	0	17
When entering food preparation area	10	19	7	19	8	10	2	12	80	53	28	63	2	6	0	4	25	60	0	33
Before handling different types of food products	8	7	68	8	0	4	3	0	0	57	4	0	0	1	0	0	0	25	0	0
When switching between raw food and RTE food	2	4	18	1	0	1	0	0	0	25	0	0	0	0	0	0	0	0	0	0
Before donning gloves	53	22	5	54	15	3	1	16	28	14	20	30	1	2	0	5	7	67	0	31
After handling PHF	4	5	11	12	2	1	3	1	50	20	27	8	0	0	0	0	0	0	0	0
Cleaning																				
After cleaning equipment, utensils	12	21	64	12	7	5	2	3	58	24	3	25	4	2	0	2	57	40	0	67
After handling soiled equipment, utensils, dishware	11	11	86	15	7	6	0	4	64	54	0	27	1	5	0	1	14	83	0	25
After cleaning	0	0	3	1	0	0	1	0	0	0	33	0	0	0	0	0	0	0	0	0
Other																				
When changing tasks	46	56	153	117	7	16	3	19	15	28	2	16	0	10	0	5	0	62	0	26
After handling money	0	0	5	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other	0	0	0	5	0	0	0	4	0	0	0	80	0	0	0	0	0	0	0	0
Total	186	199	582	300	66	60	39	69					11	36	0	21				

[a] RTE, ready-to-eat; PHF, potentially hazardous food.

[b] In compliance with Food Code procedure when the following actions were observed: soap was used, lathering occurred for at least 10 s, hands were dried with disposable towel or heated air, and faucet handles were not touched with hands after washing.

was seen when employees entered the work area (hands were washed 12 of 19 times for a frequency rate of 63%), soap was used 11 of these times, and lathering for 10 s was observed on nine occasions. Failure to wash hands after critical steps in production occurred after eating or drinking (hands washed on 3 of 14 occasions), before donning gloves to work with food (washed 16 of 54 times), and when changing tasks, such as opening refrigerator door and returning to food portioning (washed 19 of 117 occasions).

Service phase. Observations of hand washing frequency and compliance with the 2005 Food Code recommended procedures for employees in assisted living centers, childcare centers, restaurants, and schools during service are presented in Table 3. During the service phase in assisted living facilities, hands should have been washed by the 14 employees on 149 occasions, but hands were washed only 35 times, for a compliance of 23% with Food Code frequency recommendations.

In childcare centers, rates of hand washing frequency during service were similar to those found during production. Hands were washed 70 of the 197 times when they should have been washed, a frequency of 36%. The task with greatest frequency of occurrence was ''when entering the food prep area.'' However, of these 20 observations of hand washing, compliance with the 2005 Food Code recommended hand washing procedures occurred only 35% of the time.

Hand washing during the service phase in restaurants was observed most frequently before employees engaged in food preparation (11 of 20 observations). Of these 11 observations before food preparation, soap was used on all occasions, all parts of the hand and lower arm were lathered five times, and drying with a disposable towel or heated air was seen seven times, yet compliance with the 2005 Food Code procedures was 0% because on no occasion were all critical action steps observed. Hands were washed after handling soiled dishware on only 2 of 142 occasions and before donning gloves to work on only 2 of 24 occasions.

Although observers noted 250 times in schools when hands should have been washed during service, efforts to do so were observed on only 31 of these occasions, for 12% compliance with Food Code recommendations. Although soap was used in 28 of the 31 hand washing occurrences, lathering and friction were seen only 11 times. During service, there were 19 occasions when staff handled soiled equipment or dishware, yet hands were washed only eight of these times.

Cleaning phase. The compliance with frequency of hand washing during the cleaning phase for all types of retail food service operations is shown in Table 4. The frequency of compliance was higher (43%) during the cleaning phase than during the production and service phases in assisted living centers, with hands washed 45 of the 104 times that washing should have occurred. However, compliance with recommended hand washing procedures occurred only about one-third of the time. Soap was used on 39 of these 45 occasions, but hands were lathered for at least 10 s only 13 times.

During cleaning activities in childcare centers, hands were washed 70 of the 176 times they should have been, a frequency of 40%. Hand washing occurred 17 of the 99 times employees handled soiled equipment, utensils, or dishware. On these occasions, proper procedures were followed 55% of the time.

In restaurants, none of the employees that engaged in cleaning and sanitizing tasks washed their hands after touching clothes or aprons (22 observations) or touching bare skin (19 observations) or when changing tasks (32 observations). Low frequency of hand washing also was seen after handling soiled equipment (6 of 83 observations) and after handling money (4 of 26 observations). Of the six employees who washed hands after handling soiled equipment, utensils, or dishware, all used soap but hands were lathered for the recommended 10 s on only two occasions, for a 33% compliance with Food Code procedural recommendations.

During the cleaning phase in schools, 90 occasions were identified when hands should have been washed, but hands actually were washed on only 42 occasions, for a frequency of 47%. Hand washing during cleaning was low when changing tasks (hands were washed 3 of the 18 times when they should have been washed) and after eating or drinking (zero of the seven observed times). Hands were washed after handling soiled equipment 34 of the 56 times when they should have been, and soap was used on each occasion, but hands were lathered for at least 10 s on less than half of these occasions.

Overall employee compliance with Food Code recommendations for hand washing frequency for combined production, service, and cleaning phases was low. Restaurant employees should have washed their hands a total of 1,763 times but did so only 92 times, for a frequency compliance of 5%. School employees should have washed their hands a total of 640 times but did so only 142 times (frequency compliance of 22%). Childcare and assisted living center frequency compliance was similar, 31 and 33%, respectively. Hand washing should have occurred 572 times in childcare centers and 439 times in assisted living centers but did occur on only 176 and 146 occasions, respectively.

Proposed benchmarks for the number of times employees should wash their hands per hour for each of the four sectors of the food service industry during production, service, and cleaning are presented in Table 5. These benchmarks are based on observations from the current study and are proposed as a baseline for operations. For example, during production in assisted living facilities, hands should have been washed a total of 186 times during the 26 employee hours of observation; thus, a benchmark of seven times per employee per hour was calculated. Overall benchmarks determined by sector of retail food service indicate restaurant employees should wash their hands 29 times per hour, school food service employees should wash their hands 11 times per hour, and childcare workers should wash their hands 9 times per hour.

DISCUSSION

Findings from this study support previous observational research indicating that hand washing is not done fre-

TABLE 3. *Observed hand washing frequency and compliance with 2005 Food Code recommendations during service in assisted living centers (AL), childcare centers (CC), restaurants (R), and schools (S)*

Task[a]	No. of times hands should have been washed				No. of times hands were washed				% compliance with Food Code frequency				No. of times hands were washed in compliance with Food Code procedure[b]				% compliance with Food Code procedure[b]			
	AL	CC	R	S	AL	CC	R	S	AL	CC	R	S	AL	CC	R	S	AL	CC	R	S
Personal hygiene																				
After touching bare skin	11	16	34	6	1	0	2	0	9	0	6	0	0	0	0	0	0	0	0	0
After touching clothing	1	6	194	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
After coughing, sneezing	1	0	3	2	1	0	0	1	100	0	0	50	0	0	0	0	0	0	0	0
After using handkerchief	1	1	0	0	1	1	0	0	100	100	0	0	0	1	0	0	0	100	0	0
After eating, drinking	0	3	41	20	0	1	1	3	0	33	2	5	0	1	0	0	0	100	0	0
Food preparation																				
Before engaging in food preparation	5	5	20	9	1	3	11	1	20	60	55	11	0	2	0	1	0	67	0	100
When entering food preparation area	10	26	11	7	4	20	1	4	40	77	9	57	1	7	0	0	25	35	0	0
Before handling different types of food products	11	7	4	16	1	3	0	0	9	43	0	0	0	1	0	0	0	33	0	0
When switching between raw food and RTE food	10	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Before donning gloves	49	13	24	37	14	1	2	4	28	8	8	11	4	1	0	2	28	100	0	50
After handling PHF	2	3	1	3	0	1	0	2	0	100	0	67	0	0	0	0	0	0	0	0
Cleaning																				
After cleaning equipment, utensils	9	19	48	20	6	5	1	2	67	26	2	10	1	1	0	0	17	20	0	0
After handling soiled equipment, utensils, dishware	15	43	142	19	4	17	2	8	27	40	1	42	1	13	0	4	25	76	0	50
After cleaning	0	2	7	3	0	1	4	2	0	50	57	67	0	1	0	1	0	100	0	50
Other																				
When changing tasks	24	51	318	93	2	15	0	3	8	29	0	3	1	9	0	1	50	60	0	33
After handling money	0	0	83	5	0	0	2	1	0	0	2	20	0	0	0	1	0	0	0	100
Other	0	2	0	0	0	2	0	0	0	100	0	0	0	1	0	0	0	50	0	0
Total	149	197	930	250	35	70	26	31					8	38	0	10				

[a] RTE, ready-to-eat; PHF, potentially hazardous food.

[b] In compliance with Food Code procedure when the following actions were observed: soap was used, lathering occurred for at least 10 s, hands were dried with disposable towel or heated air, and faucet handles were not touched with hands after washing.

TABLE 4. *Observed hand washing frequency and compliance with 2005 Food Code recommendations during cleaning in assisted living centers (AL), childcare centers (CC), restaurants (R), and schools (S)*

Task[a]	No. of times hands should have been washed				No. of times hands were washed				% compliance with Food Code frequency				No. of times hands were washed in compliance with Food Code procedure[b]				% compliance with Food Code procedure[b]			
	AL	CC	R	S	AL	CC	R	S	AL	CC	R	S	AL	CC	R	S	AL	CC	R	S
Personal hygiene																				
After touching bare skin	2	6	19	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
After touching clothing	2	2	22	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
After coughing, sneezing	0	0	2	0	0	0	1	0	0	0	50	0	0	0	0	0	0	0	0	0
After using handkerchief	0	0	1	0	0	0	1	0	0	0	100	0	0	0	0	0	0	0	0	0
After eating, drinking	1	7	20	7	1	3	1	0	100	43	5	0	0	0	0	0	0	0	0	0
Food preparation																				
Before engaging in food preparation	0	0	10	0	0	0	5	0	0	0	50	0	0	0	0	0	0	0	0	0
When entering food preparation area	6	14	11	1	5	9	6	0	83	64	54	0	2	3	0	0	40	33	0	0
Before handling different types of food products	0	2	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
When switching between raw food and RTE food	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Before donning gloves	3	4	6	1	0	0	1	0	0	0	17	0	0	0	0	0	0	0	0	0
After handling PHF	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Cleaning																				
After cleaning equipment, utensils	15	20	15	4	7	2	1	3	47	10	7	75	0	1	0	2	0	50	0	67
After handling soiled equipment, utensils, dishware	61	99	83	56	28	29	6	34	46	29	7	61	7	16	0	5	0	55	0	15
After cleaning	0	1	1	0	0	1	1	0	0	100	100	0	0	0	0	0	0	0	0	0
Other																				
When changing tasks	14	20	32	18	4	2	0	3	28	10	0	17	3	0	0	2	75	0	0	67
After handling money	0	0	26	1	0	0	4	1	0	0	15	100	0	0	0	0	0	0	0	0
Other	0	0	0	1	0	0	0	1	0	0	0	100	0	0	0	0	0	0	0	0
Total	104	176	251	90	45	46	27	42					12	20	0	9				

[a] RTE, ready-to-eat; PHF, potentially hazardous food.

[b] In compliance with Food Code procedure when the following actions were observed: soap was used, lathering occurred for at least 10 s, hands were dried with disposable towel or heated air, and faucet handles were not touched with hands after washing.

TABLE 5. *Hand washing benchmarks during operational phases of production, service, and cleaning in assisted living centers (AL), childcare centers (CC), restaurants (R), and schools (S)*[a]

Operation phases	AL	CC	R	S
Production benchmark	7	9	28	11
No. of times hands should have been washed	186	199	582	300
Total observed hours	26	21	21	27
Service benchmark	7	9	33	12
No. of times hands should have been washed	149	197	930	250
Total observed hours	20	21	28	21
Cleaning benchmark	7	10	23	8
No. of times hands should have been washed	104	176	251	90
Total observed hours	14	18	11	12
Overall benchmark	7	9	29	11
No. of times hands should have been washed	439	572	1,763	640
Total observed hours	60	60	60	60

[a] Benchmarks are the number of times an employee's hands should be washed per hour.

quently enough in retail food service establishments and that recommended methods are not followed. During this study, employees were seen making some efforts to wash hands at the times recommended in the Food Code. During production, frequency of compliance ranged from 7% for restaurant employees to 35% for assisted living center workers. Green et al. *(11)* reported that the number of hand washing attempts by restaurant employees during tasks related to food preparation was higher (32% compliance) than the number of attempts during other activities. Almost all observed employees in all sectors during all phases failed to wash their hands between handling raw and handling ready-to-eat foods, a concern previously noted *(11).* Findings from this study indicated that institutional sectors of retail food service placed a higher value on formal food safety training than did restaurants; about half of workers in assisted living, childcare, and school sectors had completed food safety training whereas all restaurant workers identified on-the-job training as their only source of food safety information. Given the part-time employment status of most workers in restaurants and high employee turnover in this industry, this lack of training is not surprising. Low compliance with hand washing frequency in restaurants was not surprising because workers usually had multiple job responsibilities and performed various tasks during each phase of operation. The hectic nature of compressed meal periods for all sectors increased the risk of cross-contamination because of infrequent and improper hand washing during service, a situation exacerbated in the restaurant setting. Management consideration for reconfiguration of job assignments, previously suggested in the literature *(11),* is supported by observations from this study. However, the procedures used to wash hands at these recommended times were not compliant with FDA recommendations; thus, hand washing was not effective or hands could have become recontaminated. Employees at childcare centers had the highest compliance rate for hand washing procedures recommended in the Food Code among the four types of retail food services for most tasks in production, service, and cleaning phases, with procedural compliance rates of 20 to 100%. This high procedural compliance rate may be due to emphasis on hand hygiene as part of childcare licensing standards.

Mechanical ware-washing equipment was common in all retail food services, but in almost all assisted living, childcare, and restaurant operations, only one person was assigned to operate the equipment. Observations of low hand washing frequency compliance in the dishroom during the cleaning phase in childcare and assisted living centers are particularly troubling because production equipment, service utensils, and dishware can become recontaminated from soiled hands, and this contamination can pose a threat to these vulnerable groups of people. The relatively high overall compliance for hand washing frequency during the cleaning phase in schools may be due to job assignments in the dish room, in which one person loaded soiled dishware and another removed cleaned and sanitized items from the machine. This scheduling framework improved frequency compliance for schools during the cleaning phase.

Although further education to increase awareness of when and how to wash hands properly is needed, barriers to good hygiene practices as recently identified by Pragle et al. *(17)* also need to be addressed. The barrier of time pressure is high in the restaurant industry, perhaps because of the scope of the menus, high staff turnover, and competitive markets. Workers in restaurants typically have multiple responsibilities that include food or beverage preparation, service, and cleaning. Thus, the nature of commercial retail food service presented greater risk of contamination of food contact surfaces via hands than did the noncommercial operations participating in the study. Observations from this study indicated that restaurant employees should wash their hands an average of 29 times per hour. Obviously, this rate is unrealistic because the time spent hand washing (20 s for 29 times each hour) would reduce productivity significantly and result in skin irritations for employees, a concern previously reported *(4, 11).* Managers and employees should consider reconfiguration

of job duties and train staff on effective sequencing and arrangement of work tasks to reduce the number of times hands should be washed. The motivation of employees to practice known safe food handling also has been identified as a barrier *(2),* but supervisors and managers can impact this barrier by establishing policies and standards, holding employees accountable for their actions, serving as role models, controlling rewards and punishment, providing training that includes reasons why proper hand washing and other safe food handling behaviors are important, and providing needed resources. Typical age range, years of food service work experience, gender, food safety training, and part-time job status of line employees in restaurants is different than that in noncommercial sectors of the food service industry. The scope of the menus, style of service, and reward systems may contribute to the lack of attention given to hand washing by restaurant workers. Training methods and task assignments may need frequent review within organizations. Compliance with Food Code recommendations for hand washing frequency and procedures needs improvement in all types of retail food service establishments.

One training strategy may be to provide benchmarks of hand washing frequency. Because of variability in production systems, the form of purchased foods, turnover of staff, and service options, benchmarks for different sectors of retail food service are proposed. Benchmarks should be useful to operators by making them aware of how often hands are supposed to be washed and by providing guidance to staff on hand washing frequency. In previous work *(16),* suggested benchmarks for deli-type food service establishments serving ready-to-eat foods were 6 times per employee per hour during production and 11 times per employee per hour during service. These proposed benchmarks are comparable to those for assisted living centers, childcare centers, and schools, perhaps because of the limited menu offered in a deli. Full-service restaurants have a much higher benchmark because of the expanded scope of the menu and thus the number of times hands should be washed. Food service operators may need to develop a hand washing benchmark specific for their operation and then seek methods to reach that benchmark.

These proposed benchmarks can be used by managers to develop training materials specific to their type of operation and to establish internal guidelines of hand washing behaviors. The benchmark data also can help managers identify the need to reconfigure work schedules such as assigning two people to operate the dishwashing machine (one to load and one to unload) and assist staff in organization of work tasks to minimize need for hand washing, such as having the bus staff clear soiled dishware and the host or wait staff reset tables. The benchmarks identified in this study should be used in initial training that also addresses proper frequency and procedures for hand washing. Because of concerns related to lost productivity and potential skin irritations, management and staff should consider work organization, staffing, and employee motivations to ensure hands are properly washed when needed. The use of benchmarks is one tool to emphasize the importance of hand washing at the recommended times using proper procedures.

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Environmental Management Department
Val F. Siebal, Director

County of Sacramento

Divisions
Environmental Health
Environmental Compliance

ALTERNATIVE OPERATING PROCEDURES
To Use Bare Hand Contact with Ready-to-Eat Food

FOR OFFICIAL USE ONLY
Date Submitted: _____
Date Approved: _____
Approved by: _____

Section 113961 of the California Retail Food Code (CalCode) prohibits bare hand contact of food employees with ready-to-eat food. The following is a summary of required documentation necessary to be eligible for an exemption from this code section. Note: Operators serving highly susceptible populations (e.g. licensed health care facilities) are not eligible for this exemption.

In order to operate under this exemption, a retail food facility in Sacramento County must obtain prior approval from the Environmental Management Department (EMD) and make their written operating procedures available upon request. Written procedures must include a description of the proposed procedures for bare hand contact and documentation of proper handwashing practices, an employee health policy and documentation of completed required employee training.

CHECKLIST FOR USING BARE HAND CONTACT WITH READY-TO-EAT FOOD

Facility Name:	FA#:
Facility Address:	PR#:
	SR#:

SECTION I: BARE HAND CONTACT PROCEDURES

Describe your proposed alternative operating procedures for bare hand contact and list the specific ready-to-eat foods that would be touched by bare hands. Attach the description to this checklist and submit the documents to EMD for approval.

SECTION II: HANDWASHING PROCEDURES / HANDWASHING SINKS

Provide diagrams and other information showing that handwashing facilities are installed, located, and maintained in accordance with Sections 113953, 113953.1, and 113953.2, are in an easily accessible location and in close proximity to the work station where the bare hand contact procedure is conducted.

Check when completed	Your handwashing procedures must include or state all of the following:
☐	Diagram(s) showing location of all handwashing facilities in relation to work stations where bare hand contact procedures are conducted is attached for review
☐	Accessible handwashing sinks are installed in all necessary areas and kept clean and unobstructed
☐	All handwashing sinks are provided with warm water that reaches at least 100°F
☐	All handwashing sinks are provided with soap, single-use towels or a heated-air hand drying device

Attach written handwashing information to the proposed procedure(s) and submit for EMD approval.

SECTION III: WRITTEN EMPLOYEE HEALTH POLICY

Written policy must detail the manner in which the food facility complies with CalCode sections 113949, 113949.1, 113949.2, 113949.4, 113949.5, 113950 and 113950.5**.**

Check when completed	Written employee health policy must include or state all of the following:
☐	Food employees acknowledge that they have been informed to report information about their health and activities as they relate to gastrointestinal symptoms and diseases that are transmittable through food
☐	Food employees acknowledge their responsibilities for notification
☐	Person in charge acknowledges the responsibilities for notification

Attach written employee health policy to the proposed procedure(s) and submit for EMD approval. .

SECTION IV: EMPLOYEE TRAINING

Written policy must document that all food employees acknowledge they have received training in all the following areas:

Check when completed	Topics covered:
☐	Risks of contacting specific ready-to-eat foods with bare hands
☐	Proper handwashing techniques and requirements
☐	Where to wash their hands
☐	Proper fingernail maintenance
☐	Prohibition of jewelry
☐	Good hygienic practices
☐	Procedures for bandaging and covering wounds

Attach written employee training policy to the proposed procedure(s) and submit for EMD approval. .

SECTION V: PREVENTING CROSS CONTAMINATION

Include the following statement: “Hands are washed before food preparation and as necessary to prevent cross-contamination by food employees, as specified in Sections 113952, 113953.1, and 113953.3 during all hours of operation when the specific ready-to-eat foods are prepared.”

SECTION VI: CONTROL MEASURES

Written policy must document that food employees contacting ready-to-eat foods with bare hands use two or more of the following control measures to provide additional safeguards to hazards associated with bare hand contact.

Check when completed	Possible control measures: Facility must use at least two of these control measures
☐	Double handwashing (washing your hands once after restroom use and a second time at re-entry into preparation area)
☐	Nail brushes
☐	A hand antiseptic after handwashing, as specified in Section 113953.4
☐	Incentive programs such as paid sick leave that assist or encourage food employees not to report to work when they are ill
☐	Other control measure approved by EMD

Attach written control measures to the proposed procedure(s) submitted for approval to EMD.

SECTION VII: CORRECTIVE ACTIONS

Written policy must document that corrective actions will be taken when requirements specified above are not followed.

ACKNOWLEDGMENT:

- I acknowledge that approval of “Alternative Operating Procedures” is conditional and may be revoked if procedures are not consistently followed as described and approved.
- I will maintain a copy of the Alternative Operating Procedures on site and available for review at all times.

Signature: _____ **Date:** _____

Print Name: _____ **Title:** _____

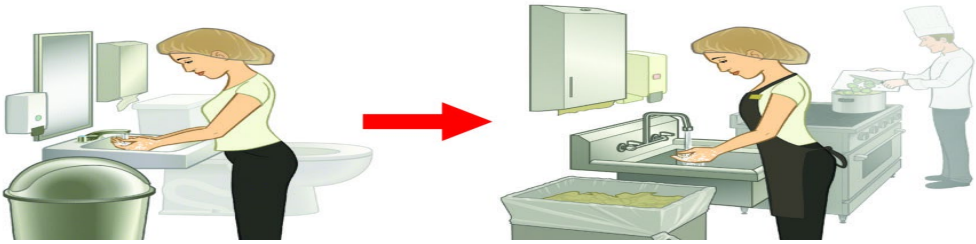
Email address: _____

HAND WASHING

WHEN TO WASH HANDS

- Before starting work/engaging in food preparation
- During work as often as is necessary to keep them clean
- After touching your clothing, skin or hair
- When switching between working with raw foods and ready-to-eat foods
- After handling soiled equipment and utensils
- After handling raw meat, poultry, seafood, or produce
- After coughing and sneezing, using a handkerchief or tissue
- After smoking, eating, drinking, or chewing (gum, tobacco, etc)
- After using the toilet*
- After handling the trash
- After any other activities, that may contaminate employees' hands.

***The FDA recommends double handwashing after using the toilet. When traveling from the restroom to the kitchen, there are obstacles and barriers that are encountered. Such barriers consist of kitchen doors, physical contact, and contact with building environment. Human waste is the most dangerous source of contamination. While public health measures protect the drinking water supply from dangerous sewage contamination, only the concerned food handler can protect food from becoming contaminated with human waste (feces).**



WASH YOUR HANDS IN A PROPERLY SUPPLIED HAND SINK:

- Wash hands in hand sinks supplied with hot and cold running water, soap and a hand drying device or disposable paper towels.
- Hot and cold running water temperature at a minimum of 100° F.
- Cleaning compound
- Disposable paper towels, or heated air hand-drying device
- A waste can for disposable towels
- A handwashing sign, poster, or icon as a reminder of handwashing at all hand-washing lavatories used by employees.

HANDWASHING REMINDERS

- Food preparation, utensil washing, or mop sinks are not approved for handwashing. Hand sinks are to be used for handwashing only (Keep utensils, cloths, foods out of the hand lavatory).
- Employees are more likely to wash their hands when lavatories are equipped.
- Managers are required to train food employees in the proper handwashing procedures, monitor, and enforce handwashing policies.
- Keep fingernails trimmed and without rough edges.

Double Hand Washing Is Essential

BY DENNIS KEITH LEAVE A COMMENT

Did you know that when restaurant and other food-service employees use the bathroom, they have to wash their hands in the bathroom and then again before they return to their duties? That's right—a double hand washing! The FDA food code specifically states that double hand washing is necessary before workers go back to their duties.

There are 3 essential reasons for this hand washing policy:

1. It's a simple yet very effective tool in reducing the possibility of a foodborne illness occurring in a facility.
2. Customer perception should be a concern. If an employee comes back from the restroom and continues to take food to tables, etc., without going back to the kitchen

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first to wash his/her hands again, how many customers might conclude that the worker didn't wash his/her hands before handling food again?

3. The easiest way to impress a health inspector is for the inspetor to witness many staff members washing hands periodically through an inspection.

So train staff about the reasons for a double hand washing, and for more information, read these helpful articles:

- Hand Washing 101
- Hand Washing to Protect the Customer's Health

FILED UNDER: FOODBORNE ILLNESS, HAND WASHING
TAGGED WITH: FDA FOOD CODE, FOODBORNE ILLNESS TIPS, HAND WASHING TIPS

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WHO IS BEHIND THE UTAH FOOD SAFETY BLOG?

Dennis Keith has been working as a restaurant and food safety professional for more than 20 years. Read more about Dennis or contact him via email or LinkedIn.

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Training Tip: Double Handwashing

When is double hand washing required?

Restrooms are notorious for harboring pathogens, and the restrooms at restaurants are no different. When food workers use the restroom, they should always wash their hands in the restroom sink and then wash them again at a hand washing sink before continuing their duties. This practice is called double handwashing.

LIVE CHAT

Double handwashing is like an insurance policy for preventing pathogens: it's an extra step to ensure you food workers' hands are clean—just in case.

As a manager, the best way to motivate your food workers to follow safety practices is by teaching them the reasons these practices are important. Food workers are more likely to take the extra time needed fo food safety if they understand the logic behind each practice. This is true with any food safety practice, b especially double handwashing, which can seem like an unnecessary extra step.

As a teenage employee at Jamba Juice, I followed the double handwashing rule out of obligation, not understanding. I didn't learn the reasons behind double handwashing until I joined the StateFoodSafety team. If I had been taught the following in my Jamba Juice days, I would have double hand-washed with enthusiasm instead of resignation.

Double the hand washing

Double hand washing removes pathogens from the food worker's hands. Some workers might think they don't need double hand washing if they have a good wash in the restroom. However, not everyone who uses the bathroom follows good rules of hygiene. An individual who doesn't wash their hands—or doesn't wash them well enough—can spread pathogens to other areas of the bathroom, like a faucet or a door. From there, pathogens can easily spread to the freshly washed hands of food workers. Double hand washing is the solution to this problem. By washing their hands in the handwashing sink, food handlers can ensure that their hands are pathogen-free and ready for work.

Double the customer's peace of mind

Customers want to eat at safe restaurants, and they are often aware of the food safety measures they see taking place. If a food worker exits the restroom, it helps ease the customers' mind if the food worker goes directly to a handwashing sink for a wash. Otherwise, customers could wonder and worry about the cleanliness of the food worker's hands.

Double the safety

The FDA Food Code includes double handwashing because it's important for food safety. As food workers understand the reasons behind this practice, they will follow it more consistently, making your restaurant that much safer.

—Suzanna Sandridge

LIVE CHAT

This post was originally published in August 2016 and has been updated for freshness, accuracy, and comprehensiveness.

<< Older
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LIVE CHAT

Template approved: 7/13/2021

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COMMITTEE NAME *Foodborne Illness Investigation Committee*

DATE OF FINAL REPORT: *11/16/2022*

COMMITTEE ASSIGNMENT: ☒ ***Council I*** ☐ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: **Catherine Feeney and Robert Brown (Co-chairs)**

COMMITTEE CHARGE(S): Overview of Committee Charges

Issue # 2020-I-015

To examine consumer purchase history with the following charges:

1. Determine if it would be appropriate to place language in the current Food Code to address regulatory authority for foodborne illness investigation and obtaining purchase history information. If appropriate, then,
    a. Draft language for an amendment to the current FDA Food Code giving regulatory authorities access during foodborne illness investigations
    b. Draft language for an amendment to the Food Code giving regulatory authorities access to consumer purchase history information.
    c. Include maintaining customer data protection as confidential when managing a foodborne illness investigation.
2. Include methods to educate and collaborate with industry and regulatory authorities.
3. Report progress back at the next Biennial meeting and complete the charges by the subsequent Biennial Meeting.

COMMITTEE WORK PLAN AND TIMELINE: S

- Meet every two weeks initially, then once a week as charges near completion.
- Survey committee members to get input
- Form subcommittee to work on "Industry Best Practices for Providing Consumer Purchase Information for a Foodborne Illness Investigation"
- Collaborate with SHOP (Shopper History Outbreak Partnership)
- Propose Issues to be drafted to address charges, vote on issues to be moved forward, finalize language based on committee consensus
- Finalize Issues and "Industry Best Practices for Providing Consumer Purchase Information for a Foodborne Illness Investigation"

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

Dates of committee meetings or conference calls:

1-6-2022
1-26-2022
2-9-2022
2-23-2022
3-23-2022
4-6-2022
5-5-2022
5-18-2022

6-1-2022
6-23-2022
7-27-2022
8-24-2022
9-14-22
10-26-22
11-2-22

OVERVIEW OF COMMITTEE ACTIVITIES:

1-6-2022
Kick off meeting, Antitrust Agreement and charges reviewed. Attendees introduced themselves and an ice-breaker activity was done.
Discussion focused on 1. b. and committee members talked about the following:

- Ways purchase info is tracked (e.g., cash or other payment) if not using a customer loyalty card.
- Cybersecurity issues with government and personal data
- Inconsistent requests from regulatory, need for best practice for needed data vs "data dump".
- The need for a formal written request by some companies and customer consent
- Ensuring customer purchase information is accurate
- Need to consider the implications for third-party delivery and language to address this platform.

1-26-2022
Discussed charges 1a. and 1.b.
CDC addressed need for charge 1a. due to impact of COVID on limiting or reducing regulatory authority to conduct investigations.
CDC presentation

- Use of purchase history during FBI investigations. Specific circumstances were mentioned including requesting info when there is a culture confirmed clinical specimen and when there is a common shopping location associated with an FBI cluster.

USDA FSIS presentation

- AFDO SHOP (Shopper History Outbreak Partnership) and the work done. Demonstrated website AFDO: Leveraging Good Purchase History to Solve Foodborne Outbreaks. Showed sections listing state regs around the issue, success stories, and the best practice document created.

Discussions followed regarding inspections vs investigations, regulatory agency adoption of Chapter 8 of FDA Food Code, where investigation authority comes from, consistency when conducting investigations and requesting product purchase data, and alignment with FDA New Era of Smarter Food Safety.
Next steps suggested:

- Voting on charges at next meeting. Then, if appropriate: begin drafting/developing acceptable language.

2-9-2022
Discussions included:

- FDA Model Food Code: Chapter 8 references that may impact outbreak investigation/inspection authority and collection of records from permit holders.
- Administrative law: food establishments (i.e., retail and restaurants) are regulated by state and local authorities and are not governed under the FDA Model Food Code per FDA.
- Discussion about the use of "Shopper Cards", "Purchase History", and "Records".
- Discussion about applicability of this committee's work to the FDA Voluntary National Retail Food Regulatory Program Standards Program Standards 5: Foodborne Illness and Food Defense Preparedness and Response.

2-23-2022

FDA Core Presentation regarding Core's structure, functions, and the use of product purchase information in outbreak investigations.

3-23-2022

Discussed Charges 1. a. and 1. b.

Summarized previous discussions about how investigations and inspections differ, where authority to do investigations comes from, and where it would be placed in the Food Code if additional language is needed.

Straw polls conducted regarding if an FDA interpretation is needed and if we agree that consumer purchase information helps to solve outbreaks

There were 12 voting members on the call and 6 said that yes to both questions.

Action Items

Discussed options including new section in the Code or an interpretation from FDA. Committee agreed to ask FDA for an interpretation to determine if the Food Code provides authority to conduct FBI investigations.

4-6-2022

Discussed survey sent out prior to meeting to elicit feedback about the committee's opinions regarding the charges.

- There is consensus that an interpretation of the FDA Food Code is needed to determine if authority to conduct FBI investigations is implied in the Code (Charge 1. a.).
- There is consensus that a guidance document related to purchase data requests for industry is needed (charge 2).
- There was little agreement regarding codified language that permits regulatory agencies to obtain product purchase data during an investigation.

5-5-2022

Reviewed charges and summarized where committee is on each.

Charge 1. a. - *Draft language for an amendment to the current FDA Food Code giving regulatory authorities authority for access during foodborne illness investigations*. The committee almost unanimously thought that it is unclear whether or not the authority already exists for regulatory agencies to do a foodborne illness investigation. After some discussion, the committee agreed to ask FDA for an interpretation of sections in chapter 8 to determine if authority exists.

Charge 1. b. - *Draft language for an amendment to the Food Code giving regulatory authorities access to consumer purchase history information.* The respondents in favor and those opposed were fairly evenly split. All seemed to agree that this issue was not likely to be resolved during this committee.

Charge 1.c. - *Include maintaining customer data protection as confidential when managing a foodborne illness investigation.* This charge is dependent on language being included in the Food Code and the committee is not recommending that at this time due to lack of agreement.

Charge 2. - *Include methods to educate and collaborate with industry and regulatory authorities.* This charge was discussed at length. Committee agreed that an industry guidance document would be useful.

Action Items

- Committee members will reach out to the industry to get input on what guidance is needed.
- Committee members will do some searching to see if guidance is out there to build upon.

- An issue will be drafted asking FDA to interpret the Code to determine if authority already exists.

5-18-2022

Drafted issues to be submitted and guidance document for industry.

Worked on two issues that were drafted for committee input regarding:

- An FDA interpretation of authority in the current Food Code to conduct FBI investigations.
- Adding language to give authority to conduct investigations.

Discussed using the Minnesota guidance document as a starting point to draft an industry best practice document.

Action Items

- Issues will be sent to committee members for review and input.
- The Minnesota guidance document will be sent to assess its usefulness as a starting point in developing an industry guidance document.

6-1-2022

Discussed issues that were drafted for committee input and edit.

- Issue one is to ask FDA for an interpretation of the Food Code to determine if authority exists to conduct foodborne illness. Bob Brown shared his screen, and some language changes were made.
- Issue two is to ask FDA to add language for regulators to have the authority to conduct foodborne illness investigations. No edits were made.

Discussed using Minnesota document to develop guidance for industry on best practices for product purchase information requests.

A subcommittee (Industry Guidance Product Purchase Workgroup) was formed. Volunteers included: Christine Fierro, Eric Puente, Kathleen O'Donnell, Kristina Stefanski, Michele DiMaggio, Cathy Feeney, and Robert Brown.

Discussed moving the full committee meeting to monthly and subcommittee to meet in between.

Action Items

- Reschedule full committee meetings to monthly (4th Wednesday of the month).
- Schedule subcommittee meetings at the time previous meeting was held (3rd Wednesday of the month).

6-23-2022

Discussion of survey results regarding issues.

Question one

Title: Amend Food Code – Include authority to conduct foodborne illness investigation into Food Code

Issue you would like the Conference to consider: We would like for the U.S. Food and Drug Administration (FDA)to add language to provide the authority for a regulatory and/or health authority to investigate reports of foodborne illness.

The Conference recommends…that a letter be sent to the FDA requesting that Chapter 8 of the most current published version of the Food Code be amended to include: The REGULATORY AUTHORITY is provided access to all relevant facilities, EQUIPMENT, FOOD, personnel, and existing records when needed during a foodborne illness investigation.

Yes 10, No 4

Question two

Title: Interpretation of Food Code – Interpretation of the Food Code to determine if authority exists to investigate and obtain needed information when there is a foodborne illness outbreak.

Issue you would like the Conference to consider: We would like for the U.S. Food and Drug Administration (FDA) to provide a Food Code interpretation to inform regulatory authorities that Food Code sections including but not limited to 8-304.11(H) coupled with 8-402.11 provides sufficient authority for the regulatory authority to investigate and obtain information, including records, that are needed as part of the foodborne illness investigation from food establishments.

The Conference recommends…that a letter be sent to the FDA requesting an interpretation of the Food Code clarifying that Section 8-304.11(H) coupled with 8-402.11 and other relevant sections provide sufficient authority for a regulatory authority to conduct a foodborne illness investigation and obtain access to needed information.
Yes 13, No 1

Survey respondents: 8 voting members, 6 nonvoting members
Regulatory –, Industry – 3, Consumer Group – 1, Academia – 1, Federal Partners – 2

Action Items

- The committee agreed that based on the results of the survey, the two issues should be submitted to CFP.

7-27-2022

Review of draft guidance.

The committee spent time reviewing the draft Industry Best Practices for Providing Consumer Purchase Information for a Foodborne Illness Investigation. Numerous revisions were made.

- There was a discussion about what form the product purchase data will be in and the recommendation that it be sortable may not be reasonable. The subcommittee will look at those portions and change or eliminate that section of the guidance.
- Discussed the Food Marketing Institute (FMI) document and it was suggested that Hillary at FMI be contacted to see if it can be shared so that our best practice document isn't duplicative or inconsistent.
- Discussed a central repository for contact information to speed up communications between industry and regulators.

8-24-2022

Activities reviewed since start of the committee.

Meeting to summarize what has been done since start of the committee in January.
Reviewed issues worked on that will be submitted and the industry guidance document that is in process.
The Shopper History Outbreak Partnership have drafted questions and answers and are asking for FBII committee feedback.

9-14-22

Discussed Shopper History Outbreak Partnership feedback for industry guidance document "Industry Best Practices for Providing Information During a Foodborne Illness Investigation".
Reviewed all comments and made changes to document based on committee approval for the revisions.

10-26-22

This meeting was to finalize the issues and best practices document that the committee developed. The committee will then vote on completed work.

Issue 1 - **Interpretation of the Food Code to determine if authority exists to investigate and obtain needed information when there is a foodborne illness outbreak.**

Issue was read to committee members. There was some discussion on the issue and then the committee voted to accept the issue as written.

Issue 2- **Amend Food Code – Include authority to conduct foodborne illness investigation into Food Code**

FDA stated that the Food Code does not give authority but rather authority comes from state or local statutes. This was debated and the committee was unable to find a solution. Committee members offered ideas for placement in the Food Code regarding where it fits best. After little progress, the committee was asked to vote on 3 options.

1- change the language to eliminate the term authority, 2- vote on the existing issue as it is, 3- discard the issue entirely. The group agreed to continue working on the issue.

Best Practices document was reviewed in the last few minutes and there were industry concerns. One ask was to eliminate the reference to the AFDO SHOP document since it was not developed by industry and the site could move resulting in a broken link. There were other concerns about types of information mentioned that is not available at point of purchase such as lot codes.

11-2-22

This meeting was to finalize the second issue and best practice document that the committee developed. The committee will then vote on completed work.

After the last meeting Co-chairs Cathy Feeney and Bob Brown met to revise the language in the issue based on the feedback received. Authority was taken out based on FDA comments. The new issue to consider is…

Issue 2- **Amend Food Code – Include access to conduct foodborne illness investigation into Food Code**

We had editing suggestions from a committee member and the group was agreeable to the new language. There was some discussion regarding placement in the Food Code, but FDA suggested that it might make sense to leave it open to FDA since other items that may be along the same lines might be added as well.

The committee voted. 13 of the 15 voting members on the call were in favor of this issue.

Food Establishment Consumer Purchase Best Practices was reviewed. One committee member offered some language changes in the introduction section, and these were accepted. The committee discussed the link to the SHOP AFDO website and asked that it be added back in to serve as a resource.

The committee voted and 9 were in favor of submitting the best practices guidance with the understanding that CFP will make changes needed for branding.

1. ***Charges COMPLETED and the rationale for each specific recommendation:***

All charges completed.

1. Determine if it would be appropriate to place language in the current Food Code to address regulatory authority for foodborne illness investigation and obtaining purchase history information.
a. Draft language for an amendment to the current FDA Food Code giving regulatory authorities authority for access during foodborne illness investigations
b. Draft language for an amendment to the Food code giving regulatory authorities access to consumer purchase history information.
c. Include maintaining customer data protection as confidential when managing a foodborne illness investigation.

The committee did not agree that it would be appropriate to place language in the current Food Code to address regulatory authority for foodborne illness investigation and obtaining purchase history information.

Instead, the committee is asking to submit an issue for an interpretation to determine if authority already exists in specific parts of Chapter 8 to conduct a foodborne illness investigation and obtain needed information when there is a foodborne illness outbreak.

In addition, the committee did agree to submit an issue to allow regulators to access the facility during an investigation.

Maintaining customer data protection as confidential was discussed throughout the committee but language not needed since regulator access to product purchase information is not being recommended at this time.

2. Include methods to educate and collaborate with industry and regulatory authorities.

The committee collaborated with FMI (Food Marketing Institute) and SHOP (Shopper History Outbreak Partnership) to develop a guidance document with an industry focus called ***"Food Establishment Consumer Purchase Best Practices".*** *SHOP has also invited industry to participate in their work to collaborate more effectively and get that much needed industry perspective.*

3. Report progress back at the next Biennial meeting and complete the charges by the subsequent Biennial Meeting.

The committee is respectively asking that this report is acknowledged, and this committee be disbanded since all charges have been met.

2. ***Charges INCOMPLETE and to be continued to next biennium:***

No incomplete charges.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE: Foodborne Illness Investigation Committee

1. Issue #1: Foodborne Illness Investigation Committee Report

a.i.a) Committee Final Report (see attached PDF)

a.i.b) Committee Member Roster (see attached PDF)

a.i.c) Committee developed "Food Establishment Consumer Purchase Best Practices"

2. Issue #2: Interpretation of Food Code – Interpretation of the Food Code to determine if authority exists to investigate and obtain needed information when there is a foodborne illness outbreak.

3. Issue #3: Amend Food Code – Include language to provide the Regulatory Authority access to conduct foodborne illness investigations into Food Code

LIST OF CONTENT DOCUMENTS SUBMITTED WITH THIS ISSUE:

☐ ***See attached revised roster PDF*** ☒ ***No changes to previously approved roster***

"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

Committee Member Roster (see attached PDF)

Other content documents:

Committee Final Report (see attached PDF)

Committee developed "Food Establishment Consumer Purchase Best Practices"

LIST OF SUPPORTING ATTACHMENTS: ☐ **NOT APPLICABLE**

The Shopper History Outbreak Partnership website

Jones, T. F., & Angulo, F. J. (2006). Eating in Restaurants: A Risk Factor for Foodborne Disease? Clinical Infectious Disease, 43, 1324-1328. doi:1058-4838/2006/4310-0017

Scallan, E., Hoekstra, R. M., Angulo, F. J., Tauxe, R. V., Widdowson, M. A., Roy, S. L., . . . Griffin, P. M. (2011). Foodborne illness acquired in the United States--major pathogens. Emerg Infect Dis, 17(1), 7-15. doi:10.3201/eid1701.091101p1

Food Establishment Best Practices for Providing Consumer Purchase Information for a Foodborne Illness Investigation

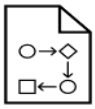
Background

Rapid and effective information sharing between the food industry and government officials helps to solve foodborne outbreaks and may prevent additional illnesses. Public health officials at the local, state, and federal level may request consumer food purchase data to investigate foodborne illness/outbreaks. This information is used to identify the food in common between ill people which may determine what made them sick. As the process to identify which ill people are part of an outbreak may take several weeks, this leads to incomplete food history recall by the ill person. Investigators request consumer purchase information from food establishments after they obtain details about the food purchased during the public health interview. This helps to bridge these gaps in food history. This information may also be used to trace the product through the supply chain to determine when and where it was produced which may lead to a faster removal of a contaminated food from sale. The time frame and scope of the request will vary based on several factors, including the shelf life of the product.

For more information about how food purchase history information is used to investigate outbreaks please visit https://www.afdo.org/resources/purchase-history/.

Best Practices

Work closely with public health officials to assist with the investigation. It is important to establish relationships prior to an investigation.



Develop a written process for how information will be shared during illness/outbreak investigations in coordination with your company's legal counsel and your state's public health and regulatory authorities. A plan that is developed in advance and communicated to staff will make the investigation go more smoothly.

Protect personally identifiable information (PII). Consumer information that directly identifies an individual beyond what has been provided by the public health or regulatory agency should be redacted. Purchases beyond food/grocery items (e.g., pharmacy, liquor, tobacco) may not be needed during a foodborne illness/outbreak investigation. Communicate with public health officials if you need clarity on what records are needed.

Send consumer purchase data to the requestor as soon as possible. Food establishments and public health officials should determine an agreed upon timeline and ensure that expectations are clear.

Capture traceability information (e.g., date of purchase, brand name, product description, product package size) at the point of sale.

Share food purchase information in a format that is sortable, if feasible. Although not required, spreadsheets such as excel will help with sorting and filtering data.

Think outside the box and consider alternatives ways to obtain purchase information. If your company can obtain purchase data using methods such as all or part of a credit card number, work with investigators to obtain permission and sufficient details to identify the correct purchase information.

Council I Committee Name: Foodborne Illness Investigations Committee

Voting Members

Last Name	First Name	Position (Chair, Member, etc.)	Constituency	Employer	City	State	Phone	Email
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Alternates

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
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Note: *Minimum council committee size is 11 (as noted above): 1-Chair; 1-Vice Chair; 1-State; 1-Local; 2-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise;*

Maximum council committee size is 23 voting members: 1-Chair; 1-Vice Chair; 4-State; 4-Local; 8-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise; 36 -Non-voting alternates.

Membership on standing committees is defined by the Executive Board. On all CFP committees, the committee chair, co-chair(s), and vice chair(s) all count towards constituency balance.

SHOPPER HISTORY:

Best Practices for Use during Foodborne Illness Investigations

October 2020

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1. Purpose and Scope

Investigating foodborne disease outbreaks is often not a straightforward task. Successfully identifying the source of foodborne outbreaks requires a detailed assessment of the case-patient's food exposures during the time periods of interest. Outbreaks caused by agents with long incubation times, products with long shelf lives, and products with a low brand recognition are especially hard to resolve through patient interviews. While accurate food histories from case-patients are the key to solving foodborne outbreaks, people's recollection of foods they have eaten can fade rapidly. Records associated with a case-patient's shopping purchase history (referred to as 'shopper history' within this document), such as paper receipts, transaction records obtained from store loyalty programs, and records of purchases made with credit or debit cards, can provide a valuable, objective source of information to investigators.[1] These records can assist with hypothesis generation and can set the stage for traceback of suspect food vehicles. Speedy and accurate exposure information can allow public health officials to quickly identify the suspected product, rule out other suspected vehicles, and prevent additional illnesses.

This document provides best practices for the request and use of shopper history during outbreak investigations and is a living document; it will be updated over time to reflect changes in outbreak investigation practices, retailer practices, purchase methods, consumer trends, and other related areas. This document focuses solely on acquisition and use of shopper history to aid in identifying a starting point for product traceback and/or identifying or confirming a common food exposure among case-patients. Details regarding best practices for a foodborne outbreak response are out of the scope for this document and can be found within the Council to Improve Foodborne Outbreak Response's (CIFOR) Guidelines for Foodborne Disease Outbreak Response. Similarly, best practices for conducting a traceback following the collection of shopper history records are out of the scope for this document and can be found within the Rapid Response Team (RRT) Best Practices Manual.

This document provides recommendations that local, state, and federal public health and regulatory officials can use when investigating foodborne outbreaks. Learning about shopper history best practices may help industry partners and consumers develop ideas for how to better collaborate with government investigators to solve outbreaks.

2. Background

a. Document Authors

This document is a product of the Shopper History Outbreak Partnership (SHOP), a group of state and federal public health and regulatory officials committed to identifying and promoting best practices for the use of shopper history during foodborne outbreaks to rapidly identify contaminated foods and prevent additional illness. More information about SHOP can be found online at: www.afdo.org/purchase-history.

b. What is Shopper History?

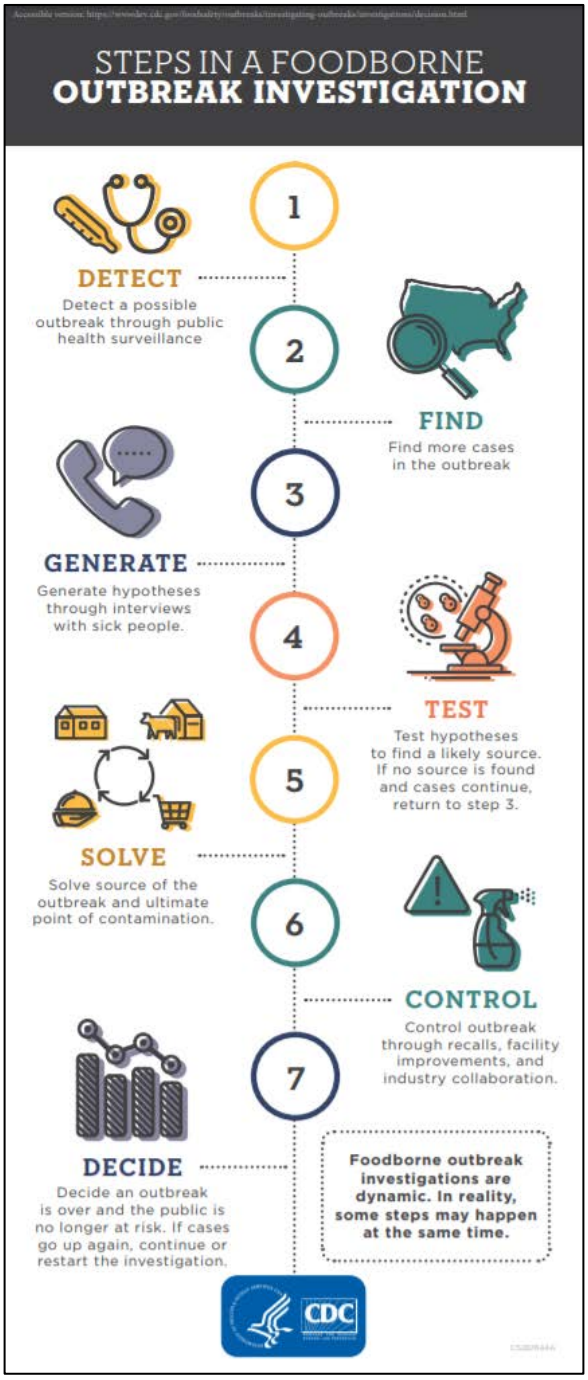
Shopper history refers to any type of record that provides information about a specific shopper's food purchases. Many different terms and sources of information can be used as shopper history. This should include, but is not limited to:

[1] Shopper history information that federal investigators obtain as part an official illness or outbreak investigation is exempt from the Paperwork Reduction Act (44 U.S.C. 3518(c); 5 CFR 1320.4(b)).

- Receipts (household shopping receipts/till receipts/register receipts that can be obtained in paper or electronic form from the shopper or from the food establishment);
- Shopper cards (also referred to as: loyalty cards, membership cards, warehouse store membership cards, rewards programs, or club cards);
- Paper or electronic credit/debit card or bank statements;
- Records of purchases made online, through a retailer app, or through a delivery service.

c. When is Shopper History Used in Outbreak Investigations?

There are several steps to a foodborne outbreak investigation. These are displayed in Figure 1 to the right, and more information about these steps is available here.[2] Foodborne outbreak investigations are dynamic, and some steps may happen at the same time. Shopper history may be of use at several points within an investigation, most commonly when generating and testing hypotheses and working to determine the source of the outbreak.



i. Generating and Testing Hypotheses

When investigators are generating and testing hypotheses about the likely source of the outbreak, specificity of information from case-patients about their food exposures is critical. Shopper history helps to obtain details of brand and product identity, purchase dates and locations, and distribution information from retailers.

Shopper history has been particularly useful for generating and testing hypotheses during the following situations:

- When a case-patient cannot remember the specific products consumed.
  - How the data are used: Shopper history can identify food purchases (including date/time of purchase) made by the case-patient, which can help inform food history recall during additional interviews with public health epidemiologists (i.e., when/how the food product was consumed, who else ate it).

[2] Source: https://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/investigations/index.html

- When case-patients report exposure to a common food establishment (or retailers under the same corporate umbrella/banner), but a common food exposure among case-patients has not been identified.
    - How the data are used: Shopper history can identify which food purchases the case-patients have in common, during a timeframe where that food could have caused illness.
- When a common food exposure of an unknown brand at one or more retailers is identified among case-patients.
    - How the data are used: Shopper history can determine whether case-patients were purchasing the same style and brand of product and whether purchases were made during the same timeframe.

ii. Determining the Source of an Outbreak

When investigators are trying to solve an outbreak by establishing a link between ill people and a contaminated source, shopper history can be essential. These records provide detailed information from restaurants and stores where case-patients purchased food to conduct a traceback and to identify a common point of contamination in the distribution chain.

Shopper history is particularly useful for identifying the source of an outbreak when an investigation identifies a suspect food vehicle. Shopper history can provide purchase dates, times, and other specifics on food products as a starting point for traceback activities. It can help to determine if there are supply chain commonalities among products purchased by different case-patients, and can support regulatory, enforcement, and/or other legal or public health actions by the state, the US Food and Drug Administration (FDA), or the US Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS).

3. Responsibility

This section explains who has responsibility for which aspects of obtaining shopper history.

a. Acquiring Information from Case-Patients during Interviews

Communicable disease investigators (i.e., public health nurses, epidemiologists) may request shopper history during a case-patient interview. This could include requesting the case-patient or household's shopper card number, credit/debit card number (or last four digits of the card number), store locations where they would have purchased items of interest, dates of purchases made, copies or originals of printed or electronic receipts, and other relevant data (i.e., company privacy policy forms) needed prior to contacting a retailer (see *V. Acquiring Information from Case-Patients During Interviews*).

b. Requesting Information from the Retailer

This responsibility varies widely depending on the agency. Local public health or environmental health jurisdictions may have their own investigation and would serve as the primary contact with the food establishment. In some states, recall coordinators may act as the point of contact; in other states the primary contact may be the epidemiology staff. The responsible party may also change as the investigation develops and more jurisdictions are involved.

If possible, shopper history data collection should be centralized to avoid duplication and to streamline communications with a retailer. In multistate outbreaks, data collection requests would

ideally be consolidated and managed centrally by a federal agency. Centralized shopper history data collection conducted by a federal agency can be initiated based on requests from state partners, industry partners, or federal agencies. Federal agencies should ensure that shopper history obtained as part of a centralized effort is shared with applicable state partners in a timely fashion.

c. Reviewing/Analyzing the Data

The responsible party varies depending on the agency and the step in the collection process. The individual requesting the information from the retailer is often responsible for verifying which products are listed on the shopper history documents through follow up questions with the retailer. The epidemiology staff are often responsible for verifying that a certain ill individual is the consumer of a certain product in question. Compilation and analysis of the data is most often done by state or federal epidemiology staff, depending on the jurisdictions involved in an outbreak.

4. Acquiring Information from Case-Patients during Interviews

a. Identifying potential sources of shopper history

During initial and follow-up case-patient interviews, investigators should:

- Ask prompting questions about grocery stores and other sources of food prepared/served at home (including meal delivery, etc.);
- Ask specifically about grocery chains in the area where the case-patient resides;
- Remind case-patients during the first interview to hold onto any records or receipts; and
- Ask about other records of food purchases such as receipts or credit/debit card statements.

b. Obtaining case-patient permission and explaining confidentiality

Asking explicitly for permission to obtain shopper history data can be done during:

- *The initial interview* – The interview would include the explanation that records will only be requested in the event of an outbreak investigation.
- *At a follow-up hypothesis-generating interview* – The interview would occur when a case-patient has been included in a cluster (e.g., through molecular lab testing) but a common exposure has not been identified.
- *During a focused outbreak interview* – This interview would take place when the case-patient has been included in a cluster and the exposure has been narrowed to a limited number of common exposures.

Examples of how shopper history is currently requested in various existing questionnaires are:

- National Hypothesis Generating Questionnaire
  - "May we have permission to retrieve purchases based on your member card information? This information will be kept confidential. May we share this information with other public health officials to help with this outbreak investigation?"
- CDC *Listeria* Initiative Case-Patient Report Form
  - "Would you be willing to release your shopper card information so we can get an exact list of your foods and when they were purchased?"
- Oregon Hypothesis Generating (Shotgun) Survey
  - "If necessary—say, because of an outbreak investigation—would you be willing to let us ask the store(s) to provide us with shopping records?"

During the request, communicate with the case-patient or their household member(s) that shopper history will only be shared on a need-to-know basis with local, state, or federal staff during the investigation. All personal identifiers will be redacted (e.g. name, shopper card number, credit or debit card number, phone number, etc.). Communicate with the case-patient that this information could help solve the outbreak and prevent additional illnesses. Additionally, the case-patient may be able to access their own shopper history through an online account.

The time frame and scope of the shopper history request may vary based on the details of the investigation. It is important to discuss this with the case-patient or their household member(s). Examples of ways to ask this include:

- We are investigating foods you purchased from January 2019 to February 2019. Would you be willing to provide us your shopper card number so we can obtain this information for that specific timeframe?
- Would you allow us to request all shopper card data or just particular types of food?

c. Obtaining clarifying details about use of the purchase method

The following questions can be asked during a case-patient interview to obtain permission to request shopper history information and to help clarify who may have consumed the food listed on the shopper history records:

- Is this shopper card or online account in your name or someone else's name? Do you have the authority to give permission to obtain records?
- Do you share your shopper card with any family members, friends, or other customers on occasion?
- Do you always use this card when you shop at this particular store?
- Can you review your bank records to confirm the purchase date(s)?

5. Requesting Information from the Retailer

This section explains the various steps and considerations behind requesting shopper history from a food establishment.

a. Considerations Specific to Various Types of Shopper History

i. Shopper/Loyalty and Warehouse/Club Membership Accounts

These types of shopper history records typically require a membership number and a name to request information from the retailer.

ii. Credit/Debit Card Records

There are various options for obtaining detailed food transaction records using credit/debit cards that were used for the purchase. These options are detailed in Appendix 1: Obtaining Food Transaction Records from Credit/Debit Cards. This includes:

- Asking the case-patient to reprint a receipt by going to the retail store
- Asking stores to find itemized transaction information in their digital systems using details from the case-patient's bank statements, including location of purchase, time of purchase, or a transaction number.
- Requesting that the case-patient calls a retailer to obtain their shopper history

iii. Accounts for Online Ordering or Delivery Services

For grocery delivery services, sometimes there is no account number identifying either the case-patient or their account. The name or account username of the individual who owns the account and their email address may need to be provided to the retailer. Alternately for this type of shopper history, the account holder may have the option of checking their purchase history online and providing it to investigators.

b. Gathering Information about the Retailer

Obtain a corporate point of contact for the retailer you are requesting information from:

- Consider whether others in your organization may have a history with this retailer and if there is already a point of contact established. This may be the case for recall coordinators in your state.
- Consider reaching out to other agencies that have had experience working with a particular retailer. This may include neighboring states, districts, or federal agencies. The Association of Food and Drug Officials (AFDO) directory of state and local officials is a useful resource to obtain contact information for other public health or regulatory agencies: http://dslo.afdo.org/.
- Look on the company website for a phone number and ask to be directed to the appropriate person. Typically, the point of contact is a director/manager of food safety or quality assurance.

c. Gathering Information about your Case-Patient

Before requesting purchase data from the retailer, consider the purchaser's exposure date, illness onset date, pathogen incubation range, details about suspect product frequency of purchase, dates purchased, and product characteristics, such as product expiration date, shelf life, and likelihood that consumers will freeze this product, to make an appropriate timeframe request.

d. Sending a Request to the Retailer

i. Mode of Communications

The mode of communications with a retailer to request shopper history varies based on preference, including phone or email, depending on the preference of the requesting agency and retailer. See Appendix 3 for template emails and Appendix 4 for a suggested phone script.

ii. Determining Dates of Shopper History Information Requested

The timeframes requested will vary in each investigation depending on pathogen and the state of the suspected food (frozen, canned, fresh, etc.). See the table below for guidance behind selecting a timeframe.

Food Items	Timeframe Details

Canned, frozen, and shelf-stable food	The timeframe for the shopper history request can be very broad. For these types of food, it is vital to obtain as much customer information as possible about the dates the suspect food was purchased.
Fresh food items, like produce and raw (non-frozen) meats	The timeframe for the shopper history request will be narrow as the product will have a short shelf life. Particularly, consider the shelf life for that particular item. For example, items like cilantro, basil, and lettuce will have much shorter shelf lives (about one week) compared to apples, grapes, and cherries which can last several weeks
Deli meats, cheeses, salads, or antipastos	The timeframe of purchase data requests could span several months since it is not uncommon for individuals to keep some types of deli items, such as unopened chubs of salami, olives, or aged cheeses, in their refrigerators for one or more months. For deli meats, the use by dates, best-by dates, and sell-by dates can be considered but should not be a final deciding factor for selecting purchaser data timeframes as businesses and buyers do not always adhere to these recommendations. Different brands of deli meats, cheeses, and salads will have a wide range of date suggestions depending upon how the meat is processed and packaged.

iii. Requesting Preferred Format

When requesting purchaser data from the retailer, ask them what type of format they are able to provide the data in. If possible, obtain the customer data in Excel. Data in Excel are easily searchable, formatted, and are compatible with most analytical software packages like SAS, R, and Epi Info. Receiving data in Excel is ideal, but if it is not an option, accept the available format and request the information be legible. PDF formats work well for keyword searches, but if more complex analytics are required, the data would need to be converted into another software package.

iv. Communicating Expectations

The retailer should send shopper/loyalty card data back to the requester as soon as possible, but within 48 hours. Communicate to the retailer that a timelier response can greatly help to identify the source of illnesses, reduce illness transmission in the community, and significantly reduce the overall impact of the outbreak. Communicate that you may reach out with questions to clarify product codes and identify products purchased.

Explain to the retailer that documentation may be shared, if requested, as part of an investigational file. This may vary state-to-state due to confidentiality laws. Request they redact any sensitive business information on the shopper history record, such as. prices for bulk products, etc.

Let retailers know that non-relevant, non-food purchases may be excluded from the records (e.g. alcohol, prescriptions, etc.).

v. Coordinating Requests with Investigation Partners

If feasible, while ensuring timeliness, batch the shopper/loyalty card data requests (instead of sending individually) by coordinating requests with investigation partners to lessen the burden on retailers, as well as encouraging continued retailer cooperation (see *IV. Responsibilities*).

e. Additional Information that May Be Helpful

If needed, consider asking the retailer to also provide the following items:

- The market share for the food item of interest to help assess baseline usage of the product (e.g., what percentage of your bagged salad is Brand A or what percentage of shoppers purchased bagged salad Brand A during the outbreak period?).
- A redacted random sample of other shopper history records from the same time period and location as the case-patient records to serve as a control group.

f. Overcoming Barriers at the Retailer

i. Notary and Other Legal Requirements by Retailers

Some retailers require a notarized signature from the cardholder before they are willing to release shopper/loyalty card records:

- Disclosure is required by law per Public Health Service Act Section 301;
- If a retailer requests notarized signatures, contact CDC at outbreakresponse@cdc.gov or the assessment epidemiologist for the cluster to request assistance (see example in Appendix 2).

Some retailers might prefer a letter on agency letterhead noting permission from the cardholder (see Appendix 3 for letter templates for both verbal and written consent from the consumer)**.** Review existing state laws and determine if retailers are required to share this information without additional consent from the cardholder during an outbreak investigation; consult with your state's legal counsel if this is unclear. A compilation of state laws can be found online at: www.afdo.org/purchase-history.

ii. Credit/Debit Card Data Records

Although there are additional sensitivities with using credit/debit card data during foodborne illness investigations, in many instances, it is possible for the retailer to provide a record of purchases for purchases made using this method; can be assessed on a case-by-case basis.

g. Limits and Caveats of Shopper/Loyalty Card Data

There can be some limitations to shopper/loyalty/credit/debit card data if the cards are not used as intended. Some limits are described in the table below.

Limitation	Outcome
The shopper may have used another person's card or the cashier's "courtesy card" behind the register.	This prevents a clear picture of what was purchased and may have been consumed due to multiple shoppers' histories tied to one card.
The shopper may have multiple	Though less common, a shopper may have multiple loyalty cards for an individual store if they have forgotten or lost a card and elect to open a

loyalty cards for the same store.	second card. Missing purchases made with the "forgotten" card may also prevent a clear record of shopper history.
The shopper may have forgotten to use the card.	If the shopper did not use the card the data needed would not be available.
The shopper may have paid in cash.	Paying in cash eliminates the method of retrieving credit/debit card purchase data and may eliminate the ability to track purchases made with a shopper/loyalty card. Purchase with a credit/debit card allow the ability to track what, where, and when an item was purchased. Note that a shopper may pay in cash but still use a shopper/loyalty card.
The consumer might not have purchased food themselves.	There are various reasons why consumers might not purchase food themselves which can make traceback difficult. It might not be possible to track down the shopper or the shopper might not recall needed information because they were not shopping for themselves.
Data from the shopper card cannot be pulled due to encryption.	With the increased use of credit cards with chips, retailers are facing difficulty retrieving records because all the purchase history information is encrypted.

6. Reviewing and Analyzing the Data

This section reviews best practices for verifying and analyzing shopper history records once they have been obtained.

a. Verifying the Products

If the meaning of codes and abbreviations for food items on the receipt are not obvious, confirm these by asking the retailer or the case-patient for additional detail. Different retailers will use different abbreviations for products on their receipts. For example, both ground beef and green beans may be abbreviated with "GB". If it is not clear exactly what the product is, this will need to be verified by the retailer and/or case-patient. The retailer will likely be able to provide more detail on the specific product such as lot numbers, weight, and source. Most retailers use a numeric code for the product. This number may be present on the receipt and providing this information to the retailer can be helpful in obtaining the exact product details for products that come in a variety of selections from a variety of brands. Pay attention to the quantity purchased as well as specificity of item (e.g., whole uncut watermelon vs. cut watermelon slices).

b. Verifying the Consumer

Before consolidating purchase data for analysis, the investigator should verify the case-patient consumed the implicated product. It is not uncommon for multiple individuals to use the same shopper or credit/debit cards. This confirmation can take place during the case-patient interview process by confirming the date the items were purchased and what was purchased. Ask the case-patient to review bank records and any available receipts to aid in confirming date of purchase and what items were purchased. It is ideal to capture this information during early interviews thereby

reducing the risk of losing case-patients to follow-up. Refer to Section V for questions that can be asked during a case-patient interview to help verify the consumer.

c. Analyzing the Data

All data must be consolidated into a format that can be easily shared and analyzed. Excel is the most common program used to consolidate, sort, and search this information and is compatible with other analytical tools like SAS, R, Epi Info, and SEDRIC. Other options include Microsoft Access or visually examining the data in the form it was received depending upon the size of the dataset.

Once the data are compiled and analyzed, create a written summary interpreting the data. The summary should include: how many times the implicated food item was purchased, dates, location name and address of where the product was purchased, manufacturer (name and address), USDA establishment number (if applicable), and other pertinent pieces of information.

Share your pertinent findings and shopper history records with other investigation partners as appropriate, including those conducting a traceback. See Appendix 7 for examples of shopper history summaries for sharing with investigation partners.

7. Data Maintenance/Confidentiality Considerations

This section details best practices in relation to maintenance of data and confidentiality of sensitive information for shopper history records. Retailers and public health officials should protect confidentiality by redacting personal identifiers and sharing information on a need to know basis in order to solve the outbreak.

a. Requesting Data from a Retailer

During the request, communicate with the retailer's responsible party that content from the purchase history could be made public following the closure of the investigation. Personal identifiers will be removed by the lead agency on the investigation (see *b.* below), but information that is not relevant to the investigation that the retailer considers sensitive should be removed or redacted by the retailer. Sensitive information may include pricing for products.

b. Requesting Data from the Case-Patient or Case-Patient Household

During the request, communicate with the case-patient or case-patient household member(s) that purchase records will only be shared on a need-to-know basis with local, state, or federal staff during the investigation. All personal identifiers will be redacted (e.g. name, credit/debit card number, phone number, etc.).

c. Data Maintenance and Storage

All data containing personal identifiers should be redacted or stored securely, whether physically or electronically, to prevent breach of confidentiality. Data will be destroyed following the closure of an investigation per each agency's data retention policy.

d. Sharing Data with Other Partners

Outbreak investigations require collaboration between local, state, and federal public health partners. Shopper/loyalty card purchase records contain personal identifiers that could be linked to a case-patient, so information should be redacted and shared on a need-to-know basis to prevent breach of confidentiality.

- Records to be shared with other partners should be "swept" for any identifying information and redacted. Personal identifiers may include credit/debit card information, account holder name, and account holder address.
- State agencies that are sharing confidential case-patient information with federal partners may not be allowed to do so under certain state laws.
- Leave at least one non-identifiable unique number on the shopper history record to link the record to a case-patient. This can include a partial shopper card number, or, alternately the PulseNet ID.
- If records were requested by a federal agency that is working with state partners during an investigation (i.e., a centralized shopper history data collection), the shopper history should be shared in a timely manner (ideally 24-48 hours) with applicable state/local partners. Records can be shared through secure email, fax, or uploaded into SEDRIC.

8. Communications During and After the Outbreak

This section reviews best practices for communications with food retailers during an outbreak, immediately following an outbreak, and moving forward for improved public health agency/retailer relationships.

a. Providing Feedback to Retailers

Provide timely feedback to retailers regarding the outbreak investigation and thank them for their cooperation. Information shared may vary from state-to-state due to confidentiality laws. It is important to keep retailers informed of developments during the outbreak investigation. Information flow should not be in one direction only where the outbreak investigators are requesting shopper and product data from the retailer but not providing any pertinent investigation updates. When appropriate, share updated investigation information with the retailer. Consult with the outbreak team before any information is released to the retailer. No personal customer information should be shared with the retailer. Assign one or two contact people to serve as the main contact(s) with the retailer and provide them with their contact information. Inform the retailer that they can contact this individual anytime with questions or concerns during or after the investigation. This will help to ensure the information provided to the retailer is concise and accurate. If the investigation is part of a multistate outbreak and a federal agency is the lead, any information shared with the retailer should be approved by the federal agency lead. People involved in clearing information could include epidemiologists, laboratory management, environmental health specialists, regulatory compliance officers, and health communication specialists. Clearing information should be a team effort and should not be conducted by an individual.

Examples of information that may be shared with a retail point of contact could include lab results of tested food (be prepared to answer questions about whole genome sequencing [WGS], polymerase chain reaction [PCR], culture-independent diagnostic tests [CIDTs], and presumptive positives), recalls and recall protocol, probable/confirmed case-patient counts, states/counties impacted, traceback activities, etc. After the outbreak has concluded, communication channels should be left open to the retailer so they can inquire about the reasoning behind decisions for the scope of the recall, lack of a recall, and interpretation of data.

b. Building Relationships with Retailers

Build and maintain relationships with retailers. Invite retailers to collaborative seminars and workgroups such as Food Protection Task Force (FPTF) meetings. FPTFs consist of public health,

regulatory, industry, academia, and consumer groups. These FPTFs create an effective nationwide infrastructure for enhancing outreach, response, integration, and information sharing in state, local, and tribal governments (https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/national-integrated-food-safety-system-ifss-programs-and-initiatives/food-protection-task-force-fptf). This consortium of FPTF members provides an environment for all of those involved in food safety to get to know each other and to learn about different organizations' roles in ensuring safe/unadulterated food to consumers. Retailers should also be included in appropriate meetings and conferences and be encouraged to participate in these meetings. Building these relationships before an outbreak investigation can help to promote timelier information sharing during outbreak investigations.

Volunteer to present educational programs at retailer meetings and internal food safety training. Many retailers do not accurately understand the process of outbreak investigation and why investigators request data. Conducting educational sessions and open forums during non-outbreak times can greatly enhance partnership during outbreak investigations. Presenting a concise summary of how outbreak investigations work and the collaborative role of retailers, including the many shared overarching goals of providing safe food to the public will lead to more open communication between regulators and retailers.

9. Glossary

See CIFOR Guidelines Glossary.

10. Resources

- Integrated Food Safety Centers of Excellence
- Møller Frederik T, Mølbak Kåre, Ethelberg Steen. Analysis of consumer food purchase data used for outbreak investigations, a review. Euro Surveill. 2018;23(24):pii=1700503. https://doi.org/10.2807/1560-7917.ES.2018.23.24.1700503

11. Appendices

Appendix 1. Key points for obtaining credit/debit transaction records (Minnesota Center of Excellence)

KEY POINTS

for Successful Foodborne Outbreak Detection and Investigation

OBTAINING FOOD TRANSACTION RECORDS FROM CREDIT/DEBIT CARDS

Successfully identifying the source of foodborne disease outbreaks requires detailed assessment of exposures during the incubation period. Asking the case to review check registers and paper or online credit card/bank statements can provide the purchase date and location of foods consumed during the time period of interest. This can be an important starting point for recalling specific food exposures in a timely manner.

During investigations of outbreaks thought to be due to commercial food items, itemized paper receipts saved by cases and transaction records obtained from store loyalty programs, co-ops, or warehouse membership cards ("shopper cards") are valuable sources of specific information about foods purchased by cases. When these sources of information are available, they should be used to the fullest extent possible. However, when these are not available (e.g., the store does not have a loyalty or membership program), another strategy exists – food transaction records can often be resurrected using credit or debit cards that were used for the purchase. Here are some key points for collecting transaction records, based on the Minnesota Department of Health's experience.

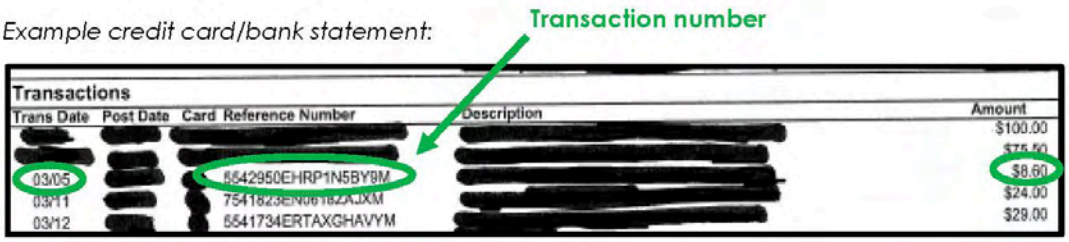
1. Receipt reprints – gathered by case

- It is becoming more common for stores to have the ability to print copies of transactions made using a credit/debit card.
- If the case is willing, it is often easiest (and the fastest way to get information to public health officials) for the case to obtain the desired records.
- Ask the case to visit the grocery store location(s) where food items eaten before illness onset were purchased. The case will need to bring the credit/debit card(s) that was used for purchases.
- The case should present their card at the store's customer service counter and request copies of receipts for all purchases made with the card during the time period of interest (typically the month prior to illness onset).
  - Stores may also have an in-store kiosk for customers to print receipts themselves using their card.
  - Some stores can also retrieve purchases made by check using the account number on a blank check.
- Investigators can pick up the printed receipts from the case, or ask the case to email or fax the receipts to the health department to facilitate rapid transfer of information. If these are not options, receipts can be mailed.

2. Digital receipts – gathered by public health/agriculture agency

- Some stores can find itemized transaction information in their digital system using details from the case's bank statements.
- The Department of Agriculture (or other agency with jurisdiction) must work with the store or their corporate contact to find out what information is needed to find the case's receipts in their digital transaction files. The information needed to find the case's digital receipts varies by store.
- Ask the case to look at paper or online credit card/bank statements and provide the needed details for all food purchases during the time period of interest (typically **the month** prior to illness onset). This may include:
  - Location of purchase
  - Date of purchase
  - Transaction number (if available – may or may not be listed depending on bank/credit card company)
  - Time of purchase (if available – more important if transaction number is not available)
  - Total dollar amount of transaction
- It is important to stress to the case that no part of the credit/debit card number needs to be shared.

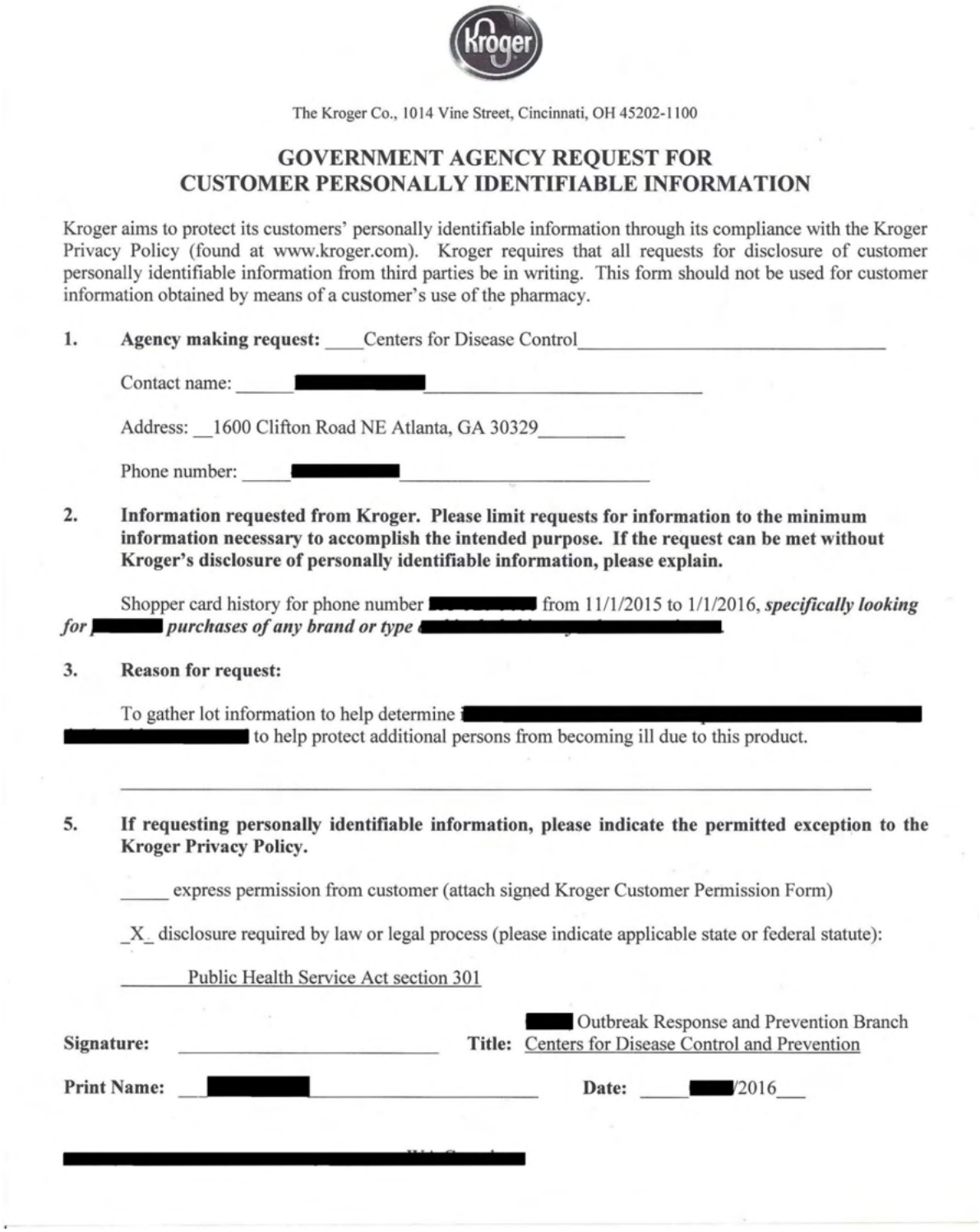
Example credit card/bank statement:



- The store may require written consent from the case to access these records. An email from the case or a letter from the epidemiologist confirming the case's verbal consent will usually suffice.
  - See our website for a template that can be used for this purpose.

MINNESOTA
Integrated Food Safety
Center of Excellence
MINNESOTA DEPARTMENT OF HEALTH • UNIVERSITY OF MINNESOTA
http://mnfoodsafetycoe.umn.edu/

Appendix 2. Example form for government agency request for customer information (Kroger, CDC request)



The Kroger Co., 1014 Vine Street, Cincinnati, OH 45202-1100

GOVERNMENT AGENCY REQUEST FOR CUSTOMER PERSONALLY IDENTIFIABLE INFORMATION

Kroger aims to protect its customers' personally identifiable information through its compliance with the Kroger Privacy Policy (found at www.kroger.com). Kroger requires that all requests for disclosure of customer personally identifiable information from third parties be in writing. This form should not be used for customer information obtained by means of a customer's use of the pharmacy.

1. **Agency making request:** ____Centers for Disease Control_____

   Contact name: _____[redacted]_____

   Address: __1600 Clifton Road NE Atlanta, GA 30329_____

   Phone number: _____[redacted]_____

2. **Information requested from Kroger. Please limit requests for information to the minimum information necessary to accomplish the intended purpose. If the request can be met without Kroger's disclosure of personally identifiable information, please explain.**

   Shopper card history for phone number [redacted] from 11/1/2015 to 1/1/2016, ***specifically looking for [redacted] purchases of any brand or type [redacted]***.

3. **Reason for request:**

   To gather lot information to help determine [redacted] to help protect additional persons from becoming ill due to this product.

5. **If requesting personally identifiable information, please indicate the permitted exception to the Kroger Privacy Policy.**

   _____ express permission from customer (attach signed Kroger Customer Permission Form)

   _X_ disclosure required by law or legal process (please indicate applicable state or federal statute):

   _____Public Health Service Act section 301

Signature: _____ **Title:** [redacted] Outbreak Response and Prevention Branch Centers for Disease Control and Prevention

Print Name: ___[redacted]_____ **Date:** _____[redacted]/2016___

[redacted]

Appendix 3-1. Shopper History Request Example (Tennessee)

To whom it may concern,

We recently requested records from your agency as part of an ongoing disease outbreak investigation in which there are reported illnesses in the community. We are requesting (**insert retailer name)** provide customer information for **(insert shopper card number/ or credit/debit)** from **(insert date range)**. The authority to collect this information comes from the Communicable Diseases Rules of the Tennessee Code Annotated. These rules give us the explicit authority to collect this type of information, which is essential to our public health investigation. Please see the specific chapter that references this authority below.

1200-14-1-.15 GENERAL MEASURES FOR THE EFFECTIVE CONTROL OF DISEASE OUTBREAKS. (1) It shall be the duty of the local health officer or the Commissioner or his designated representative, on receiving a report of a communicable disease, or of a suspected epidemic of disease or of a suspected case of a disease of public health significance to:

(a) Confer with the physician, laboratory, hospital, or person making the report;

(b) Collect such specimens for laboratory examination as may be necessary to confirm the diagnosis of the disease and/or to find the source of the infection or the epidemic;

(c) Obtain all names and information necessary to identify and contact all persons potentially exposed to the source of the disease outbreak as needed to protect the public health;

(d) Make a complete epidemiological investigation to include (but not limited to): review of appropriate medical and laboratory records of affected persons and controls, interviews of affected persons and controls, and recording of the findings on a communicable disease field record; and

(e) Establish appropriate control measures which may include examination, treatment, isolation, quarantine, exclusion, disinfection, immunization, disease surveillance, closure of establishment, education, and other measures considered appropriate by medical experts for the protection of the public's health.

https://www.tn.gov/content/dam/tn/health/documents/1200-14-01.pdf

Appendix 3-2. Shopper History Request Example (New York)

Official Letterhead

[Date]

[Contact
Information]

To Whom it may concern:

The [XXXXXXXXXX Department of Health] (Department) is currently investigating a possible food-borne illness. To conduct this investigation, the Department must review the foods that were purchased or consumed by people who became ill. Consequently, the Department is hereby requesting [enter store name] provide the purchase history associated with the loyalty card for [patron name and/or loyalty card number] for the dates of [XX/XX/XXXX to XX/XX/XXXX]. Please provide this information to [Department of Health Employee Name] with the Department at [Employee Email Address] as soon as possible.

The Department is requesting this information pursuant to the Commissioner of Health's authority under [NYS Public Health law (PHL) section 206(1)(d)] to investigate the causes of disease, epidemics, the sources of mortality, and the effect of localities, employments and other conditions upon the public health. This information is critical to our investigation. If you refuse to provide this information, the Department, pursuant to [NYS PHL § 206(4)(a)], has the authority to subpoena this information. Thank you in advance for your cooperation.

Sincerely,

[signatory]

Appendix 3-3. Shopper History Request Example (Minnesota)

Protecting, Maintaining and Improving the Health of All Minnesotans

[Date]

To Whom It May Concern:

[Name] has provided verbal consent to the Minnesota Departments of Health (MDH) and Agriculture (MDA) to obtain her complete purchase records from [Facility], as needed for a foodborne illness outbreak investigation.

As part of her verbal consent, she provided her membership number [Number]. MDH and MDA would like to receive a copy of all her purchases in [Timeframe].

Please feel free to contact me at [Phone] if I can be of any further assistance.

Sincerely,

[Epidemiologist]
Epidemiologist Senior Foodborne Diseases Unit
Foodborne, Waterborne, Vectorborne, and Zoonotic Diseases
Minnesota Department of Health
Post Office Box 64975
Saint Paul, Minnesota 55164-0975

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Appendix 3-4. Shopper History Request Example with Confirmation of Case-Patient's Verbal Consent (Minnesota)

****INSERT AGENCY LETTERHEAD****

Month Day, Year

To Whom It May Concern:

[Name of case-patient] provided verbal consent to the [State Health or Agriculture Department] to obtain his/her complete purchase records from [Retailer], as needed for a foodborne illness outbreak investigation. As part of his/her verbal consent, he/she provided his/her membership number (####). [State Health or Agriculture Department] would like to receive a copy of all his/her purchases between Month Day, Year to Month Day, Year.

Please feel free to contact me at ###.###.#### if I can be of any further assistance.

Sincerely,

Agency POC First and Last Name

Agency Name

Agency Address

City, State Zip code

Appendix 4. Template call script requesting shopper history from retailer (Minnesota)

Request to speak with someone in quality assurance (QA), food safety, or management.

Script:

Investigation Lead: Good morning/afternoon – my name is [NAME] and I work with [AGENCY], could I please speak with someone in QA, food safety, or management?

Good morning/afternoon – my name is [NAME] and I work with [AGENCY]. We are currently working jointly with [PARTNER AGENCY, IF APPLICABLE] on an investigation of a cluster of cases of [FOODBORNE ILLNESS].

No specific food item has been confirmed as the source of the outbreak at this time, but epidemiologic investigation has identified that a case of illness shopped at [FACILITY] prior to illness.

OR

[SUSPECT FOOD ITEM] has been identified as a possible source of illness, so we are reviewing case-patient purchase histories to identify possible [SUSPECT FOOD ITEM] purchases prior to illness. We have confirmed that one case of illness shopped at [FACILITY] prior to illness.

Note that we do not state the case's name over the phone, only their shopper card number.

As a part of the investigation, [AGENCY] is collecting purchase history for all of the cases of illness in Minnesota. We have received verbal permission from the [FACILITY] shopper case-patient to obtain their shopper history using their shopper card number. We are looking for [ALL PURCHASES OR SUSPECT FOOD ITEM] made during [TIMEFRAME] by the household using [SHOPPER NUMBER].

Do you need any additional information for me or have any questions regarding this request?

Thank you.

A verbal discussion routinely requires email follow-up, similar to examples in Appendices 3-1 through 3-4.

Appendix 5. Template Letter – Case-Patient requesting retailer release shopper history to government agency

Retail POC
Title
Address
City, State Zip code
Email
Phone
Fax

Dear XXXXX:

I am requesting that [Retailer] release my club card purchase history to the [State Health or Agriculture Department] for the purposes of a public health investigation. Please find my club card and personal information below.

Name of cardholder: _____

Street address: _____

City, State, and Zip code: _____

Phone number:_____

[Retailer] Card number (if card number is unknown, enter phone number linked to card):_____

Timeframe of interest: _____ to _____

The [State Health or Agriculture Department] would appreciate your faxing my purchase history directly to _____ at _____.

Thank you very much for your cooperation in this matter.

Sincerely,

Signature of Cardholder Date

Appendix 6-1: Shopper History Example (Rhode Island)

Location	Register	UPC / PLU	Tran No / Dept No	Employee	Time	Date	Quantity	Total	Flags
					14:12				
		4900002892 - SPRITE 12PK 12Z CAN	1 - Grocery				1	$6.29	TAX
		4900002892 - SPRITE 12PK 12Z CAN	1 - Grocery				1	$6.29	TAX
		4900002890 - COKE CLASSIC 12PK 12Z	1 - Grocery				1	$6.29	TAX
		4900002890 - COKE CLASSIC 12PK 12Z	1 - Grocery				1	$6.29	TAX
		64420930749 - DH CKE MIX YLLW 15.25Z	1 - Grocery				1	$2.19	
		210000230215	1 - Grocery				-1	($1.31)	Electronic Store Coupons
		64420930749 - DH CKE MIX YLLW 15.25Z	1 - Grocery				1	$2.19	
		210000230215	1 - Grocery				-1	($1.31)	Electronic Store Coupons
		4087 - TOMATOES PLUM	4 - Produce				1	$1.01	W,NS
		68826702029 - SB H&H CREAM 64 OZ.	8 - Dairy				1	$5.79	
		68826700134 - SB ORANGE SODA 2L	1 - Grocery				1	$0.79	TAX
		68826700134 - SB ORANGE SODA 2L	1 - Grocery				1	$0.79	TAX
		68826700134 - SB ORANGE SODA 2L	1 - Grocery				1	$0.79	TAX
		68826700134 - SB ORANGE SODA 2L	1 - Grocery				1	$0.79	TAX
		20540810000 - SB ITALIAN BREAD	10 - Bakery				1	$1.79	W
		210000231818	10 - Bakery				-1	($0.80)	Electronic Store Coupons
		68826712470 - SB STWB SLC W/ASP22.5Z	6 - Frozen Food				1	$4.49	
		210000235209	6 - Frozen Food				-1	($0.50)	Electronic Store Coupons
		20731770000 - SB OVN RST ROTIS CHK HT	24 - Prepared Foods				1	$4.99	TAX,W
		1500007604 - GBR 2ND SWT POT 2PK 8Z	1 - Grocery				1	$1.19	
		1500007602 - GBR 2ND PEAS 2PK 8Z	1 - Grocery				1	$1.19	
		1500007604 - GBR 2ND SWT POT 2PK 8Z	1 - Grocery				1	$1.19	
		4100000324 - LPTN NOODLE SOUP 4.5Z	1 - Grocery				1	$1.79	
		210000262373	1 - Grocery				-1	($0.20)	Electronic Store Coupons
		41200322277	1 - Grocery				-1	($3.79)	Store Coupons Scanned
		41200322277	1 - Grocery				-1	($3.79)	Store Coupons Scanned
		41200322277	1 - Grocery				-1	($3.79)	Store Coupons Scanned
		41200322277	1 - Grocery				-1	($3.79)	Store Coupons Scanned
								$36.85	
						TaxAmount		$1.32	
						Total		$38.17	
						Cash Tendered		$100.00	
						Cash Back(0)		$61.83	
						Shopper Card Other Activity ACCT#		$0.00	
						Loyalty Points Earned ACCT#		$37.00	
						Total Time:	102 (1.70 minutes)		
						Ring Time:	41 (0.68 minutes)		
						Tender Time:	13 (0.22 minutes)		
						Other Time:	48 (0.80 minutes)		
						Special Sign Off:	0 (0.00 minutes)		
						Non Checkout Time:	0 (0.00 minutes)		

Appendix 6-2: Shopper History Example (Indiana)

Store:	[redacted]		
Transaction Start Time:	05/04/2019 12:04:20 PM	Transaction End Time:	05/04/2019 12:06:53 PM
Invoice Number:	[redacted]	Terminal:	[redacted]
Customer Number:		Receipt Number:	111111
Customer Name:	Doe, John	Cashier:	11111 : Jane Doe

[redacted]	Receipt Alias	Quantity Sold		Unit Price	Ext Price	Notes
	SIX CHS RAV W/SAUC	1.000	1 /	$5.99	$5.99	Cucina di Carla Six Cheese Ravioli with Marinara Sauce
	COLES CHEESESTICKS 11.50 OZ	1.000	1 /	$4.69	$4.69	Coles Cheese Sticks, with A Twist
	2@4				($2.69)	*discount*
	COLES NACHO CHEESE PRETZEL STICK	1.000	1 /	$4.69	$4.69	Coles Pretzel Sticks, Filled with Pub Cheese
	2@4				($2.69)	*discount*
	ECK SKLS TKY S SAU	1.000	1 /	$4.39	$4.39	Eckrich Skinless Turkey Smoked Sausage
	2@5				($1.69)	*discount*
	OUI FRCH PEACH YOG	1.000	1 /	$1.59	$1.59	Yoplait Oui Yogurt, French Style, Peach
	KRAFT COOL WHIP ORIGINAL WHIPPED	1.000	1 /	$1.99	$1.99	Cool Whip Whipped Topping, Original
	UDRLY SMTH HND CRM	1.000	1 /	$2.99	$2.99	Udderly Smooth Hand Cream Original Formula
	EE PANKO	1.000	1 /	$2.29	$2.29	Essential Everyday Bread Crumbs, Crispy, Panko, Plain
	RAINBOW ROSE BUNCH 1CT	1.000	1 /	$9.99	$9.99	Rainbow Rose Bunch Dozen
	PHILADELPHIA ORIGINAL CREAM CHEE	1.000	1 /	$2.49	$2.49	PHILADELPHIA ORIGINAL CREAM CHEE
	PIL SM CINN ROLL	1.000	1 /	$1.79	$1.79	Pillsbury Cinnamon Rolls, with Icing
	FR BK BAN NUT LOAF	1.000	1 /	$5.99	$5.99	Fresh Baked Nut Loaf
	SPARKLE PRINTS 1 ROLL	1.000	1 /	$1.49	$1.49	Sparkle Paper Towels, Full Sheet, Print, 1 Regular Roll
	LEWIS NUTTY OAT	1.000	1 /	$1.69	$1.69	LEWIS NUTTY OAT
	BELLA SUN LUCI SUN DRIED TOMATOE	1.000	1 /	$3.99	$3.99	Bella Sun Luci Tomatoes, Sun Dried, Halves
	QUAKER CHEWY YOGURT COVERED GRAN	1.000	1 /	$2.99	$2.99	Quaker Chewy Yogurt Granola Bars, Strawberry
	BC SCALIPOTATOES	1.000	1 /	$1.99	$1.99	Betty Crocker Scalloped Potatoes
	[redacted]	4.000	1 /	$1.00	$4.00	[redacted]
	YELLOW ONIONS 3.0 LB	1.000	1 /	$2.99	$2.99	YELLOW ONIONS 3.0 LB
	ESSENTIAL EVERYDAY MINI PRETZELS	1.000	1 /	$1.79	$1.79	ESSENTIAL EVERYDAY MINI PRETZELS
	HUNTS MANWICH SLOPPY JOE SAUCE	1.000	1 /	$1.25	$1.25	HUNT'S MANWICH SLOPPY JOE SAUCE
	PEPPERS GREEN BELL	1.000	1 /	$1.69	$1.69	PEPPERS GREEN BELL
	JELL-O GELATIN DESSERT STRAWBERR	1.000	1 /	$1.29	$1.29	JELL-O GELATIN DESSERT STRAWBERRY
	JELL-O GELATIN DESSERT STRAWBERR	1.000	1 /	$1.29	$1.29	JELL-O GELATIN DESSERT STRAWBERRY
	EEDY OREGANO LEAVES	1.000	1 /	$1.79	$1.79	Essential everyday OREGANO LEAVES
	GRAPES RED SOLSS	2.690	1 /	$1.28	$3.44	GRAPES RED SEEDLEESS
	Check - ECC				$74.30	
	SUBTOTAL				$73.29	
	IN 7%				$1.01	
	TOTAL				$74.30	
	TOTAL TENDERED				$74.30	
	Change				$.00	
					$.00	
	--- Card Information ---				$.00	
					$.00	
	Card Type: TELEC Swiped				$.00	
	Account #: XXXXXXXXXXXXXXXX				$.00	
	Exp Date :				$.00	
					$.00	
	Amount: 74.30				$.00	
	Approval #: XXXXX				$.00	
	Date: 5/4/19 12:06:53 PM EDT				$.00	
					$.00	
	Reference #: XXXXXXXXX				$.00	
	Signature Captured				$.00	

Appendix 7: Example written summaries of shopper history findings for sharing with investigation partners

Example 1

The case-patient purchased raw yellow onions in one 3.0 lb size pre-packaged bag on 5/4/2019 from Grocery Store A located at 123 Main St. in Capital City. Additional information about the onions can be obtained by contacting the retailer.

Example 2

A cluster of eight *Salmonella* Newport infection case-patients with illness onsets ranging from 10/28 to 11/4 were identified by whole genome sequencing (WGS). All isolates are related within two alleles by cgMLKST. All case-patients reported "definitely" or "maybe" eating pre-cut fruit during their exposure period and all reported purchasing the fruit at either Store A or Store B using shopper cards. Permission to request shopper card history was obtained and the stores were asked to provide shopper history for the last two weeks in October and first week of November.

Case ID	Onset date	Grocery Store	Reported consuming pre-cut fruit	Pre-cut fruit on shopper card history	Shopper card history detail
1	11/4	Store A	Yes	Yes	Watermelon chunks in clamshell on 11/1
2	10/28	Store A	Yes	Yes	Watermelon chunks in a clamshell on 10/25
3	11/3	Store B	Maybe	Yes	Cantaloupe, honeydew and watermelon medley in clamshell 10/29, cantaloupe in clamshell 11/2
4	11/2	Store A	Yes	Yes	Cantaloupe chunks in clamshell 10/30
5	11/3	Store A	Maybe	Yes	Cantaloupe, honeydew and watermelon medley in clamshell 10/31
6	11/4	Store B	Yes	Yes	Cantaloupe chunks in clamshell 11/3, watermelon chunks in clamshell 10/29, 11/1, 11/3
7	11/2	Store A	Yes	Yes	Cantaloupe chunks in clamshell 10/30, watermelon chunks in clamshell 10/30
8	11/1	Store A	Yes	Yes	Cantaloupe chunks in clamshell 10/30, Watermelon chunks in clamshell 10/30

Amend Food Code 3-501.14 to include an option to cool TCS foods at a depth of 2inches or less, uncovered, and refrigerated, without time and temperature monitoring

The working group for this issue included:

Donald Schaffner, Rutgers University
Nick Koreen, City of Minneapolis Health Department
Janet Anderberg, Washington State Health Department (Retired)
Nicole Hedeen, Minnesota Department of Health
Susan Shelton, Washington State Health Department
And several other members

Executive Summary:

Improper cooling of hot food by restaurants is a significant cause of foodborne illness outbreaks (Brown *et al.*, 2012; Hedeen, Schaffner, & Brown, 2022). Hot foods should be cooled rapidly to minimize pathogen growth and prevent outbreaks. Unfortunately, rapid cooling is often difficult for restaurants to accomplish and for inspectors to verify. The FDA Risk Factor study (2018) found that cooling practices did not meet the cooling parameters described in the FDA Food Code at least once in 72% of 273 full-service restaurants where cooling was observed. Although the FDA Food Code provides guidance on possible cooling methods, it does not provide guidance on the specific combinations of cooling methods that will achieve compliance with the time recommendations. Our proposed option of refrigerated cooling at an uncovered depth of 2 inches or less, provides a clear cooling standard for operators and is an effective means of cooling. This option is also beneficial to inspectors, as it is simple to verify during an inspection and easy to train operators on safe cooling methods. Ultimately, this option will potentially reduce operating costs for food establishments and reduce time dedication for operators and inspection staff while providing a more reliable way to reduce illness.

1. **Define the problem that needs to be addressed**

Improper cooling of hot food by restaurants is a significant cause of foodborne illness outbreaks (Brown et al., 2012). Cooling hot foods too slowly is one of the most common pathogen growth factors contributing to restaurant-related outbreaks (Gould *et al.,* 2013), and was identified as a contributing factor in 10% of the 251 outbreaks reported to the National Environmental Assessment Reporting System during 2014-2016 (Lipcsei *et. al*, 2019). Approximately 9% of outbreaks in the United States between 2009 and 2015 were due to bacterial intoxications from pathogens such as *Clostridium perfringens*, *Bacillus cereus*, and *Staphylococcus aureus* (Dewey-Mattia *et. al*, 2018). These bacteria can multiply to disease-causing levels if foods are cooled improperly (Doyle, 2002). Approximately 10% of foodborne outbreaks in Minnesota each year are also due to bacterial intoxications (Minnesota Department of Health, unpublished data on confirmed foodborne outbreak by etiology, 2018). Bacterial intoxication outbreaks are preventable if time-temperature control measures (including proper cooling) are properly implemented.

The FDA Food Code contains specific time and temperature parameters recommended to achieve proper cooling and suggests methods that can promote rapid cooling. Even with these guidelines restaurants continue to struggle with proper cooling (Hedeen & Smith, 2020; Wittry *et. al,* 2022). A FDA

study assessing the occurrence of foodborne illness risk factors in retail settings found that cooling was out of compliance in 72% (196) of the full-service restaurants where cooling was observed (U.S. FDA, "Report on the occurrence", 2018). Evaluation of risk factor data from the City of Minneapolis Environmental Health Department identified compliance with cooling time and temperature parameters as the second most out of compliance risk factor (unpublished data, 2022). This issue is compounded by the fact that it is difficult for inspectors to observe cooling due to the limited amount of time they are in facilities. A study of 420 restaurants conducted by the Centers for Disease Control and Prevention's Environmental Health Specialists Network (EHS-Net) during 2009-2010 demonstrated that many restaurants were not meeting FDA recommendations for cooling, and about one third of kitchen managers did not know cooling regulations for their jurisdiction (Brown *et. al*, 2014). Modeling conducted in the same study showed that about a third of cooling observations in restaurants had an estimated cooling rate that was slower than the Food Code requirements (Schaffner *et. al*, 2015).

2. Describe the cause of the problem

The Food Code requirements for achieving proper cooling rely on frequent monitoring of time and temperatures. This monitoring is not always feasible for restaurant operators because of the time required to adequately monitor the cooling process (Hedeen, Schaffner, & Brown, 2022). Other factors influencing an operator's ability to monitor food temperatures include insufficient staffing, the time-of-day foods are cooled (e.g., early or late shifts), and how busy a restaurant is throughout the day (Green & Selman, 2005). Operators need to know when food reaches 135 °F so they can begin to monitor the cooling process and ensure the time and temperature parameters are met. Since cooling takes many hours and often spans multiple work shifts this further complicates monitoring. Multiple food items may also be cooling at the same time using a variety of methods. Since foods may cool at different rates, this makes it difficult for operators to verify cooling processes and monitor and track each cooling food.

Inspectors also have difficulty verifying if a food has cooled within the Food Code time and temperature parameters. Inspections are snapshots in time that generally last an hour or two whereas cooling takes place over many hours. Foods are also often cooled late into the day or overnight when inspectors are not present in the establishment. Risk factor data from the City of Minneapolis suggests that inspectors were unable to observe active cooling during 72% of retail food inspections. Other jurisdictional data suggests that this number is even higher (77% in one metro-county within Minnesota).

Inspectors may also try to assess proper cooling by discussion with the restaurant manager and by review of temperature logs, if available, to determine the cooling start time. Relying upon conversations with the operator to establish the time food began cooling is difficult because the answer provided is often an estimate, and likely a conservative estimate to avoid negative consequences. If the operator is unsure of the start time the inspector must decide what should be done with the food if it is above 41 °F at the time of inspection.

3. Explain why the current policy is not addressing the problem

Amend Food Code 3-501.14 to include an option to cool TCS foods at a depth of 2inches or less, uncovered, and refrigerated, without time and temperature monitoring

Foodborne disease outbreaks resulting from improper cooling continues to occur (Lipcsei et al., 2019; Wittry *et. al,* 2022). The Food Code recommends that retail food establishments verify that their cooling practices are effective as well as monitor and record food temperatures during the cooling process, but research suggests that many establishments do not always engage in these practices (Brown et al., 2012; Hedeen & Smith, 2020). A study by FDA (2018) found that cooling practices did not meet FDA guidelines in at least one food item in 72% of 273 full-service restaurants where cooling was observed (U.S. FDA, "Report on the occurrence", 2018). Although operators are encouraged to record cooling time and temperatures, the food code does not require them to do so, and studies have found that only about 25% of operators use a log for cooling (Brown et al., 2012; Hedeen & Smith, 2020).

Due to difficulties observing active cooling, inspectors often rely on subjective observations of FDA recommended cooling methods to determine if a food was cooled properly. The Food Code outlines methods that can promote rapid cooling of time and temperature control for safety (TCS) foods but does not specify how to apply the methods to various situations or whether some methods are more effective than others. Inspectors and operators are left to evaluate every method, or combination of methods, to determine which meet the time requirement. Additionally, many of the terms used in the FDA Food Code sections are also ambiguous, such as "shallow," "thinner,", containers that facilitate "heat transfer," and other "effective" methods." Since these terms are not defined within the code, operators and inspectors are left to interpret or guess what they mean.

The FDA Food Code designates cooling time and temperature violations as a priority violation and the use of effective cooling methods as a priority foundation violation. This message that time and temperature monitoring is the best way to determine successful cooling limits inspectors and operators due to difficulties with verification. This message also deprioritizes the focus on specific cooling methods to achieve successful cooling.

We recommend that operators and inspectors be allowed to also focus on specified cooling methods that are known to facilitate quick and proper cooling without additional time monitoring. We specifically propose that if food is uncovered, at a depth or 2-inches or less, and placed in an environment of 41 °F or less that time and temperature monitoring of that food would not be required. This alternative method can help ensure proper cooling and increase verification efficiency for inspectors and operators.

4. Present your policy recommendation and explain how it compares to possible alternatives

The current Food Code recommendations for cooling rely on time and temperature monitoring (cooling foods from 135-70°F within 2 hours and from 135-41°F within 6 hours), which is difficult to do.

We propose adding an option for meeting the requirements of 3-501.14 for cooling foods. This option requires food cooling when all three of the conditions below are true:

- food is in a shallow layer of two inches or less,
- uncovered, and
- in cooling or cold holding equipment that maintains an ambient temperature of 5°C (41°F) or less.

Amend Food Code 3-501.14 to include an option to cool TCS foods at a depth of 2inches or less, uncovered, and refrigerated, without time and temperature monitoring

This proposed option provides a clear, safe roadmap for operators and will reduce resource and time demands for monitoring cooling. This option is also beneficial to inspectors and public health as it makes it easier to verify adequate cooling during an inspection. This option will help operators and inspectors identify cooling compliance more quickly and in turn, allow them to intervene when needed.

Why 2 inches?

Two inches has been found to be a depth that facilitates rapid cooling (Schaffner et. al., 2015; Hedeen & Smith, 2020; and Igo, Hedeen, & Schaffner, 2021). Portioning foods at 2 inches or less and ventilating foods during refrigerated cooling are effective and simple ways for operators to promote rapid cooling. Two-inch pans are readily available for purchase and many restaurants already have them on hand.

Why not greater than 2 in?

Research shows that food depth is a main factor in rapid cooling. Cooling foods at a depth of 2 inches or less is conservative and limits the risk of significant *C. perfringens* or *B. cereus* growth. One study found that foods stored at a depth greater than 3 inches were twice as likely to cool more slowly than specified in the Food Code (Schaffner et. al., 2015). Another study found that containers with a food depth of 3 inches or more were more likely to have cooling rates slower than the Food Code cooling rate (Igo, Hedeen, & Schaffner, 2021). Cooling of foods at depths greater than 2 inches creates variability in cooling profiles and even less viscous foods may have a hard time cooling at depths of 3-4 inches (Schaffner et. al., 2015; Hedeen & Smith, 2020; and Igo, Hedeen, & Schaffner, 2021).

Why not focus on other methods?

The Food Code outlines several methods that can be utilized during the cooling process to facilitate proper cooling; however, food depth has been shown to be one of the most significant variables that impact cooling rates (Schaffner et. al., 2015; Hedeen & Smith, 2020; and Igo, Hedeen, & Schaffner, 2021). Additionally, “cooling at a depth of 2 inches or less, ventilated, and refrigerated” leaves little room for interpretation whereas other methods (e.g., use of ice) are more difficult to implement. The use of ice baths or ice wands is an active process that requires monitoring and is less predictable (Hedeen & Smith, 2020; Hedeen, Schaffner, & Brown, 2022). Adding ice as an ingredient, to assist with cooling, is a limited option as it is only appropriate for soups and other liquid based foods. Although blast chillers are extremely effective, they are also very expensive and not common in most foodservice kitchens.

Why not look in the Food Code Annex for more detail on how to cool?

The current information in the *FDA Food Code Annex 3 – Public Health Reasons/Administrative Guidelines* provides subjective guidance to operators and inspectors but is not codified by most states. It discusses the importance of reducing the volume of food to optimize cooling rates but provides no specific details on ideal food volumes. It mentions how foods should be ventilated and that smaller batches should be used to decrease the risk of pathogen growth, but again, provides no specific details. The annex also mentions that blast chillers are ideal for rapid cooling, but these units are not an option for most operators.

Why not just define shallow cooling? Defining “shallow cooling” (which is not currently defined in the Food Code) as food portioned at 2 inches or less would be a limited revision that might improve cooling compliance but would still retain all of the disadvantages of the current code (i.e., operators must still monitor time and temperatures during the cooling process and inspectors would still need to measure temperatures and estimate cooling rate during an inspection). Providing the option of 2-inch cooling,

without time and temperature monitoring, offers operators a less complex and less time-consuming way to cool foods safely.

5. **Describe the intended and/or unintended consequences, positive and negative, that may result from implementing the proposed policy recommendation**

Positive: This language gives operators a simpler way to cool foods properly.

The current Code focuses on time and temperature monitoring to determine if food is cooling properly (i.e., within FDA guidelines). The Code offers a list of cooling methods that help facilitate rapid cooling but does not offer guidance on which methods or combination of methods are most effective. Adding the specified performance standard as an option allows for an easy and efficient way for operators and inspectors to verify adequate cooling. The proposed addition clarifies which combination of cooling methods can be used to successfully cool. Note that we are not proposing the removal of the existing time and temperature monitoring requirements, so operators can always choose this option.

Negative: 2 inches isn't a safe enough standard

Cooling studies have shown that reducing food depth to 2 inches and cooling uncovered in a properly functioning refrigeration unit facilitates proper cooling (Schaffner et. al., 2015; Hedeen & Smith, 2020; and Igo, Hedeen, & Schaffner, 2021). Research looking at the cooling curves of foods prepared in retail settings within Minneapolis, MN shows how food depth affects cooling and provides support that foods cooled at a depth of 2-inches or less present negligible risk. We have included a summary of the data in Supplemental Figure S1**,** which breaks down the depth of the cooling food item and whether the food item cooled within the time and temperature requirements outlined in the Food Code. If the food item did not meet Code requirements, the cooling curve was run through the ComBase perfringens Predictor and the predicted log increases are reported. The data show cooling foods at a depth of 2 inches or less, reliably prevents a 1-log increase in pathogen growth and supports the contention that cooling foods at a depth of 2 inches or less, ventilated, and refrigerated, meet acceptable levels of risk.

There are a few food items that were reportedly cooled at a depth of 2 inches or less but did not cool within the time and temperature parameters outlined in the code (i.e., reached 41 °F in more than 6 hours). These cooling curves were input into the ComBase perfringens Predictor, and the predicted log increases were less than 1, indicating limited potential for significant pathogen growth. Modeling data show that *C. perfringens* growth curves and cooling rates for food cooling may not precisely follow the 6-hour cooling parameters outlined in the Code (See Supplemental Figure S2). The modeling predictions show that while the food code cooling rate is protective of public health, cooling at a slightly slower rate represents a negligible increase in risk.

The state of Washington has provided a natural experiment on the effectiveness of this cooling method for the past 17 years after they revised the model food code to explicitly allow 2 inch cooling without time monitoring (Washington State Health Department, 2022). The state has a robust outbreak detection system and investigates all foodborne outbreaks identified. Since 2-inch cooling without time-temperature monitoring was implemented, no foodborne outbreaks have been associated with this cooling method (See Supplemental Table S1). This option is strongly preferred by operators within the state (See Letter of Support from Taco Time). Seattle-King County Health Department conducted a risk

factor study in 2016, which included 2115 restaurants, and found that 75% of operators reported using the 2-inch cooling option to cool hot foods. Only 12% of operators reported using time and temperature monitoring as outlined by the FDA food code (unpublished data, Seattle-King County Health Department).

The cooling standard in Washington shows that providing an option to cool at a depth of 2 inches or less, ventilated, and refrigerated provides a solution that is consistently safe and that restaurant operators have adopted enthusiastically.

Negative: The Food Code isn't meant to be a prescriptive document.

This proposed language is not prescriptive, rather it provides an option other than time and temperature monitoring for those who want it. In a survey of 43 Minneapolis restaurant operators, 81.4% were supportive of a standardized definition of shallow as it pertains to shallow depth cooling. Operators can choose which option works best for their establishment. This language will allow a clear option that is safe and easy to follow.

Negative: Use of 2-inch pans will require more space for cooling and for operators to purchase more pans.

Cooling in deeply filled containers comes with its own costs and burden, including costs of staff and labor for monitoring, ice wands, ice, prep sinks, blast chillers, and other materials and equipment needed to properly cool. Shallow pans cost much less than these items. Pans already come in 2- or 4-inch depths and only cost around $15. Food only needs to be kept at a 2 inch depth during the cooling process. Once cooled it can be transferred to other containers so additional cooling space is only needed for a short period. Restaurants could also consider small-batching recipes, re-organizing their shelving systems, or using speed racks in walk-in coolers to help alleviate space constraints.

Amend Food Code 3-501.14 to include an option to cool TCS foods at a depth of 2inches or less, uncovered, and refrigerated, without time and temperature monitoring

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Figure S1. Analysis of Cooling Data with a Focus on Food Depth

The table below presents an analysis of the cooling data collected by the City of Minneapolis in retail restaurants. The temperature of each cold-holding unit was captured at one point in time during the cooling process and ranged from 34-40°F (average 38.1° F). The data are sorted in order of decreasing food depth. The second column indicates whether the cooling profile met the FDA Food Code or not. In those cases where the answer was "almost" or "no" we ran these data through the ComBase perfringens Predictor and the predicted log increases are shown in the third column. Where the predicted log increase was greater than one, this text has been indicated in bold. The name of the food is shown in the fourth column.

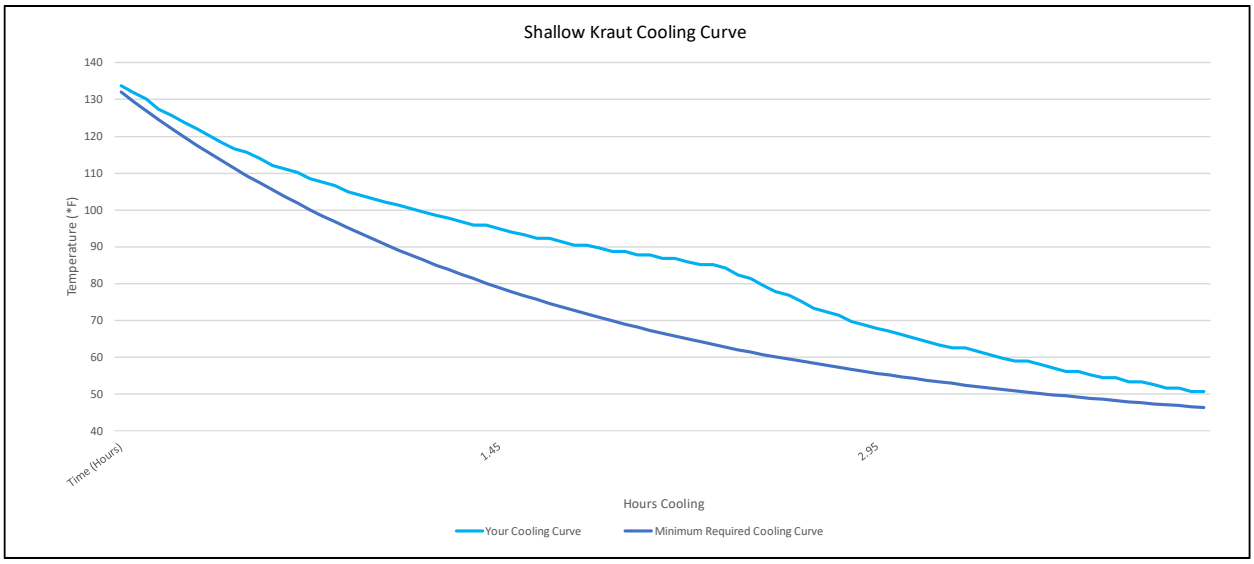
There are two instances where 2-inch cooling would appear be "risky" but are explained by mitigating circumstances. These two instances are for Sausage Gravy and Shallow Kraut. The cooling curve for Shallow Kraut is biphasic, which indicates that the ambient temperature changed during the cooling process. The cooling curve is pictured below, and we have included notes from the inspector on what may have happened. The Sausage Gravy was cooled with the ambient temperature of the cooler at 45.2° F, which would not be compliant with cooling in cold holding equipment maintaining an ambient temperature of 41°F or less. All other food items at a depth of 2 inches would result in a less than 1 log increase of *Clostridium perfringens*.

Food Depth (Inches)	Meets code	Perf predictor Log Increase	Recipe
2.5	Yes	0.029	Chicken Wings
2.5	Almost*	0.241	Shallow Potatoes
2.5	**No**	**1.332**	**Deep Kraut**
2.5	Almost	0.559	Cheese Sauce Deep
2.5	Almost	0.271	Squash Soup Deep
2.5	Almost	0.576	Spinach in Metal Pan
2.5	**No**	**1.094**	**Spinach in Plastic Pan**
2.5	Yes	0.019	Tomato Sauce
2.5	Yes	0.004	Diced Chicken
2.5	No	0.942	Chili Verde
2.5	**No**	**1.181**	**Refried Beans 2.5-inch pan**
2.25	**No**	**1.374**	**Chicken Pot Pie Mix**
2.25	Yes	0.038	Chicken Breasts
2	**No**	**1.870**	**Sausage Gravy**
2	Almost	0.652	Garden Veggie Soup
2	Yes	0.180	Chicken Curry Walk-In 2 Inches
2	Yes	0.081	Tomato Soup 2 Inch Metal Walk-In
2	Almost	0.242	Corn Chowder Plastic No Cover 2"
2	Almost	0.479	Chorizo 2"
2	Yes	0.028	Cherry Compote
2	Yes	0.028	Black Beans
1.75	Almost	0.110	Chicken Rice
1.5	Yes	0.020	Empanadas
1.5	Yes	0.011	Ground Beef
1.5	Yes	0.018	Mushroom Sauce Bottom Pan
1.5	Yes	0.013	Mushroom Sauce Top Pan
1.5	**No**	**1.280**	**Shallow Kraut***

1.5	Yes	0.138	Marinara 1.5" V1
1.5	Yes	0.202	Marinara 1.5" V2
1.5	Almost	0.123	Au Jus
1.5	Almost	0.115	Cheese Sauce Shallow
1.5	Almost	0.089	Squash Soup Shallow
1.5	Yes	0.008	Butternut Squash Soup
1.5	Yes	0.005	Mashed Potatoes
1.5	Almost	0.004	Turkey Chili
1.5	Almost	0.167	Refried Beans 1.5 Inch Pan

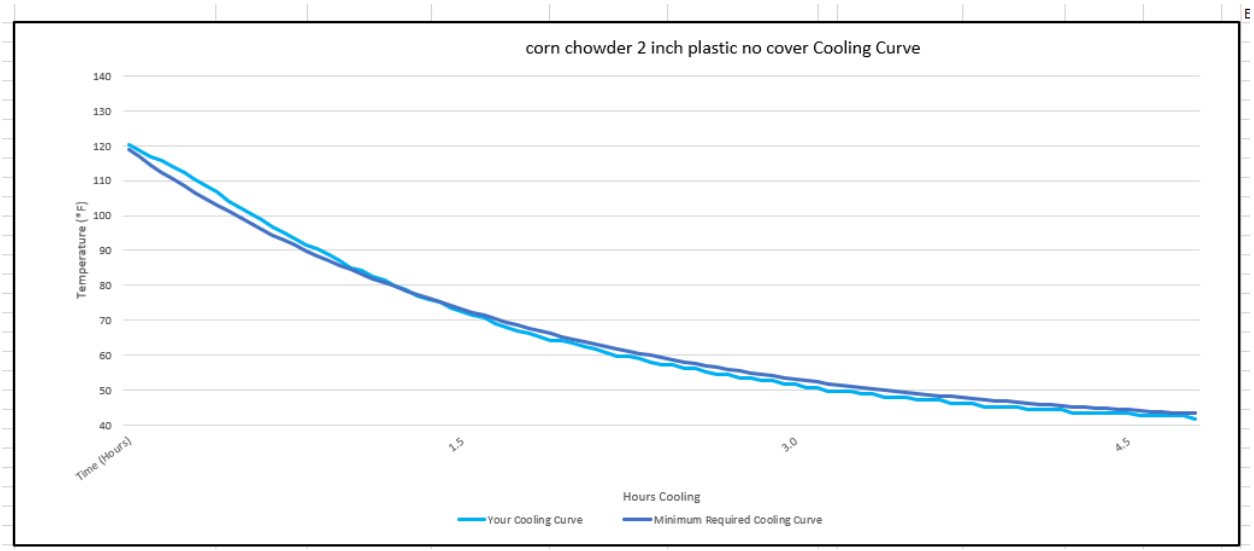
* The determination of cooling curves that “almost” meet the food code is somewhat subjective but these are curves where (a) the first phase of cooling happens more rapidly than the food code allows while the second part happens more slowly, (b) where the first part of the curve matches the food code and the second part more cools more slowly, or (c) where the entire curve is just slightly slower than the food code recommendation.

Shallow Kraut Cooling Curve:



The overall shape of the curve (a spike increase in the middle of the curve) suggests that the cooling method measurements were not maintained for the duration of the cooling curve. It is likely that the operator removed the data logger mid cooling, or the food was re-panned.

Corn Chowder (plastic no cover, 2in) Cooling Curve:



This food item didn't meet the FDA minimum time and temperature parameters for adequate cooling, and was labeled "almost" on the table above. You can see how close the curve is to the minimum required cooling curve. When this curve was run through the ComBase perfringens Predictor, there was only a 0.22 log increase.

Figure S2. Summary of Cooling Rates in relation to Food Code Requirements

The temperature change of cooling foods is not linear. Hot foods cool faster at first then more slowly as the temperature difference with the environment (and thus the driving force) is less.

The FDA Food Code recommends that hot foods be cooled 135 °F to 70 °F within two hours and then from 70 °F to 41 °F within another four hours, for a total cooling time of six hours.

According to Newtons law of cooling, the rate of cooling of an object can be described by a linear relationship if the logarithm of the difference between the object and the environment is plotted versus cooling time.

If we use the time and temperature parameters from the FDA Food Code and assume and an environmental temperature of 37°F this gives the highest R^2 value for cooling rate. The slope of this log linear plot is -0.23.

We also have validated computer models for predicting the growth rate of the two most likely spore forming pathogens found in cooling foods (*C. perfringens* and *B. cereus*). Those models are Perfringens Predictor https://browser.combase.cc/Perfringens_Predictor.aspx and Juneja, et al 2019 (Predictive model for growth of *Bacillus cereus* during cooling of cooked rice). The predictions below use pH 7, 0.5% salt for Perfringens Predictor, and assume cooked rice for *B. cereus*.

The predicted log increases assuming a food code cooling rate are 0.33 for *C. perfringens* and 0.10 for *B. cereus* and are shown in the table below. It is commonly accepted that a less than one logarithm increase for either of these pathogens constitutes a tolerable risk given the typical levels found in food and the levels needed to cause illness for these pathogens.

Linearized rate	*C. perfringens*	*B. cereus*
	log CFU increase	
-0.30	0.15	
-0.23	0.35	0.10
-0.20	0.56	0.16
-0.15	1.27	0.37
-0.10		1.13

This shows that the food code cooling rate is protective of public health, and that slightly slower cooling rates might also represent a negligible risk. For example, if we assume a log linear cooling rate of 0.20, this also results in less than a one logarithm increase for either pathogen.

If we convert this cooling rate back to an arithmetic scale this represents a food that is cooled according to this profile:

time (hr)	temp °F
0	135.0
1	98.8
2	76.0
4	52.5

6	43.2
12	37.4

As shown in the first table, a cooling rate of 0.15 would result in an unacceptable (1.26 log) increase in the concentration of *C. perfringens*.

If we convert this cooling rate back to an arithmetic scale this represents of food that is cooled according to this profile:

time (hr)	temp °F
0	135.0
1	106.4
2	86.1
4	61.6
6	49.3
12	38.6

The slowest cooling rate which results in an acceptable (e.g., approximately 0.99 log) increase in the concentration of *C. perfringens* is 0.165, which corresponds to a food cooled according to this profile:

time (hr)	temp °F
0	135.0
1	104.0
2	82.8
4	58.4
6	47.0
12	38.0

Thus, if the “2 inch food depth uncovered” protocol results in cooling slower than what is specified in the FDA Food Code this does not necessarily result in a risk to public health.

Table S1. Summary of Washington State Outbreak Data

When Washington state adopted the FDA Food Code in 2005, it added language allowing for 2 inch cooling as an alternative to time and temperature monitoring. From 2010-2021 there were 408 foodborne disease outbreaks of all types reported in Washington State.

Some of these outbreaks, 42 of 408 (10.2%) were listed as *Clostridium perfringens*, *Bacillus cereus*, or other bacterial toxin, and thus could have been caused by cooling deficiencies.

- 4/42 Laboratory confirmed outbreak
  - All *C. perfringens*
- 38/42 Suspected outbreak
  - 8/38 *B. cereus*
  - 19/38 *C. perfringens*
  - 11/38 Bacterial toxin

Cooling method utilized in outbreaks from 2010 – 2021

Grouping	Category	*Deep Pan Cooling	2 Inch Cooling, Uncovered	Room Temperature Storage	Deep Pan & Room Temperature Storage	Unknown Methods	Total
By agent status	Confirmed	1	0	1	1	1	**4**
	Suspected	21	0	5	7	5	**38**
	Total	**22**	**0**	**6**	**8**	**6**	**42**
By agent type	*B. cereus*	4	0	1	1	2	**8**
	C. perfringens	13	0	3	5	2	**23**
	Bacterial toxin	5	0	2	2	2	**11**
	Total	**22**	**0**	**6**	**8**	**6**	**42**

*Deep Pan cooling is cooling foods at a depth of greater than 2 inches.

In summary, 30/42 (71%) of the above outbreaks had Deep Pan Cooling listed as the primary Contributing Factor. Fewer 6/42 (14%) listed Room Temperature Storage as the Primary Contributing Factor. The same number 6/42 (14%) listed either Hot-holding or Cold-holding as the Primary Contributing Factor and the cooling method was not identified/evaluated. **None of 42 outbreaks was linked to use of 2 inch cooling.**

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Restaurant Food Cooling Practices†

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ABSTRACT

Improper food cooling practices are a significant cause of foodborne illness, yet little is known about restaurant food cooling practices. This study was conducted to examine food cooling practices in restaurants. Specifically, the study assesses the frequency with which restaurants meet U.S. Food and Drug Administration (FDA) recommendations aimed at reducing pathogen proliferation during food cooling. Members of the Centers for Disease Control and Prevention's Environmental Health Specialists Network collected data on food cooling practices in 420 restaurants. The data collected indicate that many restaurants are not meeting FDA recommendations concerning cooling. Although most restaurant kitchen managers report that they have formal cooling processes (86%) and provide training to food workers on proper cooling (91%), many managers said that they do not have tested and verified cooling processes (39%), do not monitor time or temperature during cooling processes (41%), or do not calibrate thermometers used for monitoring temperatures (15%). Indeed, 86% of managers reported cooling processes that did not incorporate all FDA-recommended components. Additionally, restaurants do not always follow recommendations concerning specific cooling methods, such as refrigerating cooling food at shallow depths, ventilating cooling food, providing open-air space around the tops and sides of cooling food containers, and refraining from stacking cooling food containers on top of each other. Data from this study could be used by food safety programs and the restaurant industry to target training and intervention efforts concerning cooling practices. These efforts should focus on the most frequent poor cooling practices, as identified by this study.

Improper cooling of hot food by restaurants is a significant cause of foodborne illness. In the United States between 1998 and 2008, improper cooling practices contributed to 504 outbreaks associated with restaurants or delis *(1)*. These findings suggest that improvement of restaurant cooling practices is needed. The U.S. Food and Drug Administration (FDA) Food Code, which provides the basis for state and local food codes that regulate retail food service in the United States, contains guidelines for food service establishments, aimed at reducing pathogen proliferation during food cooling *(4)*. Specifically, the Food Code states that cooked potentially hazardous food (foods that require time-temperature control to keep them safe for consumption) should be cooled ''rapidly,'' i.e., from 135 to 70°F (57.2 to 21.1°C) in 2 h or less, and from 70 to 41°F (21.1 to 5°C) in 4 additional h or less. Thus, according to the FDA, proper cooling is cooling that minimizes the amount of time that food is in the temperature ''danger zone'' of 41 to 135°F (5 to 57.2°C), the temperature range in which foodborne illness pathogens grow quickly.

The Food Code also states that procedures in the food preparation process that are critical to food safety (critical control points), such as cooling, should be tested and verified and then monitored to ensure that they work properly *(5)*. Testing and verification occurs during initial development of the cooling process; it involves measuring time and food temperatures throughout the process to ensure that the process cools effectively. Monitoring involves measuring time and temperature during the cooling process on a routine basis—again to ensure that the process continues to cool effectively. The Food Code also recommends that thermometers used to measure food temperatures be calibrated as necessary to ensure their accuracy. Finally, the Food Code recommends that temperature data obtained from monitoring critical control points be recorded so that managers can verify that cooling processes are cooling effectively.

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Further, the Food Code recommends the use of one or more of the following methods to facilitate cooling: (i) placing food in shallow pans and refrigerating it at the maximum cold holding temperature of 41°F [5°C]; (ii) separating food into smaller or thinner portions and refrigerating it at the maximum cold holding temperature of 41°F [5°C]; (iii) stirring the food in a container placed in an ice water bath; (iv) using rapid cooling equipment, such as ice wands (containers filled with ice and placed inside food) and blast chillers (a type of rapid cooling equipment); (v) adding ice as an ingredient to the food; and (vi) using containers that facilitate heat transfer. The Food Code also states that cooling food should be arranged to provide conditions for maximum heat transfer through food container walls (e.g., by not placing containers of cooling food close to each other) and be ventilated (e.g., uncovered, if protected from overhead contamination, or loosely covered) during the cooling period to facilitate heat transfer from the surface of the food. The Food Code also recommends that the person in charge of the food service establishment (e.g., manager) ensure that food is being properly cooled through routine monitoring of food temperatures during cooling.

In one of the few existing studies containing information on restaurant food cooling, the FDA found that improper cooling was a frequent foodborne illness risk factor observed in full-service restaurants. In 79% of observations, food was not cooled to the proper temperatures quickly enough to meet FDA recommendations *(6)*. Although this study provides valuable information on the prevalence of restaurants' failure to meet cooling time and temperature guidelines, it does not provide any data on restaurants' cooling practices, such as whether cooling processes are tested and verified. It also does not provide any data on the methods restaurants use in their attempts to cool food (e.g., shallow pans). Knowledge about these issues is essential to the development of effective cooling interventions. For this reason, the purpose of this study was to collect data on these topics. This study focuses on describing restaurants' food cooling practices and on the methods restaurants use to cool food (e.g., refrigeration, ice baths). Where appropriate, the study assesses the frequency with which restaurants meet FDA recommendations concerning cooling practices.

MATERIALS AND METHODS

This study was conducted by the Environmental Health Specialists Network (EHS-Net), a network of environmental health specialists and epidemiologists focused on the investigation of factors contributing to foodborne illness. EHS-Net is a collaborative project of the Centers for Disease Control and Prevention, the FDA, the U.S. Department of Agriculture (USDA), and state and local health departments. At the time this study was conducted, the EHS-Net sites were in California, Connecticut, New York, Georgia, Iowa, Minnesota, Oregon, Rhode Island, and Tennessee.

Data were collected from July 2009 through March 2010. The study protocol was cleared by the CDC Institutional Review Board and the appropriate institutional review boards in the participating sites. All data collectors (EHS-Net environmental health specialists) participated in training designed to increase data collection consistency.

Data collectors collected data in approximately 50 restaurants in each EHS-Net site. ''Restaurants'' were defined as establishments that prepare and serve food or beverages to customers but that are not institutions, food carts, mobile food units, temporary food stands, supermarkets, restaurants in supermarkets, or caterers. Data collectors contacted randomly selected restaurants in predefined geographical areas in each site via telephone to request their participation in the study and arrange for an on-site interview with a ''kitchen manager'' (defined as a manager with authority over the kitchen) and an observation of cooling practices. Data collectors attempted to schedule restaurant visits to coincide with the beginning of the restaurants' cooling processes, although this was not always possible. Only one restaurant from any given regional or national chain was included per EHS-Net site. For example, if chain A had three restaurants in an EHS-Net site, only one of those restaurants would be eligible to participate in the study in that site. Only English-speaking managers were interviewed. Data collection was anonymous; that is, no data were collected that could identify individual restaurants or managers.

Restaurant visits lasted an average of 80 min. Data collectors interviewed the manager about restaurant characteristics (e.g., chain versus independent ownership, number of meals served daily), food handling and cooling policies and practices (e.g., whether thermometers were used to check temperatures, whether temperatures of cooling food were monitored), and local regulations concerning cooling.

When possible, data collectors also recorded observation data on cooling practices occurring during their visit. For each food being cooled during the observation, data collectors recorded data on the type of food being cooled, the number of cooling steps involved in the cooling of the food, and the method used in each step to cool the food (refrigerating food at or below 41°F [5°C], ice bath, ice wand, blast chiller, ice or frozen food as an ingredient, room temperature cooling). For example, if a cooling food was first observed in an ice bath and was moved to a refrigerator later in the observation, the data collector would record an ice bath step and a refrigeration step. Additional observation data were collected on the methods of refrigeration, ice bath, and ice wand (Table 1).

In some restaurants, multiple food items were being cooled, and as described above, the cooling process for some of these food items involved multiple cooling steps. We collected data on each food item being cooled and each cooling step involved in the cooling process of each food item. Thus, the denominators for the observation data vary, and are described in the ''Results'' section.

Data collectors also recorded whether workers monitored the temperatures of the cooling foods during the observation period and took temperatures of cooling food at the beginning and at the end of the observation period. These temperature data are not discussed here.

RESULTS

Restaurant demographics. Four hundred twenty restaurant managers agreed to participate in the study. The restaurant participation rate was 68.4% (this rate is based on data from eight of the EHS-Net sites; participation rate data were unavailable for one site). According to interviewed managers, most restaurants were independently owned and served an American menu (see Table 2). The median number of meals served daily in these restaurants was 150 (25th percentile = 80, 75th percentile = 300, minimum = 7, maximum = 7,700).

TABLE 1. *Description of additional observation data collected on the cooling methods of refrigeration, ice bath, and ice wand*

Refrigeration
Type of cooling unit (walk-in coolers, reach-in coolers, freezers)
Ambient temperature of cooling unit
Whether food depth was shallow (no more than 3 in. [7.6 cm] deep)
Whether the food was ventilated (uncovered or loosely covered)
Whether the containers of cooling food were arranged to allow maximum heat transfer through container walls (containers not stacked on top of one another; at least 3 in. [7.6 cm] of open-air space provided around the top and sides of the containers)
Ice bath
Whether ice was present in the ice bath
Whether ice and water were filled to level of the cooling food
Whether food was stirred
Ice wand
Whether ice wand was inserted into the food
Whether ice and/or liquid was present in the ice wand
Whether food was stirred

TABLE 2. *Data on restaurant demographics obtained from interviews with 420 kitchen managers*

Demographic	*n*	%
Restaurant ownership		
Independent	290	69.0
Chain	130	31.0
Menu description		
American	252	60.0
Italian	47	11.2
Mexican	34	8.1
Chinese	21	5.0
Other	66	15.7

Manager interview data on general food safety practices. According to interviewed managers, over 90% of restaurants provided food safety training to managers and workers, and over 75% employed at least one food safety certified manager (Table 3). Over 95% of managers said that they used thermometers to check the temperature of food being prepared in their restaurant. Thermometers used included bimetallic probe thermometers, digital–thermocouple probe thermometers, and infrared–laser thermometers. Over 80% of managers said that someone was trained to calibrate (i.e., check the accuracy of) these thermometers. Of those who said they used thermometers to check food temperatures, about 40% said that they calibrated thermometers at least once a week; others said that they calibrated at least once a day, at least once a month, less than once a month, never, or they were unsure how often thermometers were calibrated.

Twenty percent (20.2% [85]) of managers said the cooling time and temperature regulation in their jurisdiction was the same as the FDA's—135 to 70°F (57.2 to 21.1°C) in 2 h or less and then 70 to 41°F (21.1 to 5°C) in 4 additional h or less. Ten percent (9.5% [40]) said they had a two-stage regulation like the FDA's, but the temperatures differed (140°F [60°C] rather than 135°F [57.2°C]). Two percent (1.7% [7]) said their regulation had the same temperatures as the FDA's but required a single-stage process (135 to 41°F [57.2 to 5°C] in 4 h or less). Ten percent (9.7% [41]) said their regulation had a single-stage process with temperatures that differed from the FDA's (140 to 41°F [60 to 5°C] in 4 h or less: 8.3%; 140 to 45°F [60 to 7.2°C] in 4 h or less: 1.4%). Twenty-three percent (22.6% [95]) said they had some other regulation, and 36.2% (152) did not know their jurisdiction's cooling regulation.

Manager interview data on cooling practices. Over 90% of managers said that food safety training for managers and workers covered proper cooling (Table 4). Over 85% said that their restaurant had formal processes (methods of cooling that have been established by the restaurant as a standard practice) for cooling potentially hazardous foods. In these restaurants with formal cooling processes, a third of managers said that the processes were written, and 89% said that food workers had been trained on them. Of managers in restaurants with formal cooling processes, over 60% said their processes had been tested and verified.

Sixty percent of all managers said that food cooling times or temperatures were monitored during routine cooling of foods. Of those managers who said that food cooling times or temperatures were monitored in their restaurants, most said that cooling foods were ''always'' or ''often'' monitored. Most managers who said that they monitored food cooling times or temperatures said that they used thermometers to do so. Others reported using time to monitor cooling, both thermometers and time to monitor cooling, the look or feel of the food, or some other method to monitor cooling. Of those who said they used thermometers to monitor cooling, about 50% said that they calibrated thermometers at least once a week; others said that they calibrated at least once a day, at least once a month, less than once a month, never, or they were unsure how often thermometers were calibrated. A quarter of managers said that monitored time or temperature measures were recorded.

Fifty-three percent (52.6% [221]) of managers said that they had formal cooling processes and that they were verified; 46.2% (194) of managers said that they had formal cooling processes, that these processes were verified, and that time or temperature was monitored during these processes; 42.9% (180) said that they had formal cooling processes, that these processes were verified, that time or temperature was monitored during these processes, and that they calibrated thermometers used for monitoring. Not quite 15% (14.5% [61]) of managers said that they had formal cooling processes, that these processes were verified, that time or temperature was monitored during these processes, that thermometers used for monitoring were calibrated, and that measurements from time or temperature monitoring were recorded. Thus, 85.5% (359) of managers reported cooling processes that did not incorporate all FDA-recommended components.

Observation data on cooling practices. Data collectors observed 596 food items being cooled during their visit

TABLE 3. *Data on restaurant general food safety practices obtained from interviews with 420 kitchen managers*[a]

Demographic	*n*	%
Kitchen managers receive food safety training		
Yes	401	95.5
No	19	4.5
Food workers receive food safety training		
Yes	390	92.9
No	25	6.0
Unsure	5	1.1
Restaurant has at least one certified kitchen manager		
Yes	321	76.4
No	97	23.1
Unsure	2	0.5
Thermometer is used to check food temperatures		
Yes	400	95.3
No	19	4.5
Unsure	1	0.2
Type of instrument used to check food temperatures ($N = 400$)[b]		
Bimetallic probe thermometer	298	74.5
Digital/thermocouple probe thermometer	184	46.0
Infrared/laser thermometer	16	4.0
Someone is trained to calibrate thermometers ($N = 400$)		
Yes	331	82.7
No	61	15.3
Unsure	8	2.0
Frequency with which thermometer is calibrated ($N = 400$)		
At least once a day	57	14.3
At least once a week	152	38.0
At least once a month	76	19.0
Less than once a month	17	4.3
Never	58	14.5
Other	9	2.2
Unsure	31	7.7

[a] *N* values vary throughout the table because of skip patterns in the interview; $N = 420$ unless otherwise noted.

[b] Participants were able to provide multiple responses to the question; thus, the numbers add to more than the *N*, and percentages add to more than 100%.

in 410 restaurants (10 of the 420 restaurants in the study were not actively cooling foods at the time of the visits). Seventy-one percent (291 of 410) of these restaurants were cooling one food item during the visit, but others were cooling several food items during the visit (the number of food items observed in each restaurant ranged from 1 to 6). Of the 596 food items observed being cooled, soups, stews, and chilis were the most common food items (29.9% [178]), followed by poultry and meat (25.2% [150]), sauces and gravies (15.4% [92]), cooked vegetables (6.7% [40]), rice (5.7% [34]), beans (5.2% [31]), pasta (3.9% [23]), casseroles (3.2% [19]), seafood (1.2% [7]), pudding (1.0% [6]), and other foods (2.7% [16]).

Workers were observed monitoring cooling food time or temperatures by using one or more methods (e.g., time, temperature) in 39.4% (235 of 592; data were missing for four observations) of cooling observations. Probe thermometers were most frequently used for this purpose (82.5% [194]), followed by time estimates (e.g., noting cooling time on a clock, approximating cooling time) (23.8% [56]), touching the cooling food or container (6.8% [16]), and ''other'' methods (3.8% [9]).

Data collectors collected data on 997 discrete cooling steps (the number of cooling steps observed for each food item ranged from 1 to 4). Among these 997 cooling steps, the most common cooling method was refrigeration—46.6% (466) of cooling steps involved refrigeration. Other cooling methods included ice bath (19.4% [195]), ice wand (7.7% [77]), ice or frozen food as an ingredient in the cooling food (2.7% [27]), blast chiller (0.5% [5]), room temperature cooling (16.8% [169]), and ''other'' types of cooling (6.3% [63]).

Table 5 presents data on the cooling unit types and temperatures observed in the 466 refrigeration step observations. Walk-in coolers were the most commonly used cooling unit for refrigeration, followed by reach-in coolers and freezers. Sixteen percent of cooling unit temperatures were above 41°F (5°C), the FDA-recommended maximum food cold-holding temperature. About 10% of walk-in coolers, a third of reach-in coolers, and less than 1% of freezers were above the FDA-recommended maximum temperature of 41°F (5°C).

In 39.3% (183 of 466) of these refrigeration observations, the food depth was not shallow; in 34.3% (160) of the observations, the cooling food was not ventilated; in 13.7% (64) of the observations, containers of cooling food were stacked on top of each other; and in 23.8% (111) of observations, open-air space was not provided around the top and sides of the food cooling containers (see Fig. 1).

In 1.0% (2) of the 195 ice bath observations, ice was not present in the ice bath; in 32.8% (64) of the observations, ice and water were not filled to the level of the cooling food; and in 28.7% (56) of observations, the food was not stirred during the observation period.

In 100.0% of the 77 ice wand observations, the wands were inserted into the food. In 2.6% (2) of these observations, ice was not present in the ice wand; in 2.6% (2) of observations, no liquid was in the ice wand; and in 13.0% (10) of observations, the food was not stirred during the observation period.

DISCUSSION

This study identifies multiple shortcomings in restaurant cooling practices. The data collected indicate that many restaurants' cooling practices do not meet FDA recommendations aimed at reducing pathogen proliferation during food cooling.

It is encouraging that most managers reported that they had formal cooling processes and that they provided training to food workers on these processes. Additionally, over 90% of managers in restaurants that monitored cooling said that they calibrated the thermometers used for monitoring. However, many managers reported the absence of several FDA-recommended cooling components. For example,

TABLE 4. *Data on restaurant cooling practices obtained from interviews with 420 kitchen managers*[a]

Cooling practice	*n*	%
Kitchen manager food safety training covered proper cooling ($N = 401$)[a]		
Yes	390	97.3
No	7	1.7
Unsure	4	1.0
Food worker food safety training covered proper cooling ($N = 390$)		
Yes	356	91.3
No	27	6.9
Unsure	7	1.8
Restaurant has formal cooling processes ($N = 420$)		
Yes	362	86.2
No	57	13.6
Unsure	1	0.2
Cooling processes are written ($N = 362$)		
Yes	123	34.0
No	231	63.8
Unsure	8	2.2
Food workers have been trained on cooling processes ($N = 362$)		
Yes	323	89.2
No	36	10.0
Unsure	3	0.8
Cooling processes have been tested and verified ($N = 362$)		
Yes	221	61.0
No	126	34.8
Unsure	15	4.2
Time or temperature is monitored during cooling processes ($N = 420$)		
Yes	250	59.5
No	168	40.0
Unsure	2	0.5
Frequency with which cooling processes are monitored ($N = 250$)		
Always	113	45.2
Often	92	36.8
Sometimes	39	15.6
Rarely	5	2.0
Unsure	1	0.4
Cooling process monitoring method ($N = 250$)[b]		
Probe thermometer	225	90.0
Data logging thermometer	2	0.8
Time	62	24.8
Thermometer and time	49	19.6
Sight	3	1.2
Touch	11	4.4
Other	16	6.4
Unsure	2	0.8
Frequency with which thermometers used to monitor are calibrated ($N = 226$)		
At least once a day	38	16.8
At least once a week	111	49.1
At least once a month	40	17.7
Less than once a month	6	2.7
Never	13	5.7
Other	6	2.6
Unsure	12	5.4
Cooling time or temperature measures are recorded ($N = 250$)		
Yes	66	26.4
No	183	73.2
Unsure	1	0.4

[a] *N* values vary throughout the table because of skip patterns in the interview.

[b] Participants were able to provide multiple responses to the question; thus, the numbers add to more than the *N*, and percentages add to more than 100%.

about half of managers said that they did not have tested and verified cooling processes, and 41% did not monitor time or temperature during cooling processes. Eighty percent of those who monitored cooling processes did not monitor both time and temperature, as recommended by FDA, and 6% of those who monitored cooling food temperatures with a thermometer never calibrated their thermometers. Finally, less than a third of restaurant managers said that they recorded temperature data obtained from monitoring. Lack of testing and verification means that the adequacy of the cooling process was not determined prior to implementation; this absence could result in ineffective cooling. Similarly, lack of monitoring of both time and temperature means that the effectiveness of the cooling process is not assessed on a regular basis. Lack of thermometer calibration can lead to inaccurate temperature readings, and consequently, to inadequate cooling. Lack of recording prevents managers from reviewing the data to verify that their cooling processes are working properly. These deficiencies can cause cooling foods to remain in the temperature danger zone for too long, allowing potentially unsafe pathogen proliferation.

All together, most managers described cooling processes that did not incorporate all FDA-recommended components—testing and verification, time and temperature monitoring, thermometer calibration, and time and temperature measurement recording. These data indicate that most restaurants have cooling deficiencies that should be addressed.

Over a third of interviewed managers did not know their jurisdiction's cooling regulation. If managers do not know the cooling regulations, it seems unlikely that these regulations will be followed. Clearly, more education is needed concerning cooling regulations and practices.

Refrigeration was the most common cooling method used by restaurants. However, 16% of the units used for cooling were observed operating above the FDA-recommended maximum temperature for cold holding of foods. These data are concerning, because food cooling rates decline exponentially as ambient cooling temperatures approach 41°F (5°C) and higher. Additionally, FDA recommendations for facilitating rapid cooling during refrigeration were not always followed. Most frequently, restaurants did not refrigerate food at shallow depths. They also did not always ventilate cooling food, provide open-air space around the tops and sides of food cooling containers,

TABLE 5. *Ambient temperatures taken from the cooling units used in 466 refrigeration steps observed in 410 restaurants*

Cooling unit	Median	25th percentile	75th percentile	*n*	% > 41°F (5°C)	*n* > 41°F (°C)
Walk-in coolers	39.0	36.0	40.0	344	11.6	40
Reach-in coolers	40.0	37.0	44.0	93	34.4	32
Freezers	3.0	−0.5	21.0	29	0.5	1
All	39.0	36.0	40.0	466	15.7	73

and refrain from stacking cooling food containers on top of each other. These practices facilitate rapid cooling; however, depending on the amount of food being cooled, they could also require considerable refrigerator space. A need for more refrigerator space could, at least in part, account for the prevalence of these poor cooling practices. Indeed, qualitative data suggest that food workers view the lack of adequate space as a barrier to proper cooling *(3)*.

The ice bath was the next most frequent cooling method. Again, practices that would best facilitate rapid cooling by use of this method, such as ensuring that the ice and water were filled to the outside top of the food containers and that the food was stirred regularly during the cooling process, were not always followed. These activities are relatively easy to do; it could be that food workers are unaware of their importance to proper cooling.

Although ice wands were used infrequently, they were used correctly for the most part—they were filled with ice and inserted into the cooling food. However, as with the use of ice baths, the cooling foods were not always stirred during the cooling process. The cooling methods of ice as an ingredient and blast chillers were also rarely used. Ice as an ingredient is likely used infrequently because it could affect the quality, taste of the food. Blast chillers, although effective, are expensive, and their cost likely explains the infrequency of their use.

In about a fifth of cooling steps observed, cooling food was kept at room temperature. Because room temperature storage is not a method that facilitates rapid cooling, this practice is not recommended for cooling foods that are in the temperature danger zone. However, this practice might be acceptable for foods that are not in the temperature danger zone. For example, it would be acceptable to cool a hot food at room temperature until the food cooled to 135°F (57.2°C; the high point of the temperature danger zone). At that point, however, a rapid cooling method would need to be used. Food temperature monitoring is a particularly important part of any cooling process in which room temperature is used, because it is critical to identify when the food reaches the danger zone so that a rapid cooling method can be implemented.

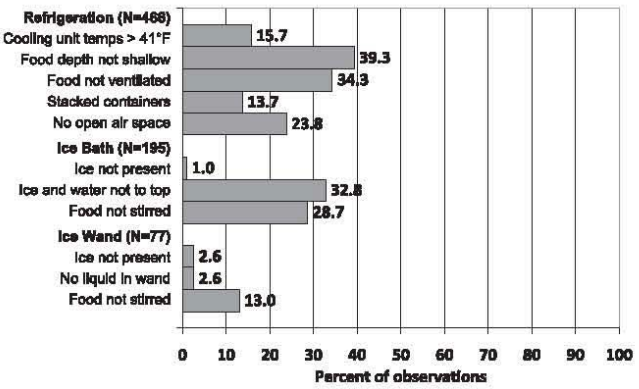

FIGURE 1. *Frequencies of improper food cooling practices observed in refrigeration, ice bath, and ice wand steps in 410 restaurants.*

This study had several limitations. First, this study included only English-speaking managers and workers. Second, the study collected self-report data (managers reported on their workers' and their own practices and policies); these data are susceptible to a bias to over-report socially desirable behaviors, such as cooling food properly. Lastly, the study also collected observation data; these data are susceptible to reactivity bias, in that food workers might have reacted to being observed by changing their cooling practices. These last two biases could have led to an underestimation of the prevalence of improper cooling practices.

Our data suggest that many restaurant managers do not understand how to cool food properly. Data from this study can be used by food safety programs and the restaurant industry to target training and intervention efforts to improve cooling knowledge, policies, and practices. An important focus of these efforts would be to emphasize the need for testing, verification, and monitoring to ensure that the cooling process works properly. These fundamental components of a food safety management system control foodborne illness risk factors *(5)*.

Training and intervention efforts should also focus on the most frequent poor cooling practices identified in this study—inadequate cooling unit temperatures, inadequate facilitation of rapid cooling during refrigeration, and inadequate ice baths. Efforts should focus not only on how to cool foods properly but also on *why* it is important to cool foods properly. Research has indicated that this ''why'' aspect is an important component of effective training *(2, 3)*. Thus, a focus on the temperature danger zone and how cooling time and temperature requirements are designed to reduce the amount of time that food remains in this zone would be appropriate. Efforts to improve cooling practices should also focus on identifying barriers and facilitators to proper cooling practices and addressing them. For example, if restaurants are implementing refrigeration cooling methods improperly because they do not have the space to do otherwise, food safety programs could work with them to identify alternative methods of cooling.

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Quantitative Data Analysis To Determine Best Food Cooling Practices in U.S. Restaurants†

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ABSTRACT

Data collected by the Centers for Disease Control and Prevention (CDC) show that improper cooling practices contributed to more than 500 foodborne illness outbreaks associated with restaurants or delis in the United States between 1998 and 2008. CDC's Environmental Health Specialists Network (EHS-Net) personnel collected data in approximately 50 randomly selected restaurants in nine EHS-Net sites in 2009 to 2010 and measured the temperatures of cooling food at the beginning and the end of the observation period. Those beginning and ending points were used to estimate cooling rates. The most common cooling method was refrigeration, used in 48% of cooling steps. Other cooling methods included ice baths (19%), room-temperature cooling (17%), ice-wand cooling (7%), and adding ice or frozen food to the cooling food as an ingredient (2%). Sixty-five percent of cooling observations had an estimated cooling rate that was compliant with the 2009 Food and Drug Administration Food Code guideline (cooling to 41°F [5°C] in 6 h). Large cuts of meat and stews had the slowest overall estimated cooling rate, approximately equal to that specified in the Food Code guideline. Pasta and noodles were the fastest cooling foods, with a cooling time of just over 2 h. Foods not being actively monitored by food workers were more than twice as likely to cool more slowly than recommended in the Food Code guideline. Food stored at a depth greater than 7.6 cm (3 in.) was twice as likely to cool more slowly than specified in the Food Code guideline. Unventilated cooling foods were almost twice as likely to cool more slowly than specified in the Food Code guideline. Our data suggest that several best cooling practices can contribute to a proper cooling process. Inspectors unable to assess the full cooling process should consider assessing specific cooling practices as an alternative. Future research could validate our estimation method and study the effect of specific practices on the full cooling process.

Improper cooling of hot foods by restaurants is a significant cause of foodborne illness in the United States. Data collected by the Centers for Disease Control and Prevention (CDC) show that improper cooling practices contributed to 504 foodborne illness outbreaks associated with restaurants or delis between 1998 and 2008 *(1)*.

Clostridium perfringens is the pathogen most frequently associated with foodborne illness outbreaks caused by improper cooling of foods. Between 1998 and 2002, 50 (almost 50%) of 102 outbreaks with known etiologies associated with improper cooling were caused by *C. perfringens (7). C. perfringens* spores can germinate during cooking, and the resulting cells grow quickly, especially when foods are cooled too slowly. *Bacillus cereus* spores can also survive the cooking process and may pose a risk during improper cooling *(7)*. The U.S. Food and Drug Administration (FDA) Food Code provides the basis for state and local codes that regulate retail food service in the United States and contains cooling guidelines for food service establishments. To combat foodborne illness outbreaks associated with improper cooling, the 2009 FDA Food Code (section 3-501.14) states that cooked foods requiring time-temperature control should be cooled ''rapidly'' (specifically from 135 to 70°F [57 to 21°C]) within ≤2 h, and cooled further from 70 to 41°F (21 to 5°C) within an additional ≤4 h *(14)*. The U.S. Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) has similar cooling requirements for commercially processed cooked meats. These requirements state that the maximum internal temperature of cooked meat should be allowed to remain between 130 and 80°F (54.4 and 26.7°C) for no longer than 1.5 h and then between 80 and 40°F (26.7 and 4.4°C) for no longer than an additional 5 h *(12)*.

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The Food Code also recommends specific methods to facilitate cooling. Some of these methods include placing food in shallow pans, refrigerating at the maximum cold-holding temperature of 41°F (5°C), and ventilating (i.e., keeping food uncovered or loosely covered) to facilitate heat transfer from the surface of the food. The Food Code also recommends that the person in charge of the food service establishment (e.g., manager) ensure that workers routinely monitor food temperature during cooling *(13)*.

Little is known about how restaurants cool food, and yet knowledge about these issues is essential to developing effective cooling interventions. Thus, during 2009 to 2010, the CDC's Environmental Health Specialists Network (EHS-Net), a group of environmental health specialists and epidemiologists focused on investigating environmental factors that contribute to foodborne illness, conducted a study designed to describe restaurants' food cooling practices and to assess the effectiveness of these practices.

This work is the second arising from this cooling study. In the first article, we presented descriptive data on restaurant cooling practices *(1)*. In this second article, we present additional quantitative analysis to determine practices that best ensure a proper cooling process. Specifically, we examine how food type, active food temperature monitoring, food pan depth, and food ventilation are related to estimated food cooling rates.

MATERIALS AND METHODS

EHS-Net, a collaborative program of the CDC, FDA, USDA, and state and local health departments, conducted this study in collaboration with Rutgers University. At the time this study was conducted, nine state and local health departments were funded by the CDC to participate in EHS-Net. These state and local health departments, or EHS-Net sites, were in California, Connecticut, New York, Georgia, Iowa, Minnesota, Oregon, Rhode Island, and Tennessee.

Personnel in each of the nine EHS-Net sites collected the data for this study. These data collectors visited approximately 50 randomly selected restaurants in each of the nine EHS-Net sites. Restaurant visits lasted an average of 80 min. Information on data-collection training, Institutional Review Board status, and sample selection for this study is available in a previous publication based on this study *(1)*. In brief, standardized data collection forms, developed by the CDC and EHS-Net site staff, were used. Forms were piloted by EHS-Net data collectors, and revisions were made based on the pilot results. Data collectors also participated in training designed to increase data collection consistency. This training included a written restaurant cooling scenario that data collectors reviewed as a group to ensure consistent interpretation and coding. These personnel were environmental health specialists, experienced and knowledgeable in food safety.

In each restaurant participating in the study, data collectors interviewed a kitchen manager about restaurant characteristics and cooling policies and practices. If food was being cooled during their visit to the restaurant, data collectors also recorded observational data on cooling practices. Data collectors recorded data on the types of food being cooled, the number of steps involved in the cooling process, and the method used in each cooling step to cool the food (refrigeration [keeping food at or below 41°F (5°C)], ice bath, ice wand, blast chiller, adding ice or frozen food as an ingredient, room-temperature cooling). Data collectors recorded additional observational data on the details of the refrigeration methods, such as whether the food depth was shallow (defined for this study as ≤7.6 cm [3 in.] deep), whether the food was ventilated (i.e., uncovered or loosely covered), and what the cooling environment temperature was.

Data collectors also recorded whether workers monitored the time or temperature of the cooling foods during the observation period. Worker monitoring actions included taking the temperature of the food with a probe or data-logging thermometer, using a timer or alarm to measure cooling time, or noting food cooling time with a clock.

Data collectors also measured the temperatures of cooling foods at the beginning and end of the observation period by inserting calibrated thermometers into the centermost point of the foods. Those beginning- and ending-point temperatures were taken in similar places in the food and were used to estimate cooling rates according to the procedure outlined in the following text. All data collectors used digital probe thermometers to measure temperatures, and they calibrated their thermometers regularly. Additionally, the method of taking each temperature was specified in the data collection protocol. For example, data collectors were instructed to take the temperature of cooling food at the centermost area of the food. Data collectors used different brands of thermometers.

When foods are cooled in accordance with either the FDA Food Code or the USDA FSIS guidelines, the required change in temperature is nonlinear with respect to time *(10)*. Such nonlinear temperature profiles are also typically observed in practice due to the physical principles that govern cooling. At the start of a cooling process, a large temperature differential, often called the driving force, exists between the food and the cooling environment. A large driving force means a rapid cooling rate. As a food cools, the driving force lessens—a smaller driving force means a slower cooling rate.

Although temperature profiles during cooling are nonlinear, the logarithm of the driving force is linear with time; therefore, cooling rates can be estimated from the beginning and ending points recorded by the data collectors. Thus, the estimated cooling rate as shown by Smith-Simpson and Schaffner *(9)* was assumed to be $[\mathrm{Log}(T_1 - T_{df}) - \mathrm{Log}(T_2 - T_{df})]/t$. T_1 and T_2 are the two temperatures measured during cooling, T_{df} is the driving force temperature, i.e., the temperature of the cooling environment, and t is the time between the two temperature measurements.

If we consider the cooling profile recommended in the 2009 FDA Food Code (from 135 to 70°F [57.2 to 21.1°C] in 2 h, from 70 to 41°F [21.1 to 5°C] in an additional 4 h), assume a driving force temperature of 37°F (2.8°C), and perform simple linear regression, the equation that matches the FDA Food Code cooling profile is $\mathrm{Log}(\Delta T) = -0.2312t + 1.9871$. ΔT is the difference between the food temperature and the driving force temperature, 37°F (2.8°C) in this case, and t is the cooling time in h. Although any driving force could be assumed, the driving force that converts the cooling profile recommended in the Food Code (135 to 70°F [57 to 21°C] in 2 h and 70 to 41°F [21 to 5°C] in an additional 4 h) to the straightest possible line (i.e., $R^2 = 0.99994$) is achieved when a driving force temperature of 37°F (2.8°C) is used. Note than 37°F (2.8°C) is actually a more sensible assumption of a driving force when refrigeration is used because, for a food to actually reach 41°F (5°C), the driving force must be less than 41°F [5°C]. Because the data collectors also recorded the environmental temperature (i.e., the driving force temperature, T_{df}), this actual value was used to calculate the cooling rate. When cooling with a different method was used, a different driving force temperature was used (e.g., room temperature cooling would be a 70°F [21.1°C] driving force temperature, and ice wand or ice bath cooling would be a 32°F [0°C] driving force temperature).

The slope of the cooling profile is the coefficient 0.2312 in the previous equation, so any food cooled at this rate can be assumed to comply with the FDA Food Code (i.e., cooling from 135°F [57.2°C] to 41°F [5°C] within 6 h). Foods cooled at a faster rate (>0.2312) cool faster than recommended in the Food Code guidelines, and foods cooled at a slower rate (<0.2312) cool slower than recommended in the Food Code guidelines. This approach does involve making the assumptions that the estimated cooling rate follows the earlier equation and can be predicted using only two points. However, an alternative approach, calling for more temperature measurements during the cooling process, would have required data collectors to be present in the restaurants for a longer period than was feasible. Cooling rate distributions were created using the histogram function of the Data Analysis ToolPak in Excel (Microsoft, Redmond, WA).

RESULTS

Restaurant sample. As noted by Brown et al. *(1),* 420 restaurant managers agreed to participate in the study, a participation rate of 68.4%. According to manager interview data, 290 (69%) of restaurants in the study were independently owned; the remaining 130 (31%) were chain restaurants. Most restaurants (252 [60%]) served an American menu, 47 (11%) served Italian, 34 (8%) Mexican, 21 (5%) Chinese, and 66 (16%) ''other.'' The median number of meals served daily was 150; the numbers of meals served daily ranged from 7 to 7,700.

Food cooling observation. As noted in Brown et al. *(1),* data collectors observed 596 food items being cooled during their visits in 410 restaurants. Soups, stews, and chilis were the most common food items being cooled (178 [30%]), followed by poultry and meat (150 [25%]), sauces and gravies (92 [15%]), cooked vegetables (40 [7%]), rice (34 [6%]), beans (31 [5%]), pasta (23 [4%]), casseroles (19 [3%]), seafood (7 [1%]), pudding (6 [1%]), and other foods (16 [3%]). Data collectors observed 1,070 steps used during the cooling of these food items. Because one food might be cooled by at least one step, and by as many as four different steps, the number of steps exceeded the number of foods. The most common cooling method was refrigeration, used in 511 (48%) of the cooling steps. Other cooling methods included ice baths (199 [19%]), room-temperature cooling (182 [17%]), ice-wand cooling (80 [7%]), adding ice or frozen food to the cooling food as an ingredient (27 [2%]), blast chillers (5 [<1%]), and other methods (66 [6%]).

Extraction of EHS-Net data. To determine the overall distribution of estimated cooling rates, we used data from cooling step observations that met key criteria for our analysis. The key criteria required for each cooling step observation were a starting temperature, an ending temperature, the elapsed time between the starting and ending temperature, and the driving force temperature (cooling environment temperature). More than 1,000 (1,014) cooling step observations from the EHS-Net data set met these criteria. For each of these step observations, an estimated cooling rate was calculated using the methods and equations described earlier. We used the same process to examine how food type and active food temperature monitoring by food workers affected estimated cooling rate. Nine hundred thirty (930) step observations had data on food type and 1,014 observations had data on cooling method. Cooling steps involving refrigeration (453) also had data on food depth and ventilation during refrigeration; these data were analyzed further.

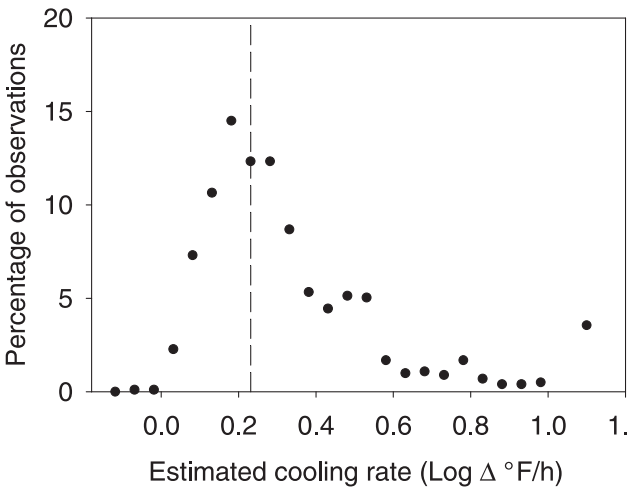

FIGURE 1. *Frequency distribution of estimated cooling rates of 1,014 observations of cooling food. Food Code cooling rate is 0.23 (cooling to 41°F [5°C] within 6 h), indicated by the dotted vertical line.*

Estimated cooling rates. Figure 1 shows the overall distribution of estimated cooling rates, based on beginning- and ending-point food temperatures taken by the data collectors. The *x* axis represents the estimated cooling rate, and the *y* axis represents the fraction of the number of times a particular estimated cooling rate was observed. The vertical line indicates the Food Code guideline cooling rate of ~0.23 (cooling to 41°F [5°C] in 6 h). Cooling step observations positioned left of this line represent foods that were cooling at rates slower than the Food Code guideline. Observations positioned right of this line represent foods that were cooling at rates as fast as or faster than the Food Code guideline. Of the observations, 660 (65%) had an estimated cooling rate that was as fast as or faster than the Food Code guideline. In 36 (~3%) observations there was a very rapid estimated cooling rate (rate of >1, cooling to 41°F [5°C] faster than 1.4 h). Conversely, 354 (~35%) observations had an estimated cooling rate slower than the Food Code guideline. One hundred forty-seven (almost 15%) observations had an estimated cooling rate that was only slightly slower than the Food Code guideline (rate of ~0.18, cooling to 41°F [5°C] in 7.7 h); this was the most frequently observed cooling rate. In 108 (~10%) of the observations, the estimated cooling rate was significantly slower than the Food Code guideline (rate of 0.13, cooling to 41°F [5°C] in 10.7 h). In 9% of observations, the estimated cooling rate was slower than 0.13 (in 74 [7%], rate of 0.08 [cooling to 41°F (5°C) in 17.4 h]; in 23 [2%], rate of 0.03 [cooling to 41°F (5°C) in >24 h]). Finally, two observations showed an estimated cooling rate of less than 0

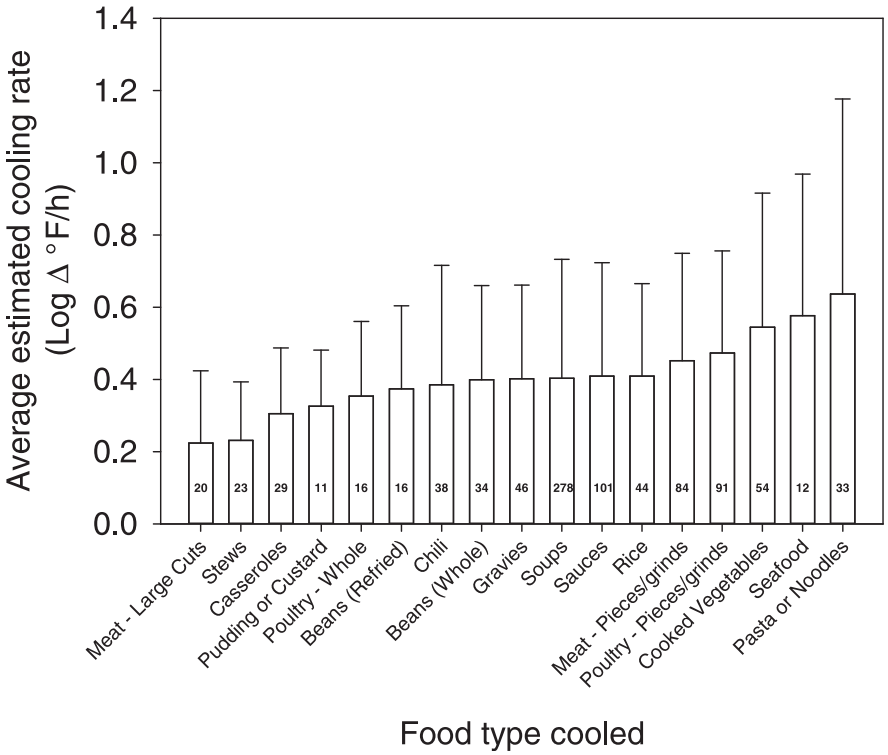

FIGURE 2. *Relationship between food type and the average estimated cooling rate. Food Code cooling rate is 0.23 (cooling to 41°F [5°C] within 6 h). Error bars represent the standard deviation of the cooling rate, and numbers superimposed on the bars represent the number of times each cooling rate was observed.*

(i.e., cooling attempts were made, but the temperatures actually increased slightly).

Estimated cooling rates and food type. Figure 2 shows the relationship between food type and the average estimated cooling rate. The *x* axis represents the food type for the cooling step observations, and the *y* axis represents the average estimated cooling rate; the standard deviation of the estimated cooling rate is shown as error bars. The numbers superimposed on the bars indicate the number of observations associated with each estimated cooling rate. Large cuts of meat and stews (in which *C. perfringens* presents a risk) show the slowest overall estimated cooling rate, a rate approximately equal to the Food Code guideline (rate of 0.23, cooling to 41°F [5°C] in 6 h). Pasta and noodles (in which *B. cereus* poses the primary risk) were the fastest cooling foods, with an average cooling rate of 0.64, which corresponds to a cooling time of just over 2 h. The large standard deviations show the high variability associated with each food type. Faster cooling rates (e.g., with pasta) were more often associated with higher variability, but even the slowest rates had high variability. Although some of these food types have pH values sufficient to prevent the growth of spore-forming bacteria, pH is seldom used as a control measure in restaurants. In addition, pH data on the products in question were not available.

Estimated cooling rates and time or temperature monitoring. Figure 3 shows the effect of monitoring of cooling food time or temperature by food workers on estimated cooling rates. The *x* axis represents the estimated cooling rate for the cooling step observations and the *y* axis represents the fraction of the time (expressed as a percentage) that this particular rate was observed for each condition (monitored and unmonitored). The vertical line indicates the Food Code guideline cooling rate of ~0.23. Closed circles indicate estimated cooling rates for foods that were monitored; open circles indicate estimated cooling rates for foods that were unmonitored. For estimated cooling rates that were slower than the Food Code guideline (positioned left of vertical line), unmonitored cooling was twice as common as monitored cooling. For estimated cooling rates that were slightly faster than the Food Code guideline (rate of 0.3, positioned slightly right of the dotted line, cooling to 41°F [5°C] in 4.6 h), monitored cooling was twice as common as unmonitored cooling. For faster cooling rates (rate of 0.4 and higher, cooling to 41°F [5°C] in 3.5 h and faster) there was little difference between monitored and unmonitored cooling. Considering all the data together, unmonitored food is more than twice as likely (2.2 times) to cool slower than the Food Code guideline.

Estimated cooling rates and food depth. Figure 4 shows how food depth affects estimated cooling rates. The *x* axis represents the estimated cooling rate for the cooling step observations, and the *y* axis represents the frequency of the estimated cooling rates. The vertical line indicates the Food Code guideline cooling rate of ~0.23. Closed circles indicate estimated cooling rates for foods that were ≤7.6 cm (3 in.) deep in containers; open circles indicate estimated cooling rates for foods that were >7.6 cm (3 in.) deep. For estimated cooling rates that were slower than the Food Code guideline (i.e., positioned left of the dotted line), cooling in deep pans was observed about twice as often as cooling in shallow pans. For estimated cooling rates that were as fast as or faster than the Food Code guideline (i.e., positioned right of the dotted line), shallow food depths were generally observed more frequently than deep food depths. Considering

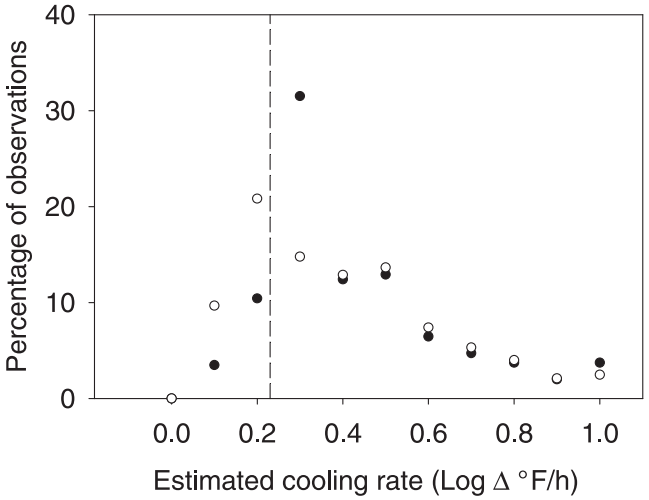

FIGURE 3. *Effect of active temperature monitoring by food workers and estimated cooling rate. Closed circles indicate cooling rates for monitored food; open circles indicate cooling rates for unmonitored food. Food Code cooling rate is 0.23 (cooling to 41°F [5°C] within 6 h), indicated by the dotted vertical line.*

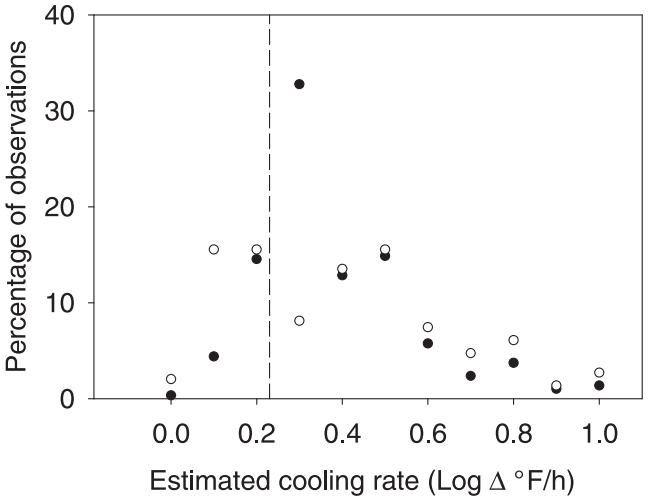

FIGURE 5. *Effect of ventilation on estimated cooling rate. Closed circles indicate ventilated food cooling rates; open circles indicate unventilated food cooling rates. Food Code cooling rate is 0.23 (cooling to 41°F [5°C] within 6 h), indicated by the dotted vertical line.*

all the data together, food deeper than 7.6 cm (3 in.) in containers is twice as likely to cool slower than the Food Code guideline.

Estimated cooling rates and ventilation. Figure 5 shows how ventilation affects the estimated cooling rate. The *x* axis represents the estimated cooling rate for the cooling step observations, and the *y* axis represents the frequency of the estimated cooling rates. The vertical line indicates the Food Code guideline cooling rate of ~0.23. Closed circles indicate ventilated food cooling rates; open circles indicate unventilated food cooling rates. For estimated cooling rates that were much slower than the Food Code guideline (rate of 0.1, cooling to 41°F [5°C] in ~14 h), unventilated cooling was observed more than three times as often as ventilated cooling. When estimated cooling rates were slightly slower than the Food Code guideline (rate of 0.2, cooling to 41°F [5°C] in ~7 h), the frequency of ventilated and unventilated cooling was similar. For estimated cooling rates that were slightly faster than the Model Food Code (rate of 0.3, cooling to 41°F [5°C] in 4.6 h), ventilated cooling was observed more than four times as often as unventilated cooling. Considering all the data together, unventilated cooling foods were almost twice (1.7 times) as likely to cool slower than the Food Code guideline.

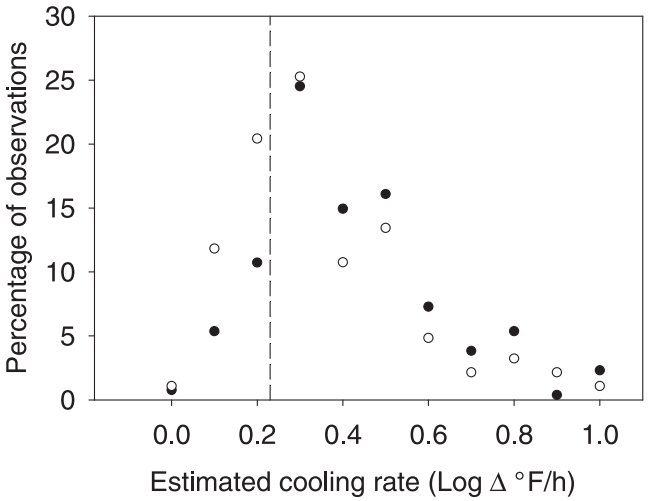

FIGURE 4. *Effect of food depth on estimated cooling rate. Cooling rates for food in shallow pans (≤3 in. [7.6 cm] deep) indicated by closed circles; cooling rates for food in deep pans (>3 in. [7.6 cm] deep) indicated by open circles. Food Code cooling rate is 0.23 (cooling to 41°F [5°C] within 6 h), indicated by the dotted vertical line.*

DISCUSSION

The data from this study indicate that about a third of restaurant cooling step observations had an estimated cooling rate that was slower than the Food Code guideline. These data are concerning because slow cooling can cause foodborne illness outbreaks *(5)*. However, many of these observations showed an estimated cooling rate that was only slightly slower than the Food Code guideline, which suggests that many restaurants may need to make only small changes to their cooling practices to comply with the Food Code guideline.

The data from this study indicate that following the Food Code guidelines concerning the cooling methods examined in this study likely will improve cooling rates and ensure compliance with Food Code guidelines. Following the Food Code guidelines (storing foods at shallow depths, ventilating foods, and actively monitoring cooling food time or temperatures) facilitated faster estimated cooling rates. Our data show that, of the three methods, active monitoring was the most effective (2.2 times more likely to meet Food Code guidelines), followed by shallow food depth (2 times more likely), and ventilation (1.7 times more likely).

Restaurants should be able to boost their cooling rates relatively easily by using one or more of these methods.

The data from this study also show that some foods, particularly large cuts of meat, are harder to cool to the Food Code guideline than other types of foods. These data are not surprising; other researchers have found similar results *(6, 11)*. These data reinforce the need for restaurants to pay particular attention to cooling these types of foods. The data from this study also confirm the difficulties of cooling food stored in deep containers; this circumstance is known to increase the risk of *C. perfringens* proliferation *(2–4)*.

This study is one of few to examine restaurant food cooling practices and processes. This lack of data may stem from the fact that assessing the full 6-h cooling process is time intensive and, thus, difficult to accomplish. The FDA attempted to assess restaurant food cooling processes in their Retail Risk Factor Study but encountered difficulties *(15)*. In that study, cooling was observed in substantially fewer retail establishments than were other food preparation practices, due, in part, to the limited amount of time data collectors had available to spend in establishments.

A limitation of this study is that it included only restaurants with English-speaking managers. Additionally, the data collected were susceptible to reactivity bias (as in any study involving observational activities). For example, food workers were aware that they were being observed and might have reacted to being observed by changing their routine behavior (e.g., monitoring cooling food temperatures more frequently).

Our study did not assess the full cooling process but instead used mathematic modeling to estimate cooling rates. The method, of necessity, had to assume that driving force temperature was constant, and at the single value measured by the data collectors, as explained in the methods above. Our data suggest that several best cooling practices can contribute to a process in which food is cooled properly. Future research could not only validate our estimation method but also further investigate the effect of specific cooling practices on the full cooling process.

It may be useful to frame the findings from this study in terms of contributing factors and environmental antecedents to foodborne illness outbreaks *(8)*. Contributing factors are factors in the environment that cause, or contribute to, an outbreak; environmental antecedents are factors in the environment that lead to the occurrence of contributing factors. In this case, slow or improper cooling is a contributing factor. Cooling practices such as storage of food in deep containers, lack of ventilation, and lack of active monitoring can be environmental antecedents to this contributing factor. Our data suggest that focusing on these environmental antecedents may help reduce outbreaks caused by slow or improper cooling.

Environmental health specialists who are not able to assess the full cooling process during their restaurant inspections may wish to consider assessing the specific cooling practices used in the cooling process (i.e., the environmental antecedents [e.g., food depth]), because these practices can be assessed far more quickly than can the full cooling process. This assessment will allow environmental health specialists to identify methods to improve the cooling process and educate restaurant managers accordingly. Our data suggest that, in many cases, the changes needed to improve the cooling process may be small and relatively easy to implement.

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Restaurant Practices for Cooling Food in Minnesota: An Intervention Study

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Abstract

Improper cooling of hot foods is a leading contributing factor to foodborne disease. Although the U.S. Food and Drug Administration (FDA) Food Code outlines the cooling parameters and methods to facilitate proper cooling, restaurants continue to have issues. The purpose of this study was to further examine restaurant cooling practices and determine the effect of an educational intervention on 30 Minnesota restaurants, each with a history of cooling violations. Descriptive data on restaurant cooling practices and a cooling curve were collected from each restaurant to determine compliance with the Food Code and to assess which cooling methods work best. Additionally, cooling education was provided to a manager and assessments were conducted preintervention, postintervention, and at the next routine inspection to determine if cooling knowledge improved. Restaurants were evaluated at their next routine inspection to see if cooling practices had changed and if cooling violations were present. Most study restaurants were not using appropriate cooling methods as per the Minnesota Food Code, and 53% of food items observed did not cool within required cooling parameters. Foods cooled in containers <3 inches in depth were significantly more likely to cool properly. Managers scored significantly higher on the postassessment and on the next routine inspection assessment than on the preassessment, suggesting that education on cooling can increase operator knowledge. Postintervention, 20% more kitchen managers reported having written cooling procedures and had verified their cooling process than was reported preintervention. However, the increase in knowledge and reported policy changes did not translate to a reduction in cooling violations at the next inspection. Our findings documented significant food safety gaps in restaurant cooling practices. Translation of knowledge into sustained, improved food safety practices remains a major challenge for the environmental health profession; overcoming this challenge should be a focus for behavioral scientists and others interested in improving practices in restaurants for the long term.

Keywords: restaurants, cooling, cooling methods, intervention, cooling curves

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Introduction

Improper cooling of hot foods is a leading contributing factor to foodborne disease (Gould *et al.*, 2013; Lipcsei *et al.*, 2019). During 2009–2015, ~9% of foodborne outbreaks in the United States were due to bacterial intoxication from pathogens such as *Clostridium perfringens* (Dewey-Mattia *et al.*, 2018); these bacteria can multiply to disease-causing levels if food is cooled improperly (Doyle, 2002). Similarly, ~10% of foodborne outbreaks in Minnesota each year are due to bacterial intoxication (Minnesota Department of Health, unpublished data, 2018), which are preventable if time–temperature control measures are properly implemented, including cooling.

To reduce the risk of foodborne disease, the U.S. Food and Drug Administration (FDA) Food Code (2017) includes guidelines for retail food service establishments to keep time and temperature control for safety foods. These guidelines state that food must be cooled from 135°F to 70°F within 2 h and from 135°F to 41°F within a total of 6 h (U.S. FDA, ''FDA Food Code,'' 2017). At the time of data collection for this study, the 1998 Minnesota Food Code was in effect, which stated that potentially hazardous foods (PHFs) must be cooled from 140°F to 70°F within 2 h and from 70°F to 41°F within 4 h (MN Dept. of Health, 1998).

The FDA Food Code contains guidelines, consistent with the 1998 Minnesota Food Code, on methods that help facilitate proper cooling, including placing food in shallow pans, using containers that facilitate heat transfer, adding ice as an ingredient, or other effective methods. However, there is no information on what methods or types of containers work best or a definition of ''shallow.'' In addition, the FDA

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recommends that operators monitor times and temperatures for cooling of foods to verify proper cooling (U.S. FDA, ''Annex 3,'' 2017). Recording times and temperatures in a cooling log is one way to provide verification.

Although these guidelines are in place, restaurants continue to struggle with proper cooling. An FDA study found that cooling was out of compliance in 72% (196) of the full-service restaurants where cooling was observed (U.S. FDA, ''Report on the occurrence,'' 2018). Another study of 420 restaurants concluded that many restaurants are not meeting FDA recommendations for cooling, and about one-third of kitchen managers did not know cooling regulations for their jurisdiction (Brown *et al.*, 2014). Modeling conducted in the same study showed that about a third of restaurant cooling step observations had an estimated cooling rate that was slower than the Food Code guidelines (Schaffner *et al.*, 2015). Restaurants are dynamic and fast-paced, making it difficult to monitor cooling of foods. Additionally, inspectors are only in restaurants for a snapshot of time, so it is difficult to determine Food Code compliance. Training and other intervention efforts are needed to teach restaurant operators how to cool food properly (Brown *et al.*, 2014; Schaffner *et al.*, 2015).

The purpose of this study was to further examine restaurant cooling practices and to determine the effect of an educational intervention on restaurant cooling practices. Specific study objectives were to (1) collect descriptive data on restaurant cooling practices; (2) capture a cooling curve on a PHF in each restaurant to determine compliance with the Food Code and assess which cooling methods work best; and (3) determine if providing cooling education to managers would increase knowledge and result in changes to restaurant cooling practices.

Materials and Methods

Two Minnesota Department of Health (MDH) environmental health specialists, both registered sanitarians, collected data from September 2016 to May 2017 from a convenience sample of 30 restaurants in 5 Minnesota counties. Inspectors in these counties were asked to provide a list of restaurants that had a cooling violation on their last routine inspection. In total, 37 restaurant names were provided to the specialists, of those, three restaurants were excluded because the restaurant manager did not speak English and four refused to participate. The five counties represented both rural and metropolitan areas of the state and are regulated by MDH. A restaurant was defined as an establishment that prepares and serves food or beverages to customers, but is not an institution, food cart, mobile food unit, temporary food stand, supermarket, or caterer.

Specialists recruited restaurants by telephone. Restaurants were told that data on cooling practices would be collected at three points in time: preintervention, postintervention, and at the next routine inspection. Participating restaurants received a DeltaTrak thermometer ($50 value) as an incentive to participate. Kitchen managers (defined as a manager with authority over the kitchen) (hereafter referred to as manager) were told that participation was voluntary and nonregulatory and that all data collected would not be identifiable. They were also told that their inspector might accompany the specialist during the visit and that improperly cooled food could not be served to customers.

Preintervention

The first appointment was scheduled at a time that would coincide with the beginning of the restaurants' cooling processes of at least one PHF (selected by the manager). Specialists placed a data logger in the center of the food item to collect a cooling curve of that product. Observations on the cooling methods were noted. Managers were told to cool the food as they normally would, to keep the probe in the center of the food, and to not turn the probe off or remove it from the food item.

Specialists also interviewed the manager about restaurant characteristics and cooling practices and administered a nine-question multiple-choice assessment (preassessment) (Supplementary Fig. S1). Scoring was out of nine, and there was only one correct answer for each question.

Educational intervention

The specialist returned for a second appointment (often later that same day) to complete cooling observations, collect the data logger, and provide the educational intervention to the manager. The educational intervention took 30–45 min and consisted of verbally explaining an infographic (Supplementary Fig. S2) about cooling, sharing a cooling fact sheet (Supplementary Fig. S3) and a cooling log, and downloading and discussing the cooling curve collected. Specialists had standardized guidelines on how to deliver the educational component. Then, the assessment was conducted again (postintervention assessment) to measure any changes in the manager's knowledge.

Next routine inspection

Cooling practices were assessed again at the restaurants' next routine inspection, which occurred on average 240 d (range: 19–427 d, median: 286 d) after the intervention. Inspectors interviewed managers on cooling practices and provided the same assessment. Due to turnover and scheduling, the manager from the first two appointments was not necessarily the one being assessed during the routine inspection. Specialists reviewed the routine inspection report and noted if cooling violations were written.

To assess the impact of study interventions on the 30 restaurants, specialists reviewed data from 6507 routine restaurant inspections conducted under MDH jurisdiction in 2016 and compiled a list of restaurants with at least one cooling violation (minus the 30 study restaurants). Inspection data on those restaurants' next routine inspection (conducted in 2017 or 2018) were reviewed to see if they had another cooling violation.

DeltaTrak model 20902 data loggers, precalibrated and set to collect time and temperature data in 5-min intervals, were used to capture cooling curves. Temperatures of the refrigerator units were taken with a calibrated thermometer from the area where the food item was cooling. Descriptive and quantitative data analyses were performed with Microsoft Excel 2017 and SAS 9.4. p-Values <0.05 were considered statistically significant; associations with p-values <0.10 were also noted.

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Results

Most of the 30 study restaurants were independent restaurants (83%, 25); the remaining 17% (5) were chains. The majority (53%, 16) of managers interviewed had been working as managers in the restaurants for 2–5 years.

Restaurant cooling practices

Preintervention, 87% (26) of managers self-reported that they had a formal procedure for cooling PHFs (Table 1). Of these, 19% (5) reported that the procedures were written and 62% (16) reported that they had tested and verified the process. Twenty-three percent (7) of managers reported recording times and temperatures in a log, and logs were verified visually by the specialist.

At the routine inspection, all 29 managers interviewed (one restaurant had closed) said that they had a formal procedure for cooling PHFs. Forty-one percent (12) reported that the procedures are written, 83% (24) had tested and verified the process, and 31% (9) said they record times and temperatures in a log (visual verification by inspector). Sixty-two percent (18) of managers reported that they had made changes to their cooling practices since participating in the study. Reported changes included using shallow containers and stainless steel containers, using ice wands, and taking temperatures throughout the cooling process.

Table 1. Restaurant Cooling Practices (Ascertained by Manager Interview)

	Pre (n = *30*)[a]		*Routine* (n = *29*)[b]	
	n	%	n	%
How long have you been a kitchen manager at this restaurant?				
<2 years	2	7	—	—
2–5 years	16	53	—	—
6–10 years	3	10	—	—
11–20 years	5	17	—	—
>20 years	3	10	—	—
Refused	1	3	—	—
Does this restaurant have a formal procedure or process for cooling potentially hazardous foods?				
Yes	26	87	29	100
No	3	10	—	—
Unsure	1	3	—	—
Are the procedures or processes written? (Pre: $n = 26$)				
Yes	5	19	12	41
No	21	81	16	55
Unsure	—	—	1	3
Are the cooling procedures tested and verified? (Pre: $n = 26$)				
Yes	16	62	24	83
No	9	35	3	10
Unsure	1	3	2	7
Do you record times and temperatures in a cooling log?				
Yes	7	23	9	31
No	22	73	20	69
Unsure	1	3	—	—

Cooling logs were also visually verified by specialists and inspectors.

[a]Pre means preintervention.

[b]At the next routine inspection (routine), one restaurant had closed, $n = 29$.

Cooling methods were observed on 34 food items: in 4 restaurants, 2 food items were observed. Types of PHFs varied and included soups, pasta, rice, meat, and sauces. Fifty-three percent (18) of foods were cooled in a stainless steel container, 35% (12) in a container <3 inches in depth, 35% (12) were stirred at some point during the cooling process, 32% (11) in an ice bath, and 26% (9) with an ice wand. Almost all (94%, 32) food items were ventilated (uncovered or loosely covered) and none were stacked.

Sixty-five percent (22) of foods were cooled using a combination of two or more of the following methods: stainless steel container, depth <3 inches, stirring, ice bath, or ice wand. Eighty-two percent (28) of foods were cooled in a refrigerator, 9% (3) in a freezer, and one in both. Most (86%, 24) refrigerators used to cool food were at or below 41°F. Eleven percent (3) of refrigerators were above 41°F.

Cooling curves

Thirty-three cooling curves were collected (Supplementary Fig. S4). For one food item, the data logger was not working properly, so start and end times and temperatures were used to determine compliance. Some food items were not completely cooled to 41°F when the specialist returned to collect the data logger. As a result, analysis on the cooling curves was grouped into the two cooling requirements outlined in the Minnesota Food Code: (1) 140°F to 70°F within 2 h and (2) 70°F to 41°F within 4 h. Fifty-nine percent (20) of the 34 foods met the first requirement. Of the 25 foods that had completely cooled, 68% (17) met the second requirement. Overall, 53% (18) of the 34 foods did not meet at least one of the cooling parameters.

Exploratory data analysis of cooling methods

Due to the limited number of food items that had completely cooled by the time data loggers were obtained, only the first cooling requirement (140–70°F within 2 h) was used to assess the effectiveness of the cooling methods (Table 2). Food cooled in containers <3 inches in depth was significantly more likely to meet the first cooling requirement ($p = 0.035$). There was also evidence that food cooled in stainless steel containers ($p = 0.091$) and food cooled in restaurants that had a written cooling procedure ($p = 0.066$) were more likely to meet the first cooling requirement. There were no significant differences in food items that were cooled using an ice bath, an ice wand, or a combination of two or more cooling methods.

Manager assessment scores

There was a significant increase in managers' scores from pre- to postintervention ($p < 0.0001$) (Table 3). There also was a significant increase in managers' scores from preintervention to the routine inspection ($p = 0.01$). However, postintervention scores were significantly better than scores at the next routine inspection ($p < 0.001$).

Postintervention inspection data

Of the 6507 restaurants at which a routine inspection was conducted by MDH in 2016, 472 (7%) had one or more cooling violations. Of those, 18% (84) had one or more

Table 2. Contingency Table of Cooling Methods and Achieving the First Parameter of Cooling Criteria

	First guideline		
	Cooling from 140°F to 70°F within 2 h		
Cooling method	*Yes*	*No*	*Sig.*[a]
<3 Inches			
Yes	10	2	0.035
No	10	12	
Written procedures			
Yes	7	1	0.067
No	13	13	
Stainless steel			
Yes	13	5	0.091
No	7	9	
>2 Methods			
Yes	15	7	0.128
No	5	7	
Ice bath			
Yes	7	4	0.495
No	13	10	
Ice wand			
Yes	5	4	0.736
No	15	10	

$n = 34$.
[a]Fisher's exact test right-sided $Pr \geq F$.

cooling violations on their next routine inspection. In the study population, of the 29 establishments still in operation, 31% (9) had one or more cooling violations on their next routine inspection. When using a chi-square goodness-of-fit test, the difference between the baseline group and study group was not statistically significant ($p = 0.07$).

Discussion

Many managers were not following Food Code guidelines to facilitate proper cooling. Most managers reported that they had a formal procedure for cooling, but many had not verified that their cooling process worked, and few had written procedures or recorded temperatures in a log. These findings were almost identical to the manager-reported practices reported by Brown *et al.* (2012).

After the intervention, 20% more managers reported that their procedures had been verified, and an additional two restaurants were recording times and temperatures in a log. Although these changes were small, they could result in better practices. Testing and verification of times and temperatures are recommended best practices in the Food Code. The likelihood of temperature abuse is reduced when employees are monitoring food temperatures (U.S. FDA, ''Annex 3,'' 2017). Similarly, by not having written procedures for cooling, food workers may deviate from the establishment's cooling process or use methods that hinder cooling. Additional research looking into the social and behavioral factors affecting policy and procedure compliance would be beneficial.

The majority of restaurants were not utilizing proper cooling methods; only half cooled food in stainless steel containers and only about a third used containers <3 inches in depth or stirred the food. This resulted in almost half of the food items not meeting the cooling parameters required in the Food Code. Just over half of the foods cooled from 140°F to 70°F within 2 h. The initial 2-h cool period is a critical element of this cooling process (U.S. FDA, ''Annex 3,'' 2017) and necessary to minimize the time that food is kept in the temperature danger zone (U.S. FDA, ''Danger Zone,'' 2017). *Clostridium perfringens*, the leading cause of bacterial foodborne intoxication outbreaks, can grow very rapidly between 109°F and 117°F. Therefore, it is important for food to cool rapidly during this first step to prevent bacterial amplification (CDC, 2018).

It is critical that establishments use a combination of cooling methods to help achieve cooling success, but it does appear that some cooling methods, such as cooling in containers <3 inches in depth, may be more effective than others. By reducing the volume of food in an individual container, the rate of cooling is dramatically increased (Schaffner *et al.*, 2015, U.S. FDA, ''Annex 3,'' 2017).

The use of stainless steel containers and having formal, written cooling procedures were also variables of interest. Stainless steel allows for better heat transfer than plastic containers, which slow cooling (U of M extension, 2018). Written procedures indicate that employees are more likely to have been trained on the cooling process and could be an indicator of good, active managerial control. Further research is needed to fully assess the success of these methods. Clear guidance on what is considered shallow and what containers best facilitate heat transfer would be beneficial to operators and regulators.

Table 3. Comparison of Cooling Knowledge Assessment Scores for Managers Pre- and Postintervention

Mean (SD)		*Mean difference*[a]	*95% CI*	t-*statistic* (df)	p
Pre vs. post[b]					
5.2 (1.18)	7.8 (1.14)	2.6	2.1–3.1	11.4 (31)	<0.0001
Pre vs. routine[c]					
5.2 (1.18)	6.1 (1.74)	1.5	0.9–2.1	2.5 (58)	0.01
Post vs. routine[c]					
7.8 (1.14)	6.1 (1.74)	1.6	0.8–2.4	4.2 (45)	<0.001

Routine has an $n = 28$, 1 establishment had closed, and in one establishment, the assessment was not completed.
[a]Mean difference calculated by taking postscore minus prescore, routine score minus prescore, and postscore minus routine score.
[b]For same respondents, a paired *t*-test was performed.
[c]Where respondents may have differed, an independent *t*-test was performed.
CI, confidence interval; SD, standard deviation.

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Providing cooling education improved manager knowledge scores. The large increase in postassessment compared with preassessment scores may partly be due to a carryover effect (Bjorndal, 2018) since most managers took the pre- and postassessments within a day. However, the routine inspection scores were also significantly higher than preassessment scores, suggesting that a long-term increase in knowledge may have occurred. Postassessment scores were significantly higher than scores at the routine inspection, which could indicate that knowledge gained decreases over time, highlighting the need for periodic refresher training. Additional research on manager training and how it relates to long-term changes in practice is necessary.

Increased manager knowledge did not decrease the number of cooling violations on future inspections. Study restaurants, compared with all MDH restaurants, had a higher percentage of cooling violations on their next routine inspection. Although this difference was not significant, it is still concerning.

It is likely that many cooling violations are being undocumented on routine inspections because inspectors are only in the restaurant for a small portion of operating hours; inspectors may have looked more closely at cooling practices onsite in the study restaurants, allowing them to find more violations. Additionally, most study restaurants were independent restaurants with managers working at the restaurant for 5 years or less. Research has shown that independent restaurants have more food safety issues than chain restaurants due to inadequate training of staff and no formal policies (Brown *et al.*, 2014) and that inexperienced managers have less food safety knowledge and training to ensure good practices (Brown *et al.*, 2014). High employee turnover and physical facility or equipment constraints are other factors that may affect the inability to maintain practice changes.

This study had several limitations, we used a convenience sample of restaurants with English-speaking managers; therefore, the restaurants included in this study may not represent all restaurants that cool food within Minnesota. Due to our small sample size, there was a lack of power, making it difficult to determine factors of significance. Additionally, self-reported data were collected through manager interviews and may be affected by social desirability bias. Percentages of restaurants with food safety errors should be viewed as minimum estimates. Last, our conclusions regarding manager knowledge at the routine inspection have limitations since managers who took the pre- and postassessments may have not been the same, and the length of time routine inspections were conducted after the intervention varied, potentially affecting knowledge retention.

Conclusions

This study identified significant food safety gaps in cooling. Restaurant managers were often unaware of the requirements pertaining to proper cooling and did not utilize cooling methods to cool food as outlined in the Food Code, resulting in improperly cooled food. Our results suggest that education on cooling can increase manager knowledge; however, this did not translate into fewer cooling violations in the next routine inspection.

The lack of translation of knowledge into sustained, improved food safety practices remains a major challenge for the environmental health profession; overcoming this challenge should be a focus for behavioral scientists and others interested in improving practices in restaurants in the long term. Restaurants are dynamic environments and it can be difficult for food workers to closely monitor cooling of food. Training food workers and regulatory staff on cooling methods that best facilitate rapid cooling, such as portioning food into shallow containers with a depth of <3 inches, can help address the issue of improper cooling.

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Supplementary Material

Supplementary Figure S1
Supplementary Figure S2
Supplementary Figure S3
Supplementary Figure S4

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Research Paper

Validation of a Simple Two-Point Method To Assess Restaurant Compliance with Food Code Cooling Rates

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ABSTRACT

Outbreaks from improperly cooled foods continue to occur despite clearly described Food Code cooling guidelines. It is difficult for regulators to enforce these guidelines because they are typically in an establishment for less than the 6 h needed to document proper cooling. Prior research proposed using a novel method to estimate cooling rates based on two time-temperature points, but this method has not yet been validated. Time-temperature profiles of 29 different foods were collected in 25 different restaurants during cooling. Cooling curves were divided into two categories: typical (21 foods) and atypical (eight foods) prior to further analysis. Analysis of the typical cooling curves used simple linear regression to calculate cooling rates. The atypical cooling profiles were studied using Monte Carlo simulations of the cooling rate. Almost all linearized typical cooling curves had high ($>$0.90) R^2 values. Six foods with typical cooling profiles that did not pass Food Code cooling times were correctly identified by the two-point model as having slow cooling rates. Three foods that did not pass Food Code cooling times were identified by the two-point model as having marginal cooling rates. Ten of 12 foods identified by the two-point model as having acceptable cooling rates met Food Code cooling times. Most (six of eight) foods that were considered to have atypical cooling curves failed to meet the Food Code cooling times. The two-point model was also able to determine whether these foods would fail based on Food Code guidelines depending upon the simulation criteria used. Our data show that food depth has a strong influence on cooling rate. Containers with a food depth $\geq$7.6 cm (3 in.) were more likely to have cooling rates slower than the U.S. Food and Drug Administration Model Food Code cooling rate. This analysis shows that the two-point method can be a useful screening tool to identify potential cooling rate problems during a routine restaurant inspection visit.

HIGHLIGHTS

- Containers with food depth $\geq$7.6 cm were likely to have slow cooling rates.
- Most (21 of 29) foods had linearized cooling rates with high ($>$0.90) R^2 values.
- Most (15 of 17) slow cooling foods were identified by the two-point method.
- All (12 of 12) fast cooling foods were identified by the two-point method.
- The two-point method can be used to identify potential cooling rate problems.

Key words: Cooling; Inspection; Model; Refrigeration; Simulation

Bacterial intoxications from *Clostridium perfringens, Bacillus cereus,* and *Staphylococcus aureus* cause approximately 10% of foodborne outbreaks in the United States *(11),* and improper cooling is a leading contributing factor in many of these outbreaks *(14)*. If foods are held out of temperature control (above 5 or below 57°C) for too long, bacteria such as *C. perfringens* and *B. cereus* can proliferate to high levels, resulting in illness *(13). C. perfringens* is typically associated with improper cooling of large cuts of meat, because the spores of the organism can survive the cooking process *(31). C. perfringens* cells can multiply between 15 and 55°C, with an optimal temperature of 45°C *(6)*. Spores germinate in response to cooking, and cells subsequently multiply rapidly during cooling, doubling as often as every 20 min (i.e., 1 log CFU increase every hour) or even faster *(27). C. perfringens* is estimated to cause 1 million illnesses in the United States each year *(15),* surpassed only by *Salmonella* and norovirus *(25). C. perfringens* caused a confirmed 15,208 illnesses, associated with 289 outbreaks between 1998 and 2010 in the United States *(15). B. cereus* can also survive the cooking process and is typically associated with improper cooling of cooked rice *(8). B. cereus* was linked to 56 confirmed outbreaks causing 881 illnesses between 1998 and 2008 in the United States *(3)*. Proper cooling time and temperature control for cooked foods can be crucial in preventing foodborne disease outbreaks by these organisms.

The U.S. Food and Drug Administration (FDA) Model Food Code has recommendations that specify time and

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temperature parameters for cooling of cooked food. These guidelines state that time-temperature control for safety (TCS) foods must be cooled from 57.2 to 21.1°C (135 to 70°F) within 2 h and from 57.2 to 5°C (135 to 41°F) within 6 h *(30)*. Many states have adopted these specific recommendations for their own state food codes, as Minnesota did in January 2019. Prior to adopting the FDA Model Food Code parameters, Minnesota was using similar but older parameters *(23),* which required that potentially hazardous foods (i.e., TCS foods) be cooled from 60 to 21.1°C (140 to 70°F) within the first 2 h, and from 57.2 to 5°C (70 to 41°F) within the next 4 h. The FDA Model Food Code also outlines methods that can help cool foods quickly, such as the use of shallow pans or the use of containers that facilitate heat transfer *(30)*. These recommendations provide minimal details on which methods are optimal or on what constitutes "shallow" or what container best facilitates heat transfer.

Even with clearly described food code guidelines, outbreaks from improperly cooled foods continue to occur *(5, 28)*. It is often difficult for operators to monitor time and temperatures during cooling due to a lack of suitable tools and the awareness of its importance. It is also often difficult for regulators to enforce these guidelines because they are typically in an establishment for a period less than the 6 h needed to document proper cooling. The FDA attempted to assess restaurant food cooling processes in their Retail Risk Factor Study, but they encountered difficulties because cooling was observed in only few retail establishments due to the limited amount of time collectors were present *(29)*.

Because observation of cooling in retail establishments over the entire 6-h time period is impractical, Schaffner et al. *(26)* proposed using a novel method to estimate cooling rates based on two time-temperature points. These researchers noted that although temperature profiles during cooling are nonlinear, the logarithm of the driving force is linear with time, so cooling rates can be estimated from any two time points in the cooling process. Whereas Schaffner et al. *(26)* made some useful observations, because their study consisted solely of time-temperature point pairs (not full cooling curves) they could not validate that their two-point method was representative of full cooling curves. Our study seeks to further examine restaurant cooling by using complete cooling curves captured from restaurant food items to calculate cooling rates and then to use these rates to validate the two-point approach proposed by Schaffner et al. *(26)* as well as to identify additional risk factors predictive of poor cooling.

MATERIALS AND METHODS

Two-point method description. Foods temperatures change in a nonlinear fashion as they cool, dropping more rapidly at the start because of the greater difference between the food temperature and that of the environment. This temperature difference is known as the driving force *(26)*. Whereas temperatures change nonlinearly with time, the logarithm of the driving force changes linearly with time. The estimated cooling rate *(27)* can be assumed to be $[\mathrm{Log}(T_1 - T_{df}) - \mathrm{Log}(T_2 - T_{df})]/t$, where T_1 and T_2 are any two temperatures measured during cooling, T_{df} is the driving force temperature (i.e., the temperature of the cooling environment), and t is the time between the two temperature measurements. Schaffner et al. *(26)* found that the FDA Food Code recommended guidelines for food cooling results in a cooling rate of 0.23, where a rate faster than 0.23 cooled faster than the Food Code recommended rate, and vice versa *(26)*. This rate is log linear for a driving force of 2.8°C (37°F). Note that this rate is the same whether calculated using °C or °F, if the units for time (i.e., hours) remain the same.

Data collection. Time-temperature profiles of 29 different foods were collected in 25 different restaurants during cooling, and time and temperature data from the center of the food (i.e., the cold spot) were recorded every 5 min *(17)*. Cooling curves were divided into two categories, typical and atypical, prior to further analysis. Curves were considered atypical when they had many dips and peaks, usually due to either stirring or a change of cooling method. Most cooling curves (21 curves of 29 total) had approximately log-linear driving force changes with time and were considered typical, whereas atypical cooling curves (8 of 29) had non–log-linear driving force changes with time, due to temperature spikes or dips from stirring or other factors.

Typical cooling curves analysis. Our analysis of the typical cooling curves (21 of 29 foods) used five points selected from each food's cooling profile. The selections corresponded to (i) the time immediately following a food temperature below 60°C (140°F), (ii) the time immediately following a food temperature below 21.1°C (70°F), and (iii) the time immediately following a food temperature below 5°C (41°F), as well as the times corresponding to interpolation between these temperatures (40.6 and 13.1°C [105 and 55.5°F]). The driving force temperature for each cooling curve was taken from the auditors' records *(17)* made at the time of their visit. The logarithm of the driving force ($\log[T - T_{df}]$) for each of the five points was plotted versus time, and simple linear regression in Excel (Microsoft Corporation, Redmond, WA) was used to calculate cooling rates.

Atypical cooling curves analysis. The atypical cooling profiles (8 of 29 foods) were studied using simulations of the cooling rate created with @Risk software (Palisade Corporation, Ithaca, NY). First, temperature and time data from each cooling profile were divided into two groups: <60 and >21.1°C (<140 and >70°F) and <21.1 and >5°C (<70 and >40°F). Next, @Risk selected one random time-temperature pair value from each group and used the two points to estimate the cooling rate. A total of 10,000 cooling rates were estimated for each food with an unusual cooling curve. Histograms and summary statistics (mean, median, mode, upper and lower 90%, and fraction of rates faster and slower than the previously measured cooling rate based on FDA Food Code recommendations) were calculated for each set of 10,000 iterations.

RESULTS

Typical cooling curves results. Table 1 shows the 21 foods with typical cooling curves and includes important characteristics of the cooling process, including cooling rate, whole container type, container depth, ventilation, and cooling method. The entries in Table 1 are sorted according to the estimated cooling rate calculated using the method from Schaffner et al. *(26)*. All linearized rates created showed strong fit as indicated by high (>0.87) R^2 values. Approximately half (11 of 21) of the foods in Table 1 failed

TABLE 1. *Estimated cooling rates created for foods with "typical" cooling profiles, sorted from slowest to fastest cooling*

Food	Cooling rate (1/h)	Speed[a]	R^2	Container	Cooling method	Ventilated?	Excess product depth >7.6 cm (3 in.)	Pass[b]
Vegetable beef soup	−0.102	Slow	0.921	Metal	Walk-in cooler	Yes	Yes	No
Vegetable beef barley soup	−0.117	Slow	0.876	Plastic	Walk-in freezer/walk-in cooler	Partially	Yes	No
Veggie burger soup	−0.122	Slow	0.999	Plastic	Walk-in cooler	Yes	Yes	No
Mashed potatoes	−0.137	Slow	0.999	Metal	Walk-in cooler	Yes	Yes	No
Bacon potato soup	−0.147	Slow	0.984	Plastic	Ice wand/walk-in	Yes	Yes	No
Chinese beef and broccoli soup	−0.176	Slow	0.964	Metal	Ice wand/walk-in	Yes	Yes	No
Rice	−0.243	Borderline	0.999	Metal	Walk-in cooler	Yes	Yes	No
Turkey (deboned)	−0.246	Borderline	0.915	Metal	Walk-in cooler	Yes	No	No
Rice	−0.252	Borderline	0.998	Plastic	Walk-in cooler	Yes	Yes	No
Alfredo sauce	−0.309	Fast	0.992	Metal	Walk-in cooler	Yes	No	Yes
Noodles	−0.312	Fast	0.969	Metal	Walk-in cooler	No	No	No[c]
Meat broth	−0.322	Fast	0.999	Metal	Reach in cooler	Yes	Yes	Yes
Mashed potatoes	−0.337	Fast	0.998	Metal	Walk-in cooler	Yes	No	Yes
Chicken wings	−0.383	Fast	0.941	Metal	Walk-in cooler	No	No	Yes
Steak and potato soup	−0.394	Fast	0.999	Plastic	Ice wand/walk-in	Yes	Yes	Yes
Rice pilaf	−0.489	Fast	0.997	Metal	Walk-in cooler	Yes	No	Yes
Toscana soup	−0.522	Fast	0.971	Plastic	Ice bath/wand/walk-in	Yes	Yes	Yes
French onion soup	−0.537	Fast	0.983	Metal	Walk-in cooler	Yes	No	No[d]
Rice	−0.643	Fast	0.974	Metal	Walk-in cooler	Yes	No	Yes
Par-cooked chicken	−1.050	Fast	0.984	Metal	Walk-in cooler	Yes	No	Yes
Chicken wild rice soup	−2.178	Fast	0.923	Metal	Walk-in cooler/ice over top	Yes	No	Yes

[a] The speed column identifies foods that cooled slower than the linearized cooling rate of 0.23 proposed by Schaffner et al. *(26),* foods that are borderline, or foods that cooled faster than the linearized cooling rate of 0.23.

[b] Pass indicates whether the food met the 2017 MN State Food Code (or FDA 2001 Model Food Code) cooling rates of ≤2 h between 60.0 and 21.1°C (140 and 70°F), and ≤4 h between 21.0 and 5°C (70 and 41°F).

[c] Food missed the guideline by only 5 min.

[d] Food had somewhat atypical profile due to formation of a surface fat layer during cooling.

to meet the cooling rates required by the 1998 MN State Food Code (or FDA 2001 Model Food Code). This is indicated in the last column of Table 1 entitled Pass, with an entry of "no." About one-third (6 of 21) of the foods had cooling rates that were less than the linearized Food Code rate (0.23) proposed by Schaffner et al. *(26)*. These six foods are shown in the top six rows of Table 1 and are identified by "slow" in the Speed column. Five of the six foods are soups, and the sixth is mashed potatoes. Not surprisingly, none of these foods met the 1998 MN/FDA 2001 Food Code cooling conditions. The next three rows of Table 1 are identified as "borderline"; they represent foods that had cooling rates just slightly faster than 0.23 but had cooling profiles that did not meet the Food Code requirements. Two of these samples are rice, and the third is deboned turkey. The rice samples missed the upper frame of the cooling profile slightly (∼10 min) but easily passed the lower frame (well under 4 h). The deboned turkey exceeded the upper frame by almost 1 h but passed the lower frame by more than 1 h. Most (8 of 9) of the foods in the "slow" or "borderline" rows of Table 1 had product depth greater than or equal to 7.6 cm (3 in.). The three other foods with product depth at or exceeding 7.6 cm (3 in.) were meat broth, steak and potato soup, and Toscana soup, and these foods had a fast cooling rate (>0.23) and met the Food Code cooling parameters. Both soups had assisted cooling, however, using an ice bath and/or ice wand. Most (18 of 21) of the foods observed in the study were properly ventilated to allow cooling. Three foods were not properly ventilated: vegetable beef barley soup was partially ventilated but had a product depth ≥7.6 cm (3 in.), cooled slower than 0.23, and did not meet the Food Code cooling parameters; noodles cooled faster than 0.23 but did not meet the Food Code cooling parameters; and chicken wings cooled faster than 0.23 and did meet the Food Code cooling parameters.

Atypical cooling curves results. Table 2 shows the mean cooling rates of foods with atypical cooling curves calculated from 10,000 Monte Carlo simulations and includes other important characteristics of the cooling process: container type, container depth, ventilation, and cooling method. Most (6 of 8) of the foods that were considered to have "atypical" cooling curves, as defined above in "Materials and Methods," failed to meet the Food Code cooling times, as indicated by "no" in the rightmost column of Table 2. Almost all (7 of 8) of these foods used a refrigeration method involving an ice bath and ice wand or both. One-quarter (2 of 8) of the foods with atypical cooling curves had average simulated cooling rates less than 0.23 ("slow" rows of Table 2), but neither met Food Code cooling parameters. Two of the three foods that had average simulated cooling rates of greater than 0.23, but less than 0.28 ("borderline" rows of Table 2), did not meet the Food

TABLE 2. *Cooling rate estimates for eight foods with atypical cooling profiles*

Food	Cooling rate (1/h)[a]	Speed[b]	Container	Refrigeration method	Ventilated?	Excess product depth >7.6 cm (3 in.)	Pass[c]
Garlic cream sauce	−0.045	Slow	Metal	Ice bath	Yes	Yes	No
Red sauce	−0.112	Slow	Plastic	Ice bath/walk-in cooler	No	Yes	No
Gumbo soup	−0.249	Borderline	Plastic	Ice bath/walk-in cooler	Yes	Yes	No
Chicken wild rice soup	−0.261	Borderline	Metal	Walk-in cooler	Yes	No	No
Chicken wild rice soup	−0.267	Borderline	Plastic	Ice bath/ice wand/walk-in	Yes	Yes	Yes
Alfredo sauce	−0.285	Fast	Plastic	Ice bath/walk-in cooler	Yes	Yes	No
Red pepper bisque	−0.298	Fast	Plastic	Ice wand/walk-in cooler	Yes	Yes	No
Refried beans	−1.101	Fast	Metal	Ice bath/walk-in cooler	Yes	No	Yes

[a] Rates are the mean of 10,000 Monte Carlo simulations where single points were picked from upper and lower parts of the cooling curve and used to estimate cooling rate.
[b] The speed column identifies foods that cooled slower than the linearized cooling rate of 0.23 proposed by Schaffner et al. *(26),* foods that are borderline, or foods that cooled faster than the linearized cooling rate of 0.23.
[c] Pass indicates whether the food met the 2017 MN State Food Code (or FDA 2001 Model Food Code) cooling rates of ≤2 h between 60.0 and 21.1°C (140 and 70°F), and ≤4 h between 21.0 and 5°C (70 and 41°F).

Code cooling parameters. Only one food (red sauce) was not properly ventilated. Two foods (chicken wild rice soup and refried beans) had a product depth <7.6 cm (3 in.). The soup had a borderline simulated average cooling rate (0.26) but did not meet the Food Code cooling parameter, whereas the beans had an acceptable simulated average cooling rate and did meet the Food Code cooling rates.

Table 3 shows the summary statistics from the results of the Monte Carlo simulations used to create cooling rates from foods that had nontypical cooling curves. The table is sorted by the percentage of time that the simulated rate (based on two randomly selected times from the upper and lower portions of the cooling curve) was faster or slower than the rate of 0.23. Note that the only two products that met the Food Code cooling rates also had simulation estimated cooling rates that cooled faster than 0.23 for the greatest percentage of simulations. Other summary statistics were less useful in predicting agreement with Food Code cooling parameters. The mean, median, mode, and 5th and 95th percentiles for the refried beans simulations all show a faster cooling rate than for all the other foods, and the refried beans data set met the Food Code cooling recommendation. Most of these summary statistics were not able to distinguish the chicken wild rice soup data set, which also met the Food Code cooling recommendation. In three or four cases, the mean, mode, or 5th percentile for foods that did not meet the Food Code cooling recommendations showed a faster rate than for chicken wild rice soup, and in one case the mode showed a faster rate. The 95th percentile of simulated cooling rates for one chicken wild rice soup data set and the refried beans data set were greater than all the other food data sets.

Table 3 indicates that the data sets from foods that showed an atypical cooling profile can result in a very wide range of simulated rates, which shows the difficulties in applying a two-point extrapolation to estimate cooling rates for atypical cooling profiles. The nuances of these difficulties can be further elucidated by examining the

TABLE 3. *Summary statistics of 10,000 Monte Carlo simulations done on foods with atypical cooling profiles*

	Cooling rate (1/h)							
	Summary statistics			Upper and lower percentiles		Simulation predicted cooling rate relative to 0.23 (1/h)[a]		
Food	Mean	Median	Mode	5th	95th	% slower	% faster	Pass[b]
Garlic cream sauce	−0.045	−0.120	0.000	−0.166	0.088	99	1	No
Red sauce	−0.112	−0.096	−0.125	−0.205	−0.066	94	6	No
Gumbo soup	−0.249	−0.224	−0.348	−0.417	−0.161	52	48	No
Chicken wild rice soup	−0.267	−0.246	−0.270	−0.481	−0.146	43	57	No
Red pepper bisque	−0.298	−0.272	−0.426	−0.514	−0.166	28	72	No
Alfredo sauce	−0.285	−0.250	−0.226	−0.464	−0.184	24	76	No
Chicken wild rice soup	−0.261	−0.251	−0.186	−0.325	−0.192	18	82	Yes
Refried beans	−1.101	−0.932	−1.522	−2.375	−0.574	0	100	Yes

[a] Fractions slower than and faster than the target represent the percentage of rates created that were slower or faster than the recommended cooling rate of 0.23.
[b] Pass indicates whether the food met the 2017 MN State Food Code (or FDA 2001 Model Food Code) cooling rates of ≤2 h between 60.0 and 21.1°C (140 and 70°F), and ≤4 h between 21.0 and 5°C (70 and 41°F).

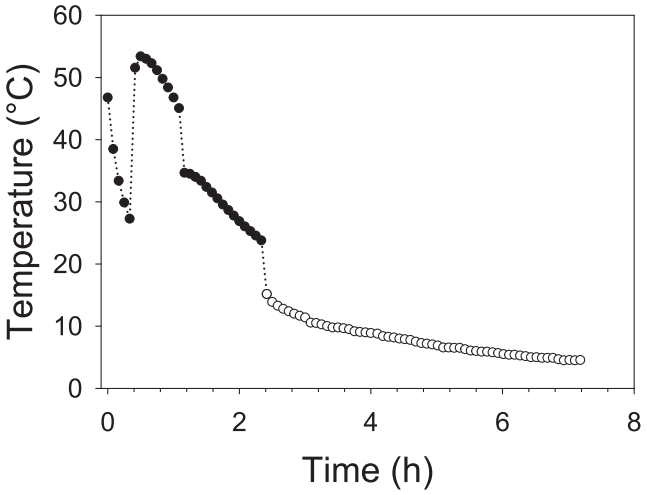

FIGURE 1. *Atypical cooling profile for Alfredo sauce. Solid circles, times and temperatures associated with product temperatures between 60.0 and 21.1°C (140 and 70°F). Open circles, times and temperatures associated with product temperatures between 21.0 and 4.4°C (70 and 41°F).*

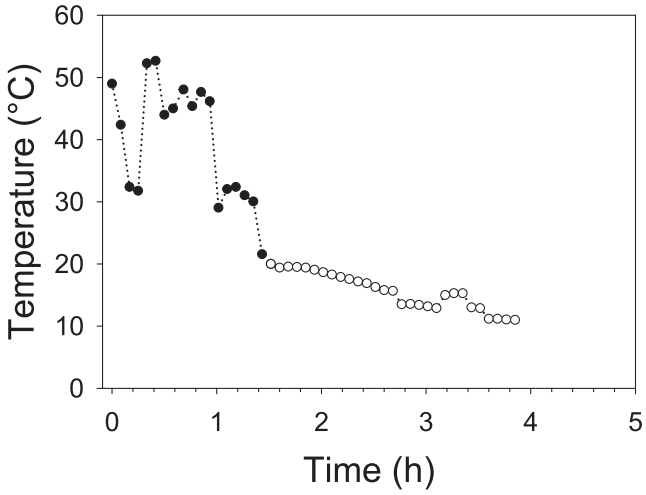

FIGURE 2. *Atypical cooling profile for chicken wild rice soup. Solid circles, times and temperatures associated with product temperatures between 60.0 and 21.1°C (140 and 70°F). Open circles, times and temperatures associated with product temperatures between 21.0 and 4.4°C (70 and 41°F).*

actual cooling profiles, which are shown in Figures 1 and 2 as representative of foods with "unusual" cooling profiles.

In Figure 1, which illustrates the atypical cooling profile for Alfredo sauce, the solid symbols show times and temperatures associated with product temperatures between 60.0 and 21.1°C (140 and 70°F), and the open symbols show times and temperatures associated with product temperatures between 21.0 and 4.4°C (70 and 41°F). When the product was removed from the stove, it was placed in an ice water bath, which produced the immediate sharp temperature drop over the first 20 min. At this point, the product was stirred; this raised the temperature being monitored by the probe, producing the sharp spike in temperature back above 50°C. The product remained in the ice bath for approximately 2 h until it was moved to a walk-in cooler set at 2.8°C (37°F). It is not known what produced the temperature shift at approximately 1 h, but it could have been additional stirring of the product that was not recorded. This particular product was stored in a plastic container, and although it was ventilated, the product depth in the container exceeded 7.6 cm (3 in.).

In Figure 2, which illustrates the atypical cooling profile for chicken wild rice soup, the solid symbols show times and temperatures associated with product temperatures between 60.0 and 21.1°C (140 and 70°F), and the open symbols show times and temperatures associated with product temperatures between 21.0 and 4.4°C (70 and 41°F). This product was in a plastic container with a product depth exceeding 7.6 cm (3 in.). Temperature monitoring began when the product was placed into an ice bath. The product was allowed to cool for approximately 15 min before it was stirred, which raised the temperature being measured by the thermocouple. The product temperature dropped slowly for the remainder of the hour until an ice wand was used to stir the product. The product was removed from the ice bath and transferred to a walk-in cooler set at 36°F (2.2°C). At approximately 1.5 h, the product was stirred again with a new ice wand, causing another temperature drop, after which the product remained in the walk-in cooler, where it was stirred again at approximately 3 h 15 min, causing another small temperature rise.

Figure 3 shows the distribution of simulated cooling rates from the Alfredo sauce simulation. The *x* axis shows the cooling rate with a vertical black line at –0.23, the cooling rate that is equivalent to the FDA Model Food Code. The *y* axis of the top panel represents iterations of the simulation that predict a cooling rate; the height of the gray bar represents the number of iterations for a given rate. Cooling rates to the right of the black line represent rates slower than permitted, whereas cooling rates to the left represent rates faster than permitted. There are a small number of iterations with relatively fast cooling rates, which are not visible in the top panel of Figure 3. These are visible once the *y* axis is transformed to a log scale, which is shown in the bottom panel of Figure 3. This figure shows that most of the simulations predicted cooling rates that were faster than what is required by code. These results indicate that an inspector using a two-point method on a cooling profile, represented by the Alfredo sauce, would, most of the time, conclude that the product was being cooled at a rate permitted by the code.

Figure 4 shows the distribution of simulated cooling rates from the chicken wild rice soup simulation. The axes and layout are all identical to those from Figure 3. Figure 4 shows a similar pattern to Figure 3, although there is less variability in cooling rates, while the overall distribution is less highly peaked. More of the chicken wild rice soup simulations result in cooling rates that are slower than that required by the code (versus Alfredo sauce), but most of the simulations also predict faster cooling rates than required. As with Figure 3, Figure 4 also shows that if an inspector used the two-point method on a cooling profile represented by the chicken wild rice soup, the inspector would generally

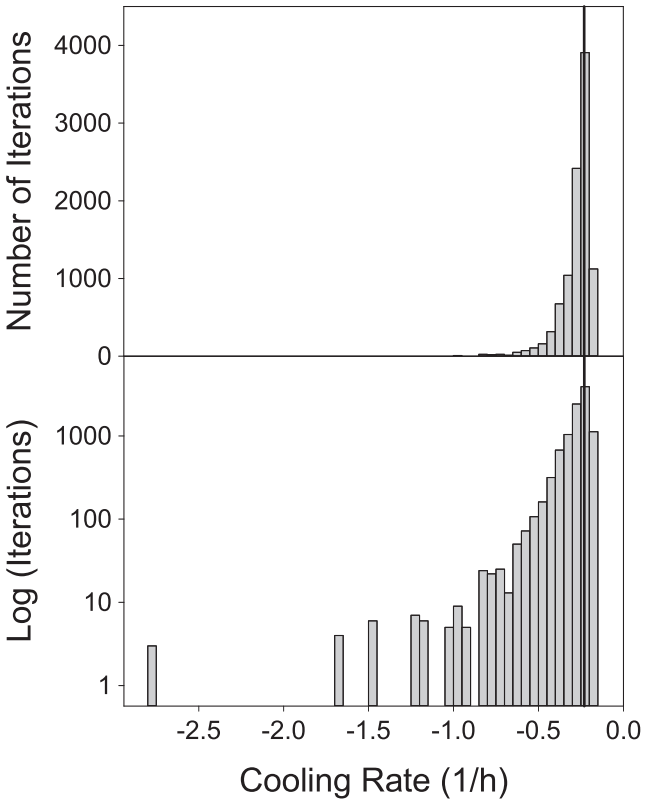

FIGURE 3. *Distribution of simulated cooling rates from the Alfredo sauce simulation. Top panel, distributions of iterations; bottom panel, log (iterations). Vertical black line, –0.23 (1/h), is equivalent to the FDA Model Food Code cooling rate. Cooling rates to the right of the black line are slower than permitted, whereas cooling rates to the left are faster than permitted.*

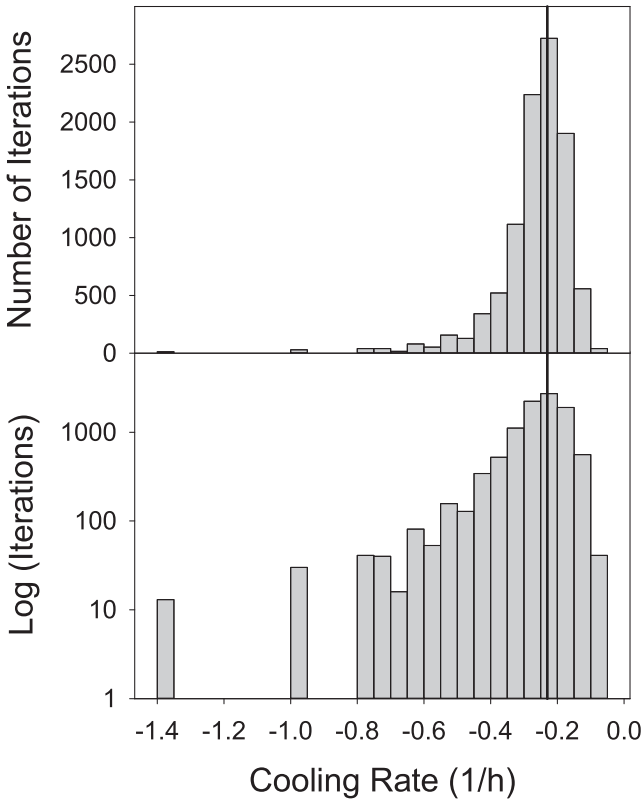

FIGURE 4. *Distribution of simulated cooling rates from the chicken wild rice soup simulation. Top panel, distributions of iterations; bottom panel, log (iterations). Vertical black line, –0.23 (1/h), is equivalent to the FDA Model Food Code cooling rate. Cooling rates to the right of the black line are slower than permitted, whereas cooling rates to the left are faster than permitted.*

conclude that product was being cooled at a rate permitted by the code.

DISCUSSION

Improperly cooled foods are a major source of foodborne illness. However, it is very difficult to monitor cooling rates of restaurant foods because they occur over ~6 h *(14),* whereas inspectors are typically only present in an establishment for 1 to 2 h. The FDA assessed restaurant food cooling processes in their Retail Risk Factor Study but encountered difficulties because cooling was observed in few retail establishments due to the limited amount of time collectors were able to spend in establishments *(29)*. Schaffner et al. *(26)* proposed use of a pair of points from the cooling curve to identify fast and slow cooling foods through a mathematical model and correlation of those model estimates with best and worst practices observed in restaurants. Schaffner et al. *(26)* could not validate their modeling approach because they did not have full cooling profiles. Our current study sought to validate the two-point approach, using full cooling curves as well as observations regarding retail establishment practices.

The data in this study showed that approximately one-third of foods that had "typical" cooling curves had rates that were unacceptable based on Food Code guidelines, which is concerning because improper cooling of foods can cause foodborne illness. In the remaining cases, the cooling rates created for foods with "typical" cooling curves were in agreement with the 1998 MN Food Code guidelines, which state that foods should be cooled to 21.1°C (70°F) in ≤2 h and then to 5°C (41°F) in an additional ≤4 h. Many of these observations showed an estimated cooling rate that was only slightly slower than the Food Code guideline, which suggests that many restaurants may need to make only small changes to their cooling practices to comply with the Food Code guideline. There were few instances of false positives, in which the cooling rate was faster than the recommended rate but failed based on the guidelines recommended by the Food Code. In one instance, the food (noodles) was only 5 min over the 4-h limit to cool from 70 to 41°F (21.1 to 4.4°C), which caused the failure, and in another instance, the food (French onion soup) had a very rapid initial cooling period, cooling from 139 to 70°F (59.4 to 21.1°C) in 1 h 25 min, followed by a very slow period of cooling of 70 to 41°F (21.1 to 5°C) in 4 h 40 min. This soup contained a large amount of butter, which formed a fat layer on top during the cooling process and may have aided in insulating the food and preventing quick cooling. It is concerning to see that the cooling rates can be skewed this heavily by rapid initial cooling stages; however, it seems to be an unusual case, because most foods that have an initial

rapid cooling phase do not tend to have such a slow secondary cooling phase.

The data show that foods with "unusual" cooling profiles are generally similar to foods that have "typical" cooling profiles, for which the two-point model was, in general, adequately able to determine whether the food would fail based on Food Code guidelines. The mean, median, and mode of the simulations were generally in agreement for all foods, with the mode being much faster or slower than the mean and median in some cases. The results that have the strongest relation to whether or not the food passed the Food Code guidelines is the percentage of simulations that created models faster or slower than the recommended rate: the two foods that passed according to the Food Code guidelines also had the lowest percentage of simulated rates that were slower than the recommended rate. This analysis shows that creating cooling rates using two points from the entire cooling profile should generally create representative cooling rates. The upper and lower percentiles do, however, show that caution needs to be taken in situations where the temperature profile of the food rapidly changes, such as if the food is stirred or rapidly cooled.

The data from Schaffner et al. *(26)* showed that following the Food Code guidelines (storing foods at shallow depths, ventilating foods, and monitoring cooling) facilitated faster estimated cooling rates. Our data support that the container depth showed a strong correlation to the cooling rate, finding that containers that were $\geq$7.6 cm (3 in.) were more likely to have cooling rates slower than the equivalent FDA Model Food Code cooling rate. Our results show little trend in the effect of the container type (metal or plastic) and cooling method. The effect that the ventilation of the foods has is inconclusive because a very limited number of foods were unventilated during cooling. The effects that observed environmental factors (e.g., refrigerator temperature, use of ice wand or baths) have on the cooling rates are also in agreement with Schaffner et al. *(26),* and we also recommend that managers monitor these environmental factors as easy ways to improve cooling rates. Some experimental data have also confirmed these observations in the cooling of brown rice *(2)*. These researchers tested various combinations of container depth, cooling method, and container ventilation to determine the effect on cooling rate of brown rice based on the parameters set in the FDA Model Food Code. Their results showed that container depth and ventilation significantly impacted the time that it took for the container to cool from 57 to 5°C (135 to 40°F), consistent with the results from our study. Although some of the conditions they observed did not meet FDA Model Food Code cooling requirements, no significant increases in *B. cereus* concentration were noted *(2)*.

Some other environmental factors that should be considered include the outside ambient temperature, which has been shown to make the cooling of foods more difficult due to the strain put on refrigeration units *(12)*. Research has shown that repeated opening and closing of refrigeration units, coupled with increased ambient temperature, could lead to increased occurrences of cold-holding violations and, potentially, breakdowns of refrigeration units *(12)*. Without consistent monitoring *(4, 16),* there could be a rise in cooling equipment temperature, which could lead to inadequate cooling rates. These studies (as well as another currently in review) also showed that the results of food cooling monitoring were often not recorded anywhere, and that only about 60% of restaurants had verified that their cooling processes adequately cooled the foods in the proper amount of time *(4, 16, 17)*. The methods used in our research may potentially prove to be a simple way to verify that cooling has been completed in an appropriate amount of time, without the need for constant temperature monitoring.

C. perfringens is the pathogen that is most closely associated with foodborne illnesses related to the cooling of foods *(1, 21)*. *C. perfringens* spores can survive the cooking process, and during inadequate cooling, the spores can begin to germinate and grow to levels that could cause illness *(18)*. *C. perfringens* is typically associated with the improper cooling of large cuts of meat; however, predictive models have been created for the growth of *C. perfringens* in many different substrates, such as rice, refried beans, and soups *(7, 9, 22, 27)*. Models have shown that *C. perfringens* can grow at low temperatures; however, growth rates decrease and lag times increase, meaning the outgrowth of spores would take significantly longer at lower temperatures *(10)*. Because *C. perfringens* cells need to grow to very high concentrations, foods held at temperatures $<$70°F (21.1°C) would most likely be much less of a health risk than foods held above this temperature for long periods of time; this shows the importance of proper temperature control, especially at the initial cooling stages. Illness due to *B. cereus* is also associated with the improper cooling of foods, because spores can survive the cooling process and, subsequently, germinate once the food has cooled *(19)*. *B. cereus* can grow in a wide range of foods but is typically associated with the improper storage of cooked rice and pastas *(20, 24)*. Predictions from growth models for *C. perfringens* and *B. cereus* could be made for the cooling profiles of the foods in this study to further characterize risk from these pathogens during cooling.

This research has confirmed the previous research from Schaffner et al. *(26)* that showed that simple linear regression models could be created using two temperature points taken from the cooling profile of restaurant foods. Our research elaborated on these models by using similar methods with additional data points, finding very similar results. Caution should be taken for foods that have been recently stirred or placed into a different cooling container, because sudden changes in temperature can cause cooling profiles to not give accurate results, as seen with the "atypical" curves. Our results were also in agreement with findings that simple methods such as reducing container depth size and adequately ventilating foods can easily help properly cool foods after cooking. The methods laid out in this paper and previous works may allow for a simple way for inspectors and operators to verify that cooling methods are adequate to conform to FDA Model Food Code guidelines without the need for lengthy periods of monitoring.

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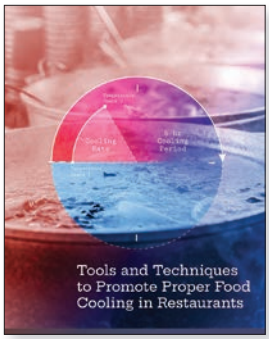
GUEST COMMENTARY



Tools and Techniques to Promote Proper Food Cooling in Restaurants

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Abstract **Slow cooling of hot foods is a common pathogen proliferation factor contributing to restaurant-related outbreaks. The Food and Drug Administration (FDA) model *Food Code* provides guidelines on the time and temperatures needed for proper cooling and recommends several methods to facilitate rapid food cooling. Restaurants continue to struggle with proper cooling even given these guidelines (Hedeen & Smith, 2020). Research summarized in this guest commentary indicates that portioning foods into containers with a depth of <3 in. and ventilating the containers during the cooling process promote rapid cooling. Restaurant operators and health department inspectors could use these cooling methods to maximize cooling efforts. Additionally, a simple method (using a mathematical equation) could help restaurant operators and inspectors to estimate the cooling rates of foods. This simple method uses only two food temperatures taken at any two points in the cooling process (using the equation [Log(T_1 - T_{df}) - Log(T_2 - T_{df})]/δt) to estimate whether the food is expected to meet FDA cooling guidelines. This method allows operators and inspectors to identify foods unlikely to meet FDA guidelines and take corrective actions on those foods without having to monitor food temperatures for the entire cooling process, which typically takes 6 hr. More research is underway to further refine aspects of this method.**

Introduction

Improper cooling of hot food by restaurants is a significant cause of foodborne illness outbreaks (Brown et al., 2012). Cooling hot foods too slowly is one of the most common pathogen proliferation factors contributing to restaurant-related outbreaks (Gould et al., 2013). Of the 251 outbreaks that occurred during 2014–2016, 10% had improper cooling as a contributing factor to the outbreak (Lipcsei et al., 2019). Hot foods should be cooled rapidly to minimize pathogen proliferation and subsequent foodborne illness risk.

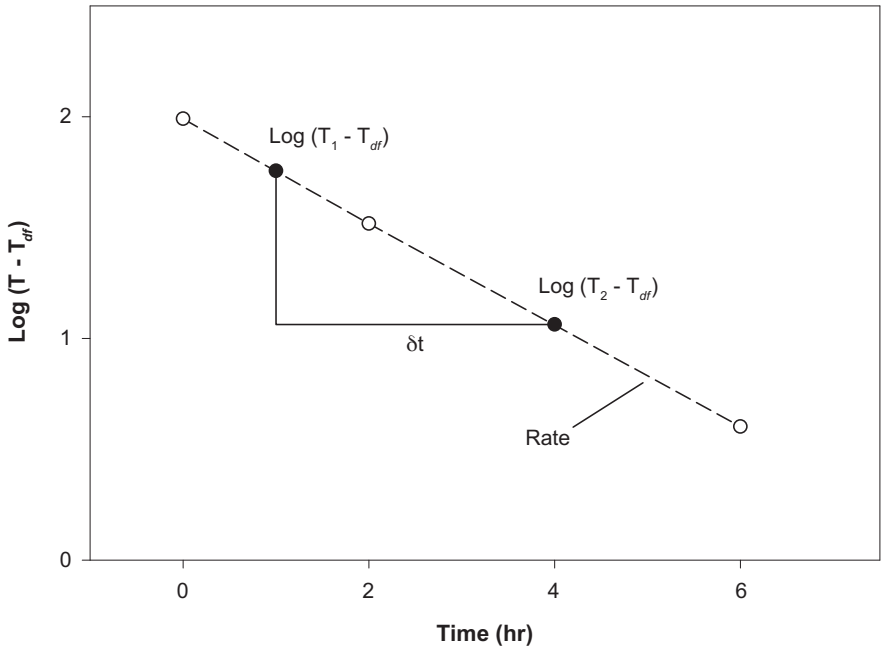
The Food and Drug Administration (FDA) model *Food Code* (Section 3-501.14) provides guidelines for retail and foodservice establishments to cool foods classified as needing time and temperature control for safety. These guidelines state that foods must be cooled from 135 °F (57 °C) to 70 °F (21 °C) within 2 hr, and from 135 °F (57 °C) to 41 °F (5 °C) within a total of 6 hr or less (U.S. Department of Health and Human Services, 2017). To help reduce foodborne illness risk, the *Food Code* also recommends several methods to promote rapid food cooling. These methods include separating food into smaller portions; stirring food in a container placed in an ice water bath; adding ice as an ingredient; and placing food in shallow pans, in containers that promote heat transfer, and in rapid cooling equipment. Even with these guidelines, restaurants continue to struggle with proper cooling (Hedeen & Smith, 2020). And as a model code for regulating retail and food service establishments, the *Food Code* does not specify how to apply cooling methods in varying situations or whether some methods are better than others.

The *Food Code* recommends that retail food establishments verify that their cooling practices are effective as well as monitor and record food temperatures during the cooling process, but research suggests that many establishments do not always engage in these practices (Brown et al., 2012; Hedeen & Smith, 2020). A study by FDA (2018) found that cooling practices did not meet FDA guidelines at least once in 72% of 273 full-service restaurants where cooling was observed.

Cooling is difficult for operators and inspectors to assess because of the time required to adequately monitor the cooling process. Restaurant operators work in a dynamic and busy environment, and fre-

FIGURE **1**

Equation to Calculate the Cooling Rate of a Food



quent monitoring of temperatures is not always feasible. Multiple factors influence an operator's ability to monitor food temperatures to ensure proper cooling. These factors can include insufficient staffing, the time of day foods are cooled (e.g., early or late shifts), and how busy a restaurant is throughout the day (Green & Selman, 2005). Inspectors are typically in an establishment for fewer than the 6 hr needed to document proper cooling. Other options for assessing proper cooling include discussions with the restaurant manager, review of temperature logs to determine cooling start time, and subsequent comparison with food time and temperatures taken during the inspection. Use of thermocouples and data loggers for later retrieval or returning later in person to continue the inspection and check temperatures are other options, although inspectors cannot always conduct multiple visits to an establishment during a day. Focusing on specific cooling methods, rather than the full cooling process, might be another way to identify cooling issues during routine inspections.

Identification of practices that best promote proper food cooling can support operators and inspectors in their efforts to cool food properly. Research conducted by the Centers for Disease Control and Prevention's Environmental Health Specialists Network (EHS-Net), Rutgers University, and the Minnesota Department of Health has identified two common themes described next regarding cooling methods that ensure proper cooling (Hedeen & Smith, 2020; Igo et al., 2021; Schaffner et al., 2015).

Shallow Depth and Ventilation

Schaffner et al. (2015) examined 596 food items being cooled in refrigerators in 410 restaurants. They measured the temperature of these foods at two time points, approximately 80 min apart, and used modeling to determine the cooling rates and compliance with *Food Code* guidelines. Foods not actively monitored by food workers were more than twice as likely to cool more slowly than recommended in the *Food Code*. Foods stored at a container depth >3 in. were twice as likely to cool more slowly than specified in the *Food Code*. Moreover, unventilated foods were almost twice as likely to cool more slowly than specified in the *Food Code*.

Hedeen and Smith (2020) used data loggers to collect time and temperature data points at 5-min intervals for 34 cooling food items. They plotted the data points to form a cooling curve for each food item. They then assessed the cooling curves of the foods and found that those cooled in containers with a depth <3 in. were more likely to meet the first cooling parameter (i.e., 140 ºF to 70 ºF within 2 hr) than those cooled in containers with a depth ≥3 in. (p = .035). As almost all the food items in this study were ventilated, the relationship between ventilation and cooling rates was not evaluated. Using these same cooling curves, Igo et al. (2021) also found that food depth has a strong influence on cooling and verified that containers with a food depth ≥3 in. were more likely to have cooling rates slower than the cooling rate specified in the *Food Code*.

Using containers with a depth of <3 in. and ventilating foods during refrigerated cooling (as recommended in Section 3-501.15 of the *Food Code*) are simple ways for operators to maximize cooling efforts. They also serve as indicators for inspectors to assess cooling at restaurants. The extra space needed to use shallow pans and ventilation is a potential drawback; to address this drawback, restaurants could small-batch recipes or use speed racks in walk-in coolers.

Two-Point Temperature Monitoring

Schaffner et al. (2015) identified a simple two-point method to measure cooling rates in restaurants and identify cooling issues. This method was developed using on-site observations of cooling food times and temperatures. Operators and inspectors can use this method to quickly determine if the cooling method used is expected to cool foods properly before the entire 6-hr period has elapsed.

The equation to calculate the cooling rate of a food is $[\text{Log}(T_1 - T_{df}) - \text{Log}(T_2 - T_{df})]/\delta t$, where T_1 and T_2 are any two temperatures measured during the cooling process, T_{df} is the driving force temperature (i.e., the temperature of the cooling environment), and δt is the time between the two temperature measurements (Figure 1). When the temperature and time values from the *Food Code* guidelines for food cooling results are plugged into this equation, and a driving force of 37 °F is assumed, this produces the best fit (i.e., highest R^2 value). The slope of this best-fit line equates to a cooling rate of 0.23 when time

is measured in hours (or 0.0039 when time is measured in minutes). Thus, a food with a cooling rate faster or equal to 0.23 would meet *Food Code* recommendations, but a rate slower than 0.23 would not (Igo et al., 2021; Schaffner et al., 2015). Under some circumstances, the driving force will not be constant, which can influence the cooling rate estimate.

Igo et al. (2021) used cooling curves for 29 different foods that were collected in 25 different restaurants to verify the two-point rate calculation method. Cooling curves were divided into two categories: typical and atypical. Curves were considered atypical when they had many dips and peaks, which are typically caused by stirring the food or changing the cooling method. Most cooling curves (21 out of 29) were considered typical (i.e., log linear rate changes with time). Atypical cooling curves (8 of 29) had non-log linear rate changes with time resulting from stirring or other factors.

Almost all typical cooling curves identified had highly predictable cooling rates (Igo et al., 2021). Among 9 foods with typical cooling curves that did not meet the cooling times recommended in the *Food Code*, the two-point model identified 6 as having slow cooling rates and 3 as having marginal cooling rates; among 12 foods identified by the two-point model as having acceptable cooling rates, 10 met the cooling times recommended in the *Food Code*. Among 8 foods that were considered to have atypical cooling curves, 6 failed to meet the cooling times recommended in the *Food Code*. These findings indicate that for most foods that are cooling at a steady rate (e.g., not stirred, not moved to a different environment), taking only two temperature measurements at any point in the cooling process should reliably indicate whether the food is going to meet the cooling guidelines in the *Food Code*.

During routine inspections, this two-point method could help inspectors identify cooling issues. Specifically, when inspectors see a food item cooling, they could note an initial time and temperature of the food. Then they could take a second temperature reading, preferably at the end of their inspection to allow for the greatest elapsed time between the two temperature readings. The simple equation described previously would enable inspectors to estimate the cooling rate. They could use the calculated rate to determine whether the cooling rate of the food is predicted to follow the recommendations in the *Food Code*. Inspectors could use this tool to educate restaurant operators. If the equation predicts that a food will not cool within the guidelines of the *Food Code*, the inspector could discuss alternative cooling methods with operators and develop a plan for properly cooling the food. Operators could also use this method to help verify whether their cooling process is effective or to evaluate the effect of changes in their process.

Additional research is needed to potentially determine ideal times during the cooling process when inspectors should take the two temperature readings (i.e., between 135 ºF and 70 ºF and then again after the food is below 70 ºF). Differences in time between the two temperature measurements also might affect the outcome (e.g., are measurements 60 min apart better than measurements 15 min apart?).

Foodborne disease outbreaks resulting from improper cooling continue to occur (Lipcsei et al., 2019). Proper cooling is sometimes difficult for restaurants to accomplish and for inspectors to verify. Although the *Food Code* provides valuable information on suggested cooling methods, beyond specifying to monitor temperatures, it does not provide guidance on determining how cooling is to take place. Logging continuous time and temperature data is an ideal way to determine if foods are cooled correctly, but this process is not always practical for operators or inspectors. Portioning foods into containers with a depth <3 in. and ventilating them during the cooling process are best practices that can promote rapid cooling and that restaurants can easily apply. As described in this study, calculating cooling rates to determine if foods meet FDA *Food Code* recommendations is one way that operators and inspectors can determine if a cooling method can be expected to work without having to monitor a food for the entire 6-hr cooling process. More research is underway to further refine aspects of this method.

Disclaimer: The findings and conclusions in this guest commentary are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention or the Agency for Toxic Substances and Disease Registry.

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Did You Know?

NEHA is a partner association of the Retail Food Safety Regulatory Association Collaborative, a group of agencies and associations working to reduce the incidence of foodborne illness at the retail level. The Collaborative has posted a variety of resources including a toolkit to help jurisdictions adopt the latest editions of the Food and Drug Administration *Food Code*, an assessment of the impact of active managerial control incentive programs, an interactive map of *Food Code* adoption by state, and more. Check it out at www.retailfoodsafetycollaborative.org.

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Operational Antecedents Associated with *Clostridium perfringens* Outbreaks in Retail Food Establishments, United States, 2015–2018

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Abstract

Clostridium perfringens is a common foodborne pathogen, frequently associated with improper cooking, and cooling or reheating of animal products. The U.S. Food and Drug Administration Food Code outlines proper food preparation practices to prevent foodborne outbreaks; however, retail food establishments continue to have *C. perfringens* outbreaks. We qualitatively analyzed responses to two open-ended questions from the National Environmental Assessment Reporting System (NEARS) to understand patterns of unique circumstances in the retail food establishment that precede a *C. perfringens* outbreak. We identified three environmental antecedents, with three subcategories, to create nine operational antecedents to help explain why a *C. perfringens* outbreak occurred. Those antecedents included factors related to (1) people (a lack of adherence to food safety procedures, a lack of food safety culture, and no active managerial control), (2) processes (increased demand, a process change during food preparation, and new operations), and (3) equipment (not enough equipment, malfunctioning cold-holding equipment, and holding equipment not used as intended). We recommend that food establishments support food safety training and certification programs and adhere to a food safety management plan to reduce errors made by people and processes. Retail food establishments should conduct routine maintenance on equipment and use only properly working equipment for temperature control. They also should train workers on the purpose, use, and functionality of the equipment.

Keywords: foodborne outbreak, *Clostridium perfringens*, retail food, environmental health

Introduction

Clostridium perfringens, the third-most common foodborne pathogen, causes around 1 million foodborne illnesses each year in the United States (Scallan *et al.*, 2011). *C. perfringens* is a bacterium found on raw animal products and produces spores that form a coating to help it survive cooking. When food is kept at unsafe temperatures during cooking, cooling, and holding processes, *C. perfringens* can proliferate (Smith-Simpson and Schaffner, 2005). Proper reheating can kill *C. perfringens* that survived the original cooking process or multiplied during improper cooling (Taormina and Dorsa, 2004).

Data obtained from investigations of *C. perfringens* outbreaks provide important insights into the prevention of *C. perfringens* illness; these data can identify food preparation practices and circumstances that lead to illness. For example, the Centers for Disease Control and Prevention's (CDC) outbreak investigation data indicate that *C. perfringens* outbreaks are commonly associated with foods prepared in large quantities (CDC, 2018).

The U.S. Food and Drug Administration (FDA) Food Code contains food safety guidelines intended to reduce foodborne illness risk from pathogens, such as *C. perfringens,* in retail food establishments. The Food Code lists specific time and temperature ranges for proper cooking, holding, cooling, and

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reheating (FDA, 2017b). Despite these guidelines and our increased understanding of the foods and practices associated with *C. perfringens* outbreaks, illnesses and outbreaks continue to occur (Hedeen and Smith, 2020).

Understanding environmental antecedents, the root causes, to *C. perfringens* outbreaks can help us prevent future outbreaks. Environmental antecedents are factors in the environment that ultimately lead to pathogen contamination, proliferation, or survival to cause an outbreak (CDC, 2015).

We examined data from the National Environmental Assessment Reporting System (NEARS), a voluntary reporting system that some state and local environmental health regulatory programs use to report data to the CDC from their investigations of retail food establishment outbreaks (CDC, 2019). NEARS data from *C. perfringens* outbreak investigations describe the environment in which the outbreaks occurred and can identify outbreak antecedents (Lipcsei *et al.*, 2019). This study analyzed these data to better understand environmental antecedents of *C. perfringens* outbreaks. These data were used to identify operational antecedents of outbreaks, or the actions or factors that occur during food operations that explain the survival or proliferation of pathogens in food.

Methods

The NCEH/ATSDR Human Subjects Contact has reviewed this data collection system and determined that it is not research and does not require CDC Institutional Review Board (IRB) review. Ten state and local health departments reported 41 confirmed or suspected *C. perfringens* outbreaks that occurred from 2015 to 2018 to NEARS. We excluded seven outbreaks that were missing 75% or more NEARS data. The final data set consisted of 34 single-setting retail food establishment outbreaks that occurred in Connecticut, Georgia, Iowa, Minnesota, New York, Rhode Island, South Carolina, Tennessee, Washington, and Wisconsin.

During their investigations, environmental health staff interview outbreak establishment managers about establishment characteristics (e.g., food safety policies and practices that might have contributed to the outbreak). They also observe worker food preparation, especially of items suspected to be associated with the outbreak. Afterward, investigators report selected information and observations from their investigations to CDC through the NEARS web-based reporting system (Brown *et al.*, 2017; Lipcsei *et al.*, 2019).

Our analysis focused on qualitative data collected from two open-ended questions investigators answered about the outbreak establishments' food operations after they completed their establishment observations:

(1) Were there any differences to the physical facility, food handling practices you observed on your initial visit, or other circumstances that were different at the time of exposure?
(2) During the likely time the ingredient/food was prepared, were any events noted that appeared to be different from the ordinary operating circumstances or procedures as described by managers and/or workers?

The first question was designed to identify differences or unusual circumstances in establishment operations during the time customers were exposed to *C. perfringens*. If the investigation implicated a food item associated with the outbreak, investigators also answered the second question. These questions were asked because research suggests that unusual circumstances frequently precede outbreaks (World Health Organization, 2008). Understanding these circumstances can enhance our understanding of outbreak antecedents.

Analysis

We first calculated descriptive statistics on several outbreak and establishment characteristics collected through manager interviews and establishment observations to describe our sample (Table 1). We then conducted a qualitative analysis of the data from the two open-ended questions about differences in establishment operations at the time of *C. perfringens* exposure. We used the grounded theory

Table 1. Outbreak and Establishment Characteristics of *Clostridium perfringens* Outbreaks, United States, 2015–2018 ($N=34$)

Characteristic	n *(%)*
Agent ($N=34$)[a]	
Suspected	20 (58.8)
Confirmed	14 (41.2)
Primary contributing factor[b,c] ($n=32$)	
Contamination	2 (6.2)
Proliferation	29 (90.6)
Survival	1 (3.2)
When the primary contributing factor occurred[b,c] ($n=32$)	
Before food vehicle entering establishment	1 (3.2)
While food vehicle was at the establishment	26 (81.2)
After food vehicle left the establishment	5 (15.6)
Establishment type[d] ($N=34$)	
Complex	34 (100.0)
Cook–Serve	0 (0.0)
Preparation–Serve	0 (0.0)
Facility type[c] ($N=34$)	
Caterer	4 (11.8)
Mobile food unit	2 (5.9)
Restaurant	28 (82.3)
Ownership type[d] ($N=25$)	
Independent	21 (84.0)
Chain	4 (16.0)
Meals per day[d] ($N=24$)	
≤100	11 (45.8)
>100	13 (54.2)
Menu type[c] ($N=34$)	
American	11 (32.3)
Latin	14 (41.2)
Other	9 (26.5)
Critical violations on last inspection[e] ($N=34$)	
0–1	19 (55.9)
2–9	15 (44.1)

[a]Obtained from investigators' epidemiology and laboratory counterparts.
[b]Contributing factors are food preparation practices that lead to pathogens contaminating, proliferating, and surviving in food.
[c]Environmental health investigator determination.
[d]Data obtained from the investigator's interview with the establishment manager.
[e]Critical violations are those more likely to contribute to the contamination of food or the proliferation or survival of the pathogens if not corrected. These are determined on a routine inspection and unrelated to the foodborne outbreak.

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approach, in which we identified patterns and groupings in the qualitative data using inductive reasoning (i.e., from the ''ground up'') (Corbin and Strauss, 1990). The food system environmental antecedent conceptual model was used to categorize the data; researchers have theorized that five main variables of environmental antecedents influence food safety in establishments (Selman and Guzewich, 2014):

(1) People (characteristics and attitudes of people working in the establishments)
(2) Processes (characteristics of the processes used to prepare food and food preparation complexity)
(3) Economics (costs and profit margins)
(4) Equipment (the physical layout and equipment of establishments)
(5) Food (the inherent qualities of food prepared in establishments)

Two independent coders reviewed the raw text responses to the two open-ended questions with other NEARS variables to obtain a comprehensive view of the outbreak; they identified environmental antecedent themes based on the above model. They then again reviewed the raw text responses and further grouped the environmental antecedents into subcategories for each theme, or operational antecedents, applying theoretical comparison coding. For each review of the data, the coders independently identified their antecedents and then compared them. If the coders differed in their groupings, they each reviewed the data again, repeating this process until they reached a consensus. The final framework consisted of three environmental antecedents and nine operational antecedents (Fig. 1).

Results

Outbreak and establishment characteristics

In 41.2% of the outbreaks, the pathogen was confirmed in one or more clinical or environmental samples (Table 1). The primary outbreak contributing factor was pathogen proliferation (90.6%) and occurred while the food was at the establishment (i.e., during food preparation) (81.2%). Most of the outbreak establishments were restaurants (82.3%) and independently owned (84.0%). The majority served more than 100 meals per day on average (54.2%) and had a menu type classified as Latin cuisine (41.2%).

Among the outbreak establishments, 44.1% had two or more critical violations (i.e., violations more likely to contribute to pathogen contamination, proliferation, or survival) on their last routine inspection. All establishments engaged in complex food processes (i.e., food preparation requiring a kill step and holding beyond same-day service or a kill step and some combination of holding, cooling, reheating, and freezing). These processes present a higher risk for bacterial contamination, proliferation, and survival.

For 13 outbreaks (38.2%), investigators answered the question about differences or unusual circumstances in establishment operations during the time customers were exposed to *C. perfringens*. For 32 outbreaks (94.1%), investigators answered the question about differences from ordinary operating procedures at the time customers were exposed, as described by managers or workers. A qualitative analysis of these responses (see Table 2 for text excerpts) yielded the identification of three categories of antecedents: people, processes, and equipment. Further analysis of these antecedents led to nine operational antecedents. Although the antecedents of food and economics were considered, analysis found they were not applicable to this data set.

Antecedents related to people

People antecedents were identified in 27 outbreaks (79.4%). All three operational antecedents in this category were related to workers' failure to follow food safety practices to prevent pathogen survival and proliferation.

(1) In 15 outbreaks (55.6%), workers did not follow established food safety procedures designed to control bacterial survival and proliferation. In some of these outbreaks, investigators noted that the establishments had formal food safety procedures, but workers were not following them. For example, during one investigation, some pieces of meat required three attempts at reheating to achieve the proper internal temperature even though the establishment's process was to reheat only once.
(2) A lack of food safety culture (i.e., the values, shared assumptions, and behaviors of workers) anteceded eight outbreaks (29.6%); examples included a documented pattern of poor inspections, long-standing critical violations, and a history of outbreaks. This antecedent is characterized by multiple, consistent poor food safety practices. For example, one investigator noted that the establishment was ''in the exact same (poor) condition as during a previous norovirus outbreak investigation.'' Many establishments had multiple temperature issues; one investigator said, ''there is a history of repeated temperature violations, including reheating, cold holding, hot holding and room temperature storage noted on 3 consecutive visits in the last 8 months.''
(3) A lack of managerial control, or food safety supervision, to ensure adherence to food safety policies or processes was mentioned for four outbreaks (14.8%). In one outbreak, the manager was on leave at the time of the outbreak and many workers did not show up to work, leaving the establishment short-staffed and vulnerable to food safety errors. In two outbreaks, untrained persons were responsible for food safety at a catered event; they did not ensure that food temperatures were monitored and controlled.

Antecedents related to processes

At least one process antecedent was identified in 14 outbreaks; a total of 18 process antecedents (52.9%) were associated with these outbreaks. All three categories in this antecedent theme were characterized by insufficient processes to control foodborne pathogens.

(1) In 11 of the outbreaks with process issues (61.1%), preparation of the implicated food item differed from the establishment's normal procedure. For example, in one establishment, time constraints caused by the late arrival of a food item led to suspension of standard preparation processes. Other observations included workers using ineffective cooling procedures (e.g., inappropriate food depth, cooling at room temperature), and failing to verify temperatures during cooling.

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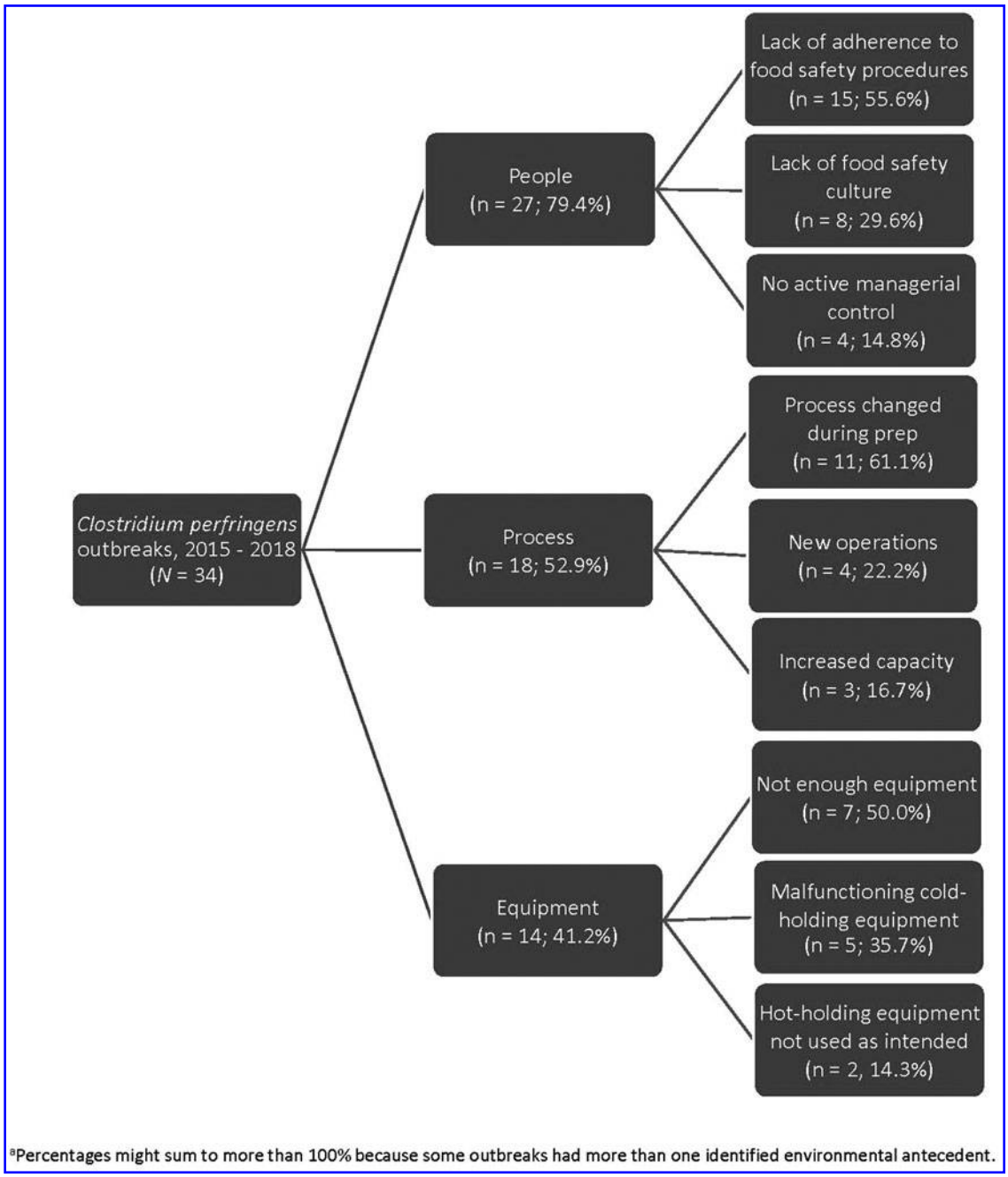

FIG. 1. Operational antecedents in *Clostridium perfringens* outbreaks, National Environmental Assessment Reporting System, 2015–2018 ($N = 34$).

(2) A new circumstance, such as a new establishment, food preparation process, or event type, was mentioned for four outbreaks (22.2%). For example, an establishment prepared a large roast for a holiday buffet, but the staff were not familiar with the proper procedure of cooking and holding this item. One establishment (which did not have a permit to operate) stored food in ''a car from 6:00 a.m. to 6:00 p.m.,'' and neglected to ensure that time or temperature parameters were met.

(3) Increased capacity led to three outbreaks (16.7%). Because of increased demand, these establishments exceeded their typical operational volume and were unable to manage food safety risks. For example, one establishment experienced an extremely busy night, during which they prepared large quantities of food for a large number of people in a short time.

Another establishment catered three events on the same night. The investigator noted that ''this is an unusually large amount of food for the establishment, a higher volume of food being prepared in the establishment at one time.'' These establishments were not equipped to handle the increased volume and had difficulty properly cooling the food.

Table 2. Text Excerpts from Two Open-Ended Questions

Theme	*Operational antecedent*	*Selected text excerpts*
People	Lack of adherence to food safety procedures	While cold and hot holding temperatures are monitored and recorded, cooling, cooking and reheating temperatures are not being monitored or recorded. During the environmental assessment, it was observed that some larger pieces of the carnitas required three attempts at reheating in the fryer to reach an internal temperature of 165°F. The normal establishment process is to only to fry once, then place in team table, without verifying internal temperature of pork before hot holding.
		Chicken was partially cooked then stored at room temperatures, then improperly cooled, stored at room temperature again, stir-fried to order.
	Lack of food safety culture	Improper cooling and hot holding of beans. Hot holding has been an ongoing problem at this facility. Cold holding problems regularly observed.
		Here is a history of repeated temperature violations – including reheating, cold holding, hot holding, and room temperature storage noted on three consecutive visits within the last 8 months.
		Establishment is in the exact same poor condition as during a previous noro outbreak investigation.
		Noncontinuous cooking done improperly, RTS of foods, improper cooling of foods, unclean equipment and utensils used. Many foods found improperly cooled, undercooked, cross-contaminated.
	No active managerial control	Kitchen manager was on vacation, many workers did not show up for shift. Operating without hot water, cold hold units not maintaining proper temperature.
		The caterer had no other reports of issues from food served to other customers from the same pork that day. Also, the food was for a graduation party and most likely left out for an extended period of time.
Process	Process changed during preparation	Managers said they were cooling with ice, but multiple large containers of food found out of temp. In walk-in cooler-hadn't cooled properly and were covered. Items discarded.
		Unusually large batch of pork was cooled improperly in large containers, in a walk-in cooler that was undersized, slow reheat. No temps recorded at any point in process.
	New operations	This is the first time that the facility prepared the large steamship round roast for the easter buffet.
		Warm food stored in a car from 6:00 a.m. to 6:00 p.m. Cooking/cooling in an unpermitted kitchen-caterer.
		The firm does not normally cater events. The cooking process for this event did not involve a cool step for food prepared for the event. Cook serve only.
	Increased capacity	Caterer had three large events to provide food for on the same evening, this is unusually large amount of food for him—higher volume of food being prepared in the establishment at one time—unusually large batch of pork was cooled improperly in large containers, in a walk in cooler that was undersized, slow reheat. No temps recorded at any point in process.
		Very large quantities of food prepared for large number of people over a short time
	Not enough equipment	Food was placed in cardboard boxes and transported without appropriate temperature control.
		Hot holding units were not functioning properly or adequately for food capacity.
		The food establishment has insufficient cold storage space for the amount of food preparation they do for events. Most foods are prepared the day before and many hot foods are kept in a small reach in cooler.
	Malfunctioning cold-holding equipment	Walk-in was being repaired due to temperature issues on the meal date in question which may have contributed to time/temperature abuse of food items.
		Deep pan cooling, covered cooling, cooling in broken refrigerator. (1) Rice improperly cooled in deep pans stored in a broken refrigerator at 65°F. (2) Goat was cooled in deep pan and broken refrigerator then cold held in 65°F refrigerator. Reheated for service.
		Slow cooling at room temperature and in a broken refrigerator of both rice and chicken. (1) After thawing, chicken is partially cooked, then cooled in malfunctioning refrigerator—reheated to order. No temperatures taken. (2) Rice held in steamer overnight—unattended and improperly cooled in bags in a malfunctioning refrigerator then microwaved to order.
	Hot-holding equipment not used as intended	Phfs stored in turned off oven, sometimes overnight. Continued history of hot holding, cold holding, and reheating of phfs. (1) Beans stored in the turned off oven. Room temperature storage followed by inadequate reheating. (2) Cooked carne asada held on the grill inadequate hot holding. (3) Ground beef held in the oven (turned off) at unsafe temperatures. Room temperature storage followed by inadequate reheating. (4) Rice hot held at 118°F. Extra rice held in the turned off oven followed by inadequate reheating.
		Roasts were stored in nonmechanical holding units for transport. Followed by inadequate reheating and hot holding of roasts at food service location.
		The establishment did not properly hot hold the hamburgers. Hamburgers were held in cambros that did not plug in and were meant for transport only.

Were there any differences to the physical facility, food handling practices you observed on your initial visit, or other circumstances that were different at the time of exposure?

During the likely time the ingredient/food was prepared, were any events noted that appeared to be different from the ordinary operating circumstances or procedures as described by managers and/or workers?

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Antecedents related to equipment

Equipment antecedents were identified in 14 outbreaks (41.2%). Retail food equipment includes cold-holding (e.g., refrigerators, freezers) and hot-holding equipment (e.g., bain-marie or hot-holding cabinets), and food storage and insulated transportation containers. The three categories in this antecedent theme were related to failure of equipment intended to prevent bacterial growth in food.

(1) In seven outbreaks (50.0%), the establishment did not have enough equipment or used inappropriate alternatives to approved equipment for food storage or holding. For example, in one outbreak, food was transported in cardboard boxes, which lacked appropriate temperature control, instead of in insulated or temperature-controlled units. In addition, in five outbreaks, investigators reported that the cold- or hot-holding equipment used was not large enough for the establishment's operational demand.
(2) Malfunctioning cold-holding equipment that did not keep food cold enough to minimize pathogen proliferation anteceded five outbreaks (35.7%). Several investigators reported that establishments were using inoperable or malfunctioning refrigerators for cooling and storing hot foods. One investigator stated that the establishment's ''walk-in was being repaired due to temperature issues on the meal date in question.''
(3) Hot-holding equipment was not used as intended in two outbreaks (14.3%). Thus, foods were not held at temperatures hot enough to control pathogen proliferation. For example, one establishment held hot foods in an oven without power; another used containers designed for food transportation, rather than for maintaining appropriate temperatures, to hold hot foods.

Discussion

This qualitative analysis identified three environmental antecedents of *C. perfringens* outbreaks—people, processes, and equipment—which break down further into nine operational antecedents. These antecedents led to inadequate temperature control of food, which led to *C. perfringens* survival and proliferation in food and subsequent outbreaks among those who ate the food. Our findings suggest that establishments and regulators should consider focusing outbreak prevention efforts on workers, food preparation processes, and equipment used to prepare, store, and serve food.

People

Overall, most outbreaks had a people operational antecedent characterized by workers' lack of adherence to food safety procedures. In some outbreaks, workers did not follow established food safety procedures. This oversight could be attributed to several factors, including a lack of food safety culture, a lack of knowledge about proper procedures, and feelings of ''burn-out'' (Powell *et al.*, 2011; Sahin, 2012).

Some research indicates that establishments with higher frequencies of regulatory inspections are less likely to be associated with foodborne outbreaks (Kufel *et al.*, 2011). Regulatory programs might consider providing additional support to establishments with a pattern of poor inspections, long-standing critical violations, or a history of outbreaks. FDA data indicate that cooling violations are among the most common problems noted by inspectors in restaurants that engage in complex food preparation practices (FDA National Retail Food Team, 2018). Regulatory programs might consider developing a better understanding of complex food preparation to identify risks and target worker training.

Establishment workers with food safety training or certification have greater food safety knowledge than those without (Hedberg *et al.*, 2006; Sumner *et al.*, 2011; Brown *et al.*, 2014, 2016; Hoover *et al.*, 2020). Inspectors could educate managers about the public health reasoning behind food safety errors to empower managers to train other workers. By providing a train-the-trainer approach, establishments might be more likely to follow sustainable food safety practices to prevent risk factors and avoid errors.

Certification and training alone are likely not sufficient to control all foodborne risks. Active managerial control and a strong food safety management system, such as a hazard analysis critical control point (HACCP) plan, are strategic approaches to reduce food safety errors (FDA, 2017a). Corrective actions, including monitoring and recording of food temperatures, or the critical limits of critical control points, and the verification of the HACCP plan, are essential steps to ensure safe food. Regulatory programs and the restaurant industry should consider supporting food safety training and certification programs and active managerial control, cultivation of a food safety culture, and the use and verification of a robust food safety management system.

Process

Standard food preparation processes were not followed at many outbreak establishments; instead, a different process that contributed to food temperature abuse and pathogen proliferation was used. Often, these differences resulted from unusual circumstances, such as preparation of larger food amounts than usual and increased customer volume. Ensuring that workers follow their establishment's procedures, rather than revising processes (e.g., taking shortcuts) regardless of unusual circumstances, is key to outbreak prevention.

Studies show that proper cooling is critical to avoiding *C. perfringens* proliferation and that cooling errors are a common cause of *C. perfringens* outbreaks (Kalinowski *et al.*, 2003; Smith-Simpson and Schaffner, 2005; Hedeen and Smith, 2020). Research suggests that many establishments do not follow proper cooling procedures (e.g., no recording or verification of cooling processes) (Brown *et al.*, 2012; Hedeen and Smith, 2020). Establishments can help prevent *C. perfringens* proliferation by monitoring temperatures during cooling and taking corrective actions when temperatures are not met.

The use of HACCP principles to develop a risk control plan can help establishments identify process failures to avoid pathogen proliferation (FDA, 2017a). If process parameters (i.e., time and temperature) are too difficult to use, managers could consider using physical parameters, such as cooling pan depth, to ensure proper cooling. For example, one jurisdiction assesses whether foods are cooled using procedures likely to ensure rapid cooling (uncovered in

shallow [≤2 inches] containers), rather than assessing time and temperature. This alternative method can help ensure proper cooling and increase verification efficiency for inspectors and operators (Oravetz, 2019).

Equipment

Equipment operational antecedents included a lack of or improper equipment for food storage and holding. Ensuring that an establishment has proper equipment for these processes requires an understanding of the establishment's operational capacity, which is based on the volume of complex preparation food items and the capacity and functionality of existing equipment. Other equipment issues included malfunctioning cold-holding equipment and improper use of hot-holding equipment.

Hedeen and Smith (2020) recently found that improper cooling procedures and inadequate equipment are prevalent in the retail food industry. Research has also found that equipment problems are the most common barrier to holding food properly in restaurants (Green and Selman, 2005), restaurants with sufficient refrigeration capacity were more likely to have properly cold-held food (Liggans *et al.*, 2019), and restaurants with multiple refrigerators had a lower likelihood of bacterial outbreaks (Kramer, 2019).

Equipment issues also could be related to the antecedent theme of economics. Financial challenges might limit establishments' ability to buy new equipment or maintain existing equipment. The role that economics plays in outbreaks is difficult for outbreak investigators to evaluate. They might not understand establishments' financial situations and are likely unable to collect economic data (e.g., profit margins). Further research is needed to understand and identify economic antecedents to outbreaks.

To help prevent equipment antecedents to *C. perfringens* outbreaks, establishments can conduct routine maintenance of equipment used for temperature control and worker training on proper equipment use and maintenance. Regulators can also assess equipment during routine inspections to ensure it meets the establishment's capacity and operational requirements and to verify that workers know how to properly use and maintain the equipment.

Limitations

The generalizability of this study's findings is limited because the sample is only a subset of all *C. perfringens* outbreaks—outbreaks investigated by state and local agencies that report to NEARS. The qualitative data we analyzed consisted of observations and perspectives of the investigator, which might be influenced by their unique experiences. Therefore, the investigative approach and outbreak explanation might vary between investigators and reporting sites. The results are qualitative and should not be generalized to a larger population in any statistical sense. However, these results can be useful for guiding future work in food safety.

Conclusion

Data on outbreak operational antecedents can inform food safety interventions to prevent future foodborne outbreaks. We recommend that retail food establishments and regulators educate workers about why food safety tasks are performed. This will help instill a culture of food safety and support use of sustainable and robust food safety management systems.

We also recommend incorporating principles of HACCP, a prevention tool used to prevent foodborne outbreaks and correct process failures, to verify food safety processes at establishments. Finally, regulators and establishments can train workers to use equipment properly and to determine when corrective actions are required to avoid equipment failures that contribute to pathogen proliferation and survival. More research will help to further understand the underlying antecedents of *C. perfringens* outbreaks and prevent them.

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December 14, 2022

Nicole Hedeen
Senior Epidemiologist
Minnesota Department of Health

Dear Ms. Hedeen:

On behalf of the National Restaurant Association, this letter is to express our support of the proposed revision to Section 3-501.14(B) of the Food and Drug Administration's Model Food Code. Specifically, we support the concept of allowing for "shallow layering" of foods being actively cooled. We acknowledge that this will be presented as an Issue to the 2023 Conference for Food Protection.

The data you have shared show a correlation between this method of cooling and control of *Bacillus cereus* and *Clostridium perfringens* – both spore-forming bacteria that can cause public health concern when cooling foods. Additionally, the data suggest that this method is safe and allows for easier management of actively cooling foods within a restaurant setting.

The National Restaurant is the largest foodservice trade association in the world. We represent and advocate on behalf of more than 500,000 restaurant businesses. Our mission is to serve our industry and impact its success. We strengthen operations, mitigate risk, and develop talent; advance and protect business vitality through national, state, and local advocacy; and drive knowledge and collaboration.

Thank you for sharing the data you have collected and thank you for your efforts to promote and protect public health and food safety.

Sincerely,
Patrick L Guzzle

Patrick L Guzzle
Vice President, Food Science
National Restaurant Association

July 29, 2022

Taco Time would like to endorse the shallow pan cooling (2”) cooling method – instead of manually tracking the 6 hour cooling curve.

- Taco Time NW have been successfully using this procedure at our 75 restaurants.
- We have used this procedure with black beans (whole), pinto bean (blended/smooth) and chicken.
- We have found this procedure to be simple and easy for our staff to follow, and easy for the PICs to visually evaluate.
- This procedure is less labor intensive for our staff to track.
- The labeling of pans allows our staff to know which product to use first and rotate newly added pans with hot food to the upper shelves of the cooling racks with appropriate spacing.

Colin Ury
Taco Time Northwest
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applied sciences

MDPI

Article

Effect of Time and Temperature on Physicochemical and Microbiological Properties of Sous Vide Chicken Breast Fillets

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Abstract: Temperature and time are two critical parameters in sous vide cooking which directly affect eating quality characteristics and food safety. This study aimed to evaluate physicochemical and microbiological properties of sous vide chicken breast fillets cooked at twelve different combinations of temperature (60, 70, and 80 °C) and time (60, 90, 120, and 150 min). The results showed that cooking temperature played a major role in the moisture content, cooking loss, pH, a* color value, shear force, and thiobarbituric acid reactive substances (TBARS). Increasing cooking temperature caused an increase in cooking loss, lipid oxidation, TBARS, and pH, while moisture content was reduced ($p < 0.05$). Cooking time played a minor role and only moisture content, cooking loss, and a* color value were affected by this parameter ($p < 0.05$). Total mesophilic aerobic bacteria, *Psychrotrophic* bacteria, and *Enterobacteriaceae* were not detected during 21 days of storage at 4 °C. Cooking at 60 °C for 60 min showed the optimum combination of temperature and time for sous vide cooked chicken breast fillets. The result of this study could be interesting for catering, restaurants, ready-to-eat industries, and homes to select the optimum combination of temperature and time for improving the eating quality characteristics and ensuring microbiological safety.

Keywords: chicken breast fillets; color; cooking loss; cooking temperature; cooking time; microbiological safety; shear force; sous vide cooking; TBARS

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1. Introduction

Meat plays a key role in human nutrition and evolution thanks to its components, including proteins and essential micronutrients such as Zn, Se, Fe, vitamin A, vitamin B_{12}, and folate [1,2]. Most often, raw meat is subjected to various cooking methods such as boiling in water, grilling, steaming, microwave radiation, and sous vide to enhance its digestibility, sensory characteristic, and to improve its hygienic quality [3–5]. In each type of cooking method, several changes occur as a consequence of heating, such as denaturation, aggregation, and degradation of proteins, fiber shrinkage, and collagen solubilization [5–7]. The bio-accessibility of nutrients also can be affected during the cooking process mainly due to the degradation of vitamins, amino acids, and minerals [8]. Therefore, selecting an appropriate cooking method is a critical step before consumption which directly affects physicochemical, textural, and microbiological properties. Among different cooking methods, sous vide cooking has received considerable attention from catering, restaurants, ready-to-eat industries, and homes [9,10]. This technique provides more efficient heat transfer from water to food compared to other cooking methods [11], resulting improvement in eating quality characteristics such as texture, tenderness, juiciness, color, flavor, and

also provides high nutritional value [6,12,13]. Besides, this technique is simple to apply for cooking different kinds of food (e.g., meat, cereals, legumes, etc.) [14]. The term "sous vide" is a French word that refers to the uniform cooking of food inside the food grade and heat-stable vacuumed pouches incubated in a circulating water bath with monitored conditions of temperature and time followed by chilled storage [15,16]. Sous vide cooking has been reported to enhance the quality attributes, inhibiting off-flavors from lipid oxidation, reducing aerobic bacteria and the risk of post-cooking contamination during storage [9,17–19]. Besides, it is beneficial for preserving vitamins, antioxidant compounds, essential amino acids, and unsaturated fatty acids during solubilization, volatilization, and high-temperature application [11,15].

Selecting the right temperature and time combinations plays an important role in sous vide cooking to reduce the risk of overcooking, loss of volatile compounds, and heat-sensitive nutrients [8]. In this context, the effect of cooking temperature and time in sous vide has been reported on the physicochemical properties and eating quality of pork [20–23], lamb [7], beef [24,25], turkey [26,27], and chicken [28–30]. Sánchez del Pulgar et al. [23] found that sous vide pork cheeks cooked at 60 °C had lower water losses, more moisture content, more lightness (L*), and redness (a*) compared to those cooked at 80 °C. Roldán et al. [7] reported that sous vide lamb loins cooked at 60 °C had the highest lightness and redness compared to those cooked at 70 and 80 °C. Besides, increasing cooking temperature caused an increase in cooking loss and a decrease in moisture content. However, the interaction between time and temperature was only effective on microstructural properties. Bıyıklı et al. [26] found that sous vide turkey cutlet cooked at 65 °C had a lower cooking loss, thiobarbituric acid reactive substances (TBARS), and pH compared to those cooked at 70 °C and 75 °C. Besides, the cooking loss, fat content, and pH were increased by increasing cooking time from 20 min to 60 min.

According to the United Nations Food and Agriculture Organization (FAO), poultry meat is the second most widely eaten meat in the world after pork. It is estimated that global poultry consumption will reach 133 million tons by 2024. This is mainly due to the high consumer demands for a healthier diet with high protein content, good amino acid composition, low levels of fat and cholesterol, as well as lower selling price [31]. Because of these features, poultry meat, including chicken breast fillets, has received much attention recently. To the best of our knowledge, literature concerning the combinations of temperature and time on physicochemical and microbiological properties of sous vide chicken breast fillets is still limited. Therefore, the focus of this research was to evaluate the effect of these parameters on eating quality characteristics such as moisture content, cooking loss, lipid oxidation, pH, shear force, color, and microbial safety of sous vide chicken breast fillets.

2. Materials and Methods

2.1. Experimental Design

Fresh skinless and boneless raw chicken breasts were purchased from the local market (Reggio Emilia, Italy) supplied by the same producer within 24 h postmortem and transported to the Department of Life Sciences, University of Modena and Reggio Emilia, Italy using a thermocol box filled with ice and used immediately. Surface fat was trimmed off and samples were cut into pieces with 125 ± 5 g weight and 2.5 ± 0.2 cm thickness. Samples were randomly assigned into the 13 groups. Twelve groups were vacuum-sealed in the food-grade nylon-polyethylene plastic pouches (150 × 200 mm^2) using a vacuum sealer (La Grandispensa, Elegen, Reggio Emilia, Italy) with a pump flow rate of 30 L per minute to create 98% vacuum degree inside the pouches. Plastic pouches had wide thermal stability (−40 °C–+120 °C) with O_2 permeability of 9 cm^3/day m^2 (4 °C/80% relative humidity), and water vapor permeability of 1.2 g/day m^2 (Joelplas SL, Barcelona, Spain). As a control group, chicken breast fillets sealed in plastic pouches without a vacuum (0% vacuum degree) were boiled at 100 °C for 60 min. The samples were cooked in a sous vide cooker (Elegen, Reggio Emilia, Italy). Three independent replicate trials with two repeats

based on different combinations of temperature (60, 70, and 80 °C) and time (60, 90, 120, and 150 min) were analyzed (Table 1). Overall, a total of 78 chicken breast fillets were analyzed (13 groups of samples × 3 independent replicate × 2 repeats). The sous vide chicken breast fillets were cooled in an ice bath for one hour and overnight in the fridge at 2–4 °C. Moisture content, cooking loss, pH, color, TBARS, and shear force were measured the day after the cooking process [7].

Table 1. Temperature, Time, and Vacuum Conditions Applied in This Study for Cooking Chicken Breast Fillets.

Group	Temperature (°C)	Time (min)	Vacuum Degree (%)
Control	100	60	0
1	60	60	98
2	60	90	98
3	60	120	98
4	60	150	98
5	70	60	98
6	70	90	98
7	70	120	98
8	70	150	98
9	80	60	98
10	80	90	98
11	80	120	98
12	80	150	98

2.2. Moisture Content and Cooking Loss

The moisture content and cooking loss were determined according to the AOAC International 950.46 method [32]. The moisture content of the chicken fillets (5 g) was calculated as the percentage of weight loss to a constant weight (M_d) after drying in an oven at 105 ± 2 °C and the initial weight (M_i) according to Equation (1):

$$\text{Moisture content (\%)}: (M_i\text{-}M_d)/(M_i) \times 100 \quad (1)$$

The cooking loss was measured by the weight difference of meat samples (5 g) before (W_1) and after cooking (W_2) according to Equation (2):

$$\text{Cooking loss (\%)}: (W_1\text{-}W_2)/(W_1) \times 100 \quad (2)$$

Moisture content and cooking loss measurements were performed in triplicate.

2.3. pH

The pH value was measured before and after cooking according to the AOAC 981.12 method [32] using a pH meter equipped with a Xerolite electrode (Crison Instrument, Allela, Spain). The pH was determined by blending a 10 g sample with 50 mL distilled water for 60 s in a homogenizer (IKA, Labortechnik, Staufen, Germany). The analysis was performed in triplicate.

2.4. Color

The color of meat samples before and after cooking was measured on the external surface of each fillet with a colorimeter (CR-400, Konica Minolta, Osaka, Japan) equipped with a standard illuminant D65 and 10° observer angle [33]. The results are reported as L* (lightness), a* (redness/greenness), and b* (yellowness/blueness). The instrument was calibrated with a white standard (L* = 99.36, a* = −0.12, b* = −0.06) before each measurement [34]. The average of six measurements at different positions was calculated.

2.5. Warner-Bratzler Shear Force (WBSF)

The WBSF was performed according to Honikel [35] with slight modification. Texture analyzer (Z1.0, Zwick/Roell, Ulm, Germany) with loading cell of 1000 N and crosshead speed 250 mm/min was used to perform shear force analysis on cooked chicken breast fillets ($3 \times 1.5 \times 1$ cm^3) using a Warner-Bratzler blade [22]. The data was obtained from TestXpert® II 161 (V3.31) software (Zwick/Roell, Ulm, Germany). The maximum peak force (kg) to shear the sample was reported as a shear force. The average of five measurements was recorded.

2.6. Thiobarbituric Acid Reactive Substances (TBARS)

TBARS measurement was carried out based on Siu and Draper [36]. A total of 2.5 g of minced meat sample and 12.5 mL distilled water were homogenized at 9500 rpm for 120 s using an ultra-turrax homogenizer (IKA, Labortechnik, Staufen, Germany). The homogenized sample mixed with 12.5 mL of 10% trichloroacetic acid (TCA) (CAS Number: 76-03-09, Sigma-Aldrich, Milan, Italy) and centrifuged for 20 min at 2000 rpm at 4 °C. The supernatant was filtered by a filter paper (Whatman No. 1). A total of 4 mL of the filtrate aliquots was mixed with 1 mL of 0.06 M 2-thiobarbituric acid (TBA) (CAS Number: 504-17-6, Sigma-Aldrich, Milan, Italy) and the solution was heated in a water bath at 80 °C for 90 min. A distilled water-TCA-TBA reagent was also prepared and presented as a blank. The absorbance at 532 nm was measured in duplicate by a spectrophotometer (Jasco Corporation, Tokyo, Japan). Results were expressed as mg of malondialdehyde (MDA) equivalents/kg sample. The average of three measurements was recorded.

2.7. Microbiological Analyses

Microbiological analysis was performed during the storage at 4 °C for 21 days [20]. For each day (0, 5, 10, 15, and 21 days) of analysis, 10 g sliced chicken breast fillets were collected aseptically, and 90 mL sterile saline solution (0.9% NaCl) was added and homogenized for 2 min in a stomacher (Lab blenders Stomacher 400, Instrument Lab Control, Reggio Emilia, Italy). Appropriate dilutions were made with sterile saline solution and 1 mL was plated onto the culture media. Total mesophilic aerobic bacteria counts were determined after aerobic incubation at 30 °C for 48 h using Plate Count Agar (Biolife, Milan, Italy) in accordance with ISO 4833-1: 2013 [37]. Total *Psychrotrophic* counts were determined after aerobic incubation at 4 °C for 10 days using Plate Count Agar (Biolife, Milan, Italy) in accordance with ISO 17410: 2019 [38]. *Enterobacteriaceae* were counted on Violet Red Bile Glucose Agar (Biolife, Milan, Italy) after aerobic incubation at 37 °C for 24 h in accordance with ISO 21528-1: 2017 [39]. The average of three measurements was recorded.

2.8. Statistical Analysis

The experiment was performed in three independent replicates and the number of repeats varied from one analysis to another and was reported in each subsection. The data were analyzed through two-way analysis of variance (ANOVA). The differences between means were compared by Tukey's post-hoc test ($p < 0.05$). A principal component analysis (PCA) was then performed to establish the variations and relationships among physicochemical properties of sous vide chicken breast fillets cooked at twelve different combinations of temperature and time. All the analysis was performed in SPSS software (IBM SPSS 20, New York, NY, USA).

3. Results and Discussion

3.1. Moisture Content, Cooking Loss, and pH

Moisture content is one of the important physicochemical characteristics in meat which plays a basic role in the palatability of meat. Moisture content of raw chicken breast fillet 24 h post-mortem is presented in Table 2. Raw meat showed a moisture content of 72.4%. These results were consistent with those obtained by Sanchez Brambila et al. [40].

Table 2. Moisture Content, Thiobarbituric Acid Reactive Substances (TBARS), Color Parameters (L*: Lightness, a*: Redness/Greenness, and b*: Yellowness/Blueness), and pH of the Raw Chicken Breast Fillet 24 h Post-Mortem.

Parameters	Results
Moisture (%)	72.4 ± 1.02
TBARS (mg/Kg)	0.08 ± 0.011
Weight (g)	125 ± 5
L*	58.4 ± 1.7
a*	0.8 ± 0.1
b*	9.1 ± 0.9
pH	5.8 ± 0.03

Values are presented as means ± standard deviations (n = 3).

The moisture content of sous vide chicken breast fillets cooked at different temperature and time combinations ranged from 68.25% to 71.89% (Table 3). Moisture content was affected by cooking temperature, cooking time, and interaction between temperature and time ($p < 0.05$). As expected, there was a reduction in moisture content by increasing temperature from 60 °C to 80 °C. Control treatment cooked at 100 °C for 60 min showed the lowest moisture content with 68.25% ($p < 0.05$). Increasing cooking time from 60 min to 150 at higher temperatures (70 and 80 °C) caused a reduction in moisture content ($p < 0.05$). During cooking, the fluid is released as water and other ingredients such as fat and soluble proteins. Releasing the sarcoplasmic fluid from the muscle fibers results in lower water content at higher temperatures [6,8,41]. Murphy et al. [42] reported that the denaturation of myosin and actin at higher temperatures caused structural changes and changes in porosity of the chicken breast patties which can directly affect the moisture content. This result is in accordance with those obtained for chicken and beef [28,43].

Cooking loss is an important factor to consider because it is directly related to juiciness which could influence the consumer's perception of the final product [25]. The cooking loss is defined as total liquid and soluble matter lost from the meat during cooking and it is influenced by different factors such as the quality of the raw meat, genetics of the animals, and cooking conditions. This loss relies on the mass transfer process during heat treatment [44]. In this study, cooking loss ranged from 10.23% to 28.08%. Control samples cooked at 100 °C showed the highest cooking loss ($p < 0.05$). Cooking loss was affected by both cooking temperature and cooking time and it was increased by increasing cooking temperature and time ($p < 0.05$). Increasing temperature causes denaturation of myofibrillar proteins and the actomyosin complex, resulting in shrinkage of the muscle fiber. Thus, less water can be captured within the protein structures kept by capillary forces [41,45]. Our result is in agreement with previous studies on sous vide cooking on chicken [28], beef [25,43], pork [23], and lamb [7]. According to Purslow et al. [46], the cooking loss is mainly determined by the shrinkage of myofibrillar proteins (40–60 °C), shrinkage of collagen (60–70 °C), and denaturation of actin (70–80 °C). Denaturation of proteins occurs with increasing temperature which causes structural changes and the release of fluid from muscle fiber leading to a decrease in the water holding capacity and higher cooking loss [47].

The pH of raw chicken breast fillet 24 h post-mortem was 5.8 (Table 2). The pH value of sous vide chicken breast fillets cooked at different temperature and time combinations slightly increased and ranged from 6.07 to 6.3. The pH was affected by temperature and the interaction between temperature and time. Increasing temperature from 60 °C to 80 °C caused an increase in pH value. Similarly, Bıyıklı et al. [26] reported that increasing cooking temperature from 65 °C to 75 °C and cooking time from 20 min to 60 min caused an increase in the pH of sous vide turkey cutlet. Becker et al. [20] reported that increasing temperature caused an increase in pH mainly due to the protein denaturation and the change in protein charge.

Table 3. Moisture Content, Cooking Loss, Shear Force, TBARS, Color Parameters (L*: Lightness, a*: Redness/Greenness, and b*: Yellowness/Blueness), and pH of Sous vide Chicken Breast Fillets Cooked at Different Temperature and Time Combinations.

Temp (°C)	**60**				**70**				**80**				**100**				
Time (min)	**60**	**90**	**120**	**150**	**60**	**90**	**120**	**150**	**60**	**90**	**120**	**150**	**60**	**SEM**	**Temp**	**Time**	**Temp × Time**
Moisture (%)	71.41 ^{f,g}	71.30 ^{e,f,g}	71.72 ^{f,g}	71.89 ^{g}	71.71 ^{f,g}	70.86 ^{e,f,g}	69.97 ^{c,d,e}	70.46 ^{d,e,f}	70.43 ^{d,e,f}	69.76 ^{b,c,d}	69.47 ^{a,b,c}	69.02 ^{a,b}	68.25 ^{a}	0.21	*	*	*
Cooking loss (%)	10.23 ^{a}	11.02 ^{a}	12.42 ^{a,b}	12.47 ^{a,b}	14.01 ^{a,b,c}	16.88 ^{b,c,d}	18.38 ^{c,d,e}	18.69 ^{c,d,e}	17.86 ^{c,d,e}	21.77 ^{d,e,f}	22.77 ^{e,f}	24.23 ^{f,g}	28.08 ^{g}	3.11	*	*	N.S
Shear force (kg)	0.75 ^{a}	0.83 ^{a,b}	0.76 ^{a}	0.62 ^{a}	0.66 ^{a}	0.73 ^{a}	0.62 ^{a}	0.63 ^{a}	0.88 ^{a,b}	0.97 ^{b}	0.79 ^{a}	0.88 ^{a,b}	1.37 ^{c}	0.02	*	N.S	N.S
TBARS (mg/kg)	0.29 ^{a}	0.77 ^{a,b}	0.92 ^{a,b}	0.94 ^{a,b}	1.50 ^{b}	1.47 ^{b}	1.63 ^{b}	1.71 ^{b}	2.31 ^{c}	2.42 ^{c}	2.54 ^{c}	2.60 ^{c}	2.91 ^{d}	0.12	*	N.S	N.S
L*	80.94 ^{a}	81.71 ^{a}	80.11 ^{a}	79.63 ^{a}	80.82 ^{a}	81.72 ^{a}	82.27 ^{a}	82.43 ^{a}	81.39 ^{a}	81.19 ^{a}	80.85 ^{a}	81.15 ^{a}	80.75 ^{a}	2.65	N.S	N.S	N.S
a*	1.95 ^{a}	1.95 ^{a}	1.81 ^{a}	1.71 ^{a}	1.73 ^{a}	1.71 ^{a}	1.74 ^{a}	1.50 ^{ab}	1.44 ^{b}	1.39 ^{b}	1.33 ^{b}	1.29 ^{b}	1.29 ^{b}	0.05	*	*	N.S
b*	14.71 ^{a}	14.65 ^{a}	14.95 ^{a}	15.15 ^{a}	14.91 ^{a}	14.83 ^{a}	14.95 ^{a}	15.40 ^{a}	15.64 ^{a}	15.55 ^{a}	15.60 ^{a}	15.36 ^{a}	14.82 ^{a}	0.41	N.S	N.S	N.S
pH	6.17 ^{a,b,c}	6.14 ^{a}	6.07 ^{a}	6.08 ^{a}	6.11 ^{a}	6.14 ^{a,b}	6.07 ^{a}	6.13 ^{a}	6.15 ^{a,b}	6.25 ^{b,c}	6.30 ^{d}	6.27 ^{c,d}	6.17 ^{a,b,c}	0.93	*	N.S	*

Means value with different superscripts letters (a–g) in the same row indicate a significant difference ($p < 0.05$). Values are presented as means (n = 3). SEM: Standard error of the mean. N.S: not significant; *: indicate a significant difference ($p < 0.05$).

3.2. Color

The L*, a*, b* values of raw chicken breast fillet 24 h post-mortem were 58.4, 0.8, and 9.1, respectively (Table 2). Color parameters are usually used as an indicator of the doneness of cooked meat which directly impacts the appearance and attractiveness of the product [8,19]. The color is mainly affected inside the muscle by myoglobin content, oxidative state of myoglobin, muscle fiber orientation, space between the muscle fibers, packaging conditions, Millard reactions, and pH [48,49]. Color parameters of chicken breast fillets cooked at different temperature-time combinations are presented in Table 3. The L* value (lightness) was not affected by cooking temperature, time, and their interaction ($p > 0.05$). A similar result was reported by Park et al. [29] in sous vide chicken breast cooked at different combinations of temperature (60 and 70 °C) and time (60, 120, and 180 min). In contrast to this result, Sánchez del Pulgar et al. [23] reported that sous vide pork cheeks cooked at 60 °C had a higher L* compared to those cooked at 80 °C. The authors concluded that samples cooked at lower temperatures preserved more water during cooking which might be released to the surface during the slicing process before color measurement. On the other hand, the chicken breast color can be classified into pale (L* > 53), dark (L* < 46), and normal (46 < L* < 53) based on the L* value [33]. In our study, sous vide chicken breast fillets in all combinations of temperature and time showed a pale appearance.

The a* value (redness/greenness) ranged from 1.29 to 1.95. The low a*value in poultry meat is mainly due to the presence of white muscle fibers with low myoglobin content [50]. In this study, a* value was affected by cooking temperature and cooking time ($p < 0.05$). Control samples cooked at 100 °C revealed a lower a* value than those cooked at 60 °C and 70 °C ($p < 0.05$). A similar result was reported by Naveena et al. [28] and García-Segovia et al. [51]. The pink color in poultry meat is evidence of a poorly cooked product. Holownia et al. [52] defined a subjective pink threshold at a* = 3.8 in chicken breast fillets. In our study, a* values were under this threshold level at all different temperatures and time combinations. In a general context, a* value is conversely linked to the degree of myoglobin thermal denaturation in cooked meat [23]. Myoglobin thermal denaturation happens quickly with increasing temperature which can directly interact with by-products of lipid oxidation leading to a reduction in a* value [50].

The b* value (yellowness/blueness) ranged from 14.65 to 15.64. The b* value was not affected by cooking temperature, time, and their interaction ($p > 0.05$). In contrast to our result, Park et al. [29] reported that b* value was affected by cooking temperature in sous vide chicken samples cooked at different combinations of temperature (60 and 70 °C) and time (60, 120, and 180 min).

3.3. Lipid Oxidation

A thiobarbituric acid reactive substances (TBARS) test was used to determine secondary lipid oxidation products (e.g., aldehydes) as an indicator of oxidative deterioration [45], off-flavors, and rancidity [13]. Raw meat showed a TBARS value of 0.08 mg/Kg (Table 2). TBARS values of chicken breast fillets cooked at different temperature-time combinations ranged from 0.29 to 2.60 mg/Kg (Table 3). This parameter was only affected by the cooking temperature ($p < 0.05$). Chicken breast fillets cooked at 60 °C at every time point showed TBARS values below one. Akoğlu et al. [27] reported that oxidative rancidity cannot be detected by a sensory panel under a threshold level of one (mg/kg). TBARS value was increased by increasing temperature up to 80 °C ($p < 0.05$). Control treatment cooked at 100 °C showed a similar value to sous vide chicken cooked at 80 °C. In contrast to our result, Sánchez del Pulgar et al. [23] reported that time (5 and 12 h) and temperature (60 and 80 °C) and their interaction were affected by the TBARS of sous vide pork cheeks.

3.4. Warner-Bratzler Shear Force (WBSF)

The WBSF is commonly used for evaluating tenderness. It is an important eating quality character due to the impact on texture and consumer acceptance [53]. The WBSF

values of chicken breast fillets cooked at different temperature-time combinations are presented in Table 3. The WBSF was only affected by cooking temperature and it was increased by increasing temperature ($p < 0.05$). This parameter ranged between 0.62 and 1.37 kg. The lowest shear force was found in sous vide chicken treatment cooked at 60 °C and 70 °C. This result might be associated with higher moisture content and lower cooking loss of samples cooked at lower temperatures [29,41]. Cooking at low temperatures reduces the protein–protein association and gelation and increases water retention [6,22]. On the other hand, the control sample cooked at 100 °C showed the highest WBSF, which could be attributed to higher cooking loss, lower moisture content, and formation of gelatin due to the collagen denaturation and myofibrillar hardening [54]. Barbanti and Pasquini [55] reported that the enhancement of tenderness is mainly caused by the solubilization of connective tissues, while denaturation of myofibrillar proteins led to toughening. Overall, from previous studies it was suggested that solubilization of the connective tissue [51,56], aggregation of sarcoplasmic proteins [6,9], and water retention inside the muscles [25,53,57] are three major factors contributing to the increase in tenderness.

3.5. Principal Component Analysis (PCA) Analysis

Figure 1 reports the loading plot of the PCA model computed on the physicochemical variables considered in this study. The analysis showed that about 59.84% of the total variation is explained by the first principal component (PC1) and 14.58% by the second principal component (PC2). These two PCs account for about 74.42% of the total data variance. PC1 correlated positively with shear force, cooking loss, TBARS, and pH, while it had a negative correlation with moisture and a* color value. This tendency confirms the opposite relationship between moisture content and shear force, cooking loss, TBARS, and pH. PC2 was only correlated positively with L* color value. A similar result was reported by Fabre et al. [53].

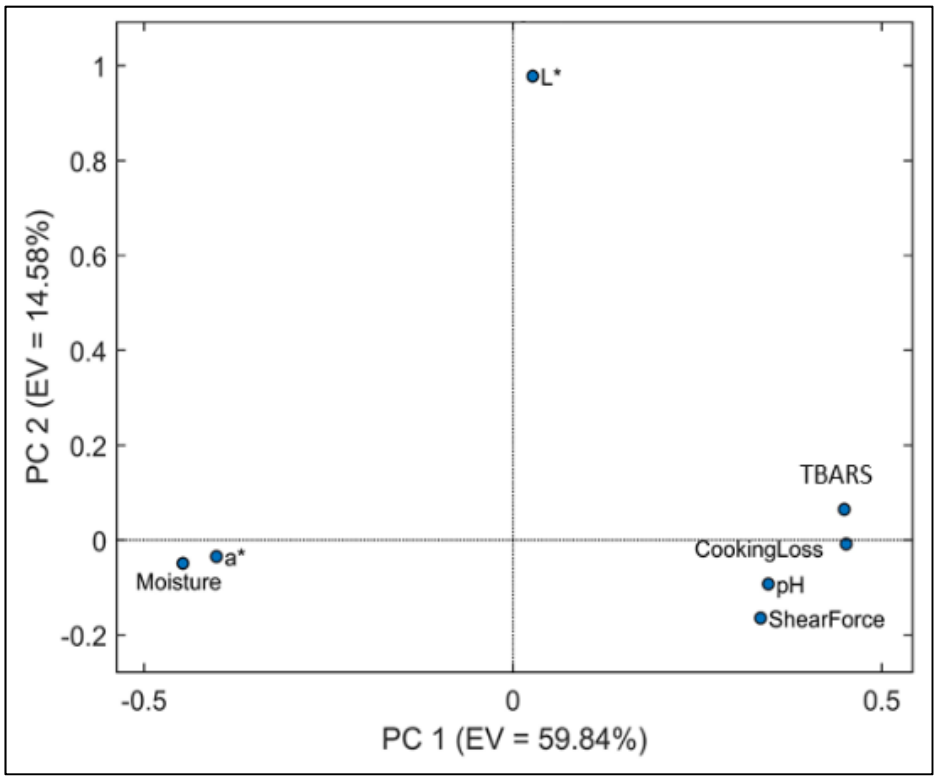

Figure 1. PC1 vs. PC2: Loading plot of physicochemical variables studied in sous vide chicken fillet breasts cooked at different combinations of temperature (60, 70, 80, and 100 °C) and time (60, 90, 120, and 150 min).

Figure 2 reports the score plot. The colors on the plot refer to the different temperatures (60, 70, 80, and 100 °C) while the numbers indicate the cooking time (60, 90, 120, and 150 min). Chicken breast samples cooked at 60 °C and 70 °C were at negative values of PC1. Conversely, the chicken breast samples cooked at 80 and 100 °C were at positive values of PC1. By comparing the score plot with the corresponding loading plot, it is possible to interpret the relationships between samples and variables [58]. The score plot in conjugation with the loading plot demonstrated that increasing cooking temperature caused an increase in cooking loss, lipid oxidation, TBARS, and pH. Comparing the results in Table 3 with the PCA model allowed us to conclude that the cooking temperature played a major role in measured variables while the effect of cooking times seemed to be negligible.

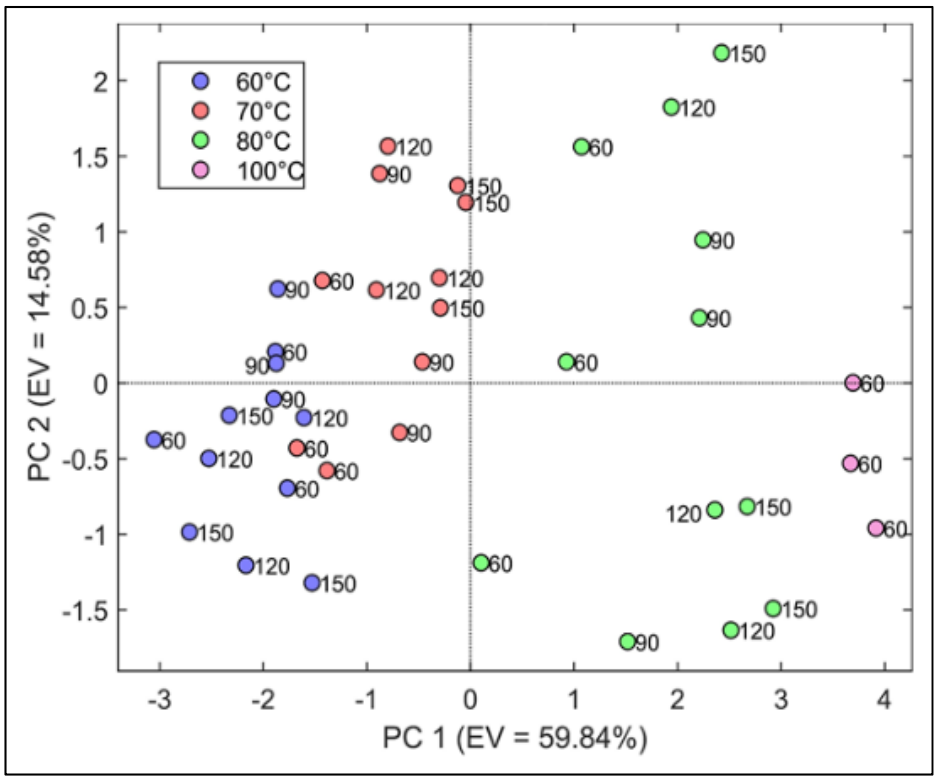

Figure 2. PC1 vs. PC2: Score plot of physicochemical variables studied in sous vide chicken fillet breasts cooked at different combinations of temperature (60, 70, 80, and 100 °C) and time (60, 90, 120, and 150 min). The symbol's color corresponds to cooking temperature (60, 70, 80, and 100 °C) and the number beside the symbol corresponds to cooking time (60, 90, 120, and 150 min).

3.6. Microbiology

The microbial load before and after sous vide cooking was analyzed to verify different temperature and time combinations applied in this study guarantee microbiological safety. The microbial counts of mesophilic aerobic bacteria, *Psychrotrophic* bacteria, and *Enterobacteriaceae* at raw chicken breast fillets are presented in Table 4. The selection of these three groups was based on their significant importance in food quality and safety. Raw chicken breast fillets showed 2.8 and 2.3 log CFU/g counts for total mesophilic aerobic bacteria and *Enterobacteriaceae*, respectively. The *Psychrotrophic* bacteria count was lower than 1 log CFU/g. These results are below reference values recommended by food quality standards for fresh poultry meat (EC No. 2073/2005). The counts of all microbial groups were not detectable at 4 °C for 21 days in sous vide chicken breast fillets confirming that even the lowest temperature and time combinations (60 °C–60 min) were enough to pasteurize meat. This result might be due to the growth inhibition of microorganisms under anaerobic conditions caused by vacuum packaging together with heat treatment and storage at a low temperature (4 °C) [17,27]. In accordance with these results, Can and Harun [31] re-

ported that total mesophilic aerobic bacteria, *Psychrotrophic* bacteria, and *Enterobacteriaceae* counts were for sous vide chicken meatballs cooked at 90 °C for 20 min. In contrast to our results, Akoğlu et al. [27] found that total mesophilic aerobic bacterial counts exceeded 5 log CFU/g for sous vide turkey cutlet cooked at 45 °C for 60 min and stored at 4 and 12 °C, respectively. The presence of total mesophilic aerobic bacteria might be due to the low temperature (45 °C) applied in this study which was not enough to inhibit the growth of microorganisms.

Table 4. Microbiological Counts of the Raw Chicken Breast Fillet 24 h Post-Mortem (Day 0) and Sous Vide Chicken Breast Fillets (Cooked at All Different Combinations of Temperature and Time) during 21 Days of Storage at 4 °C.

Table	Treatment	Total Mesophilic Aerobic Log (CFU/g)	*Enterobacteriaceae* Log (CFU/g)	*Psychrotrophic* Aerobic Log (CFU/g)
0	Raw meat	2.8 ± 0.6	2.3 ± 0.4	<1
0	Sous vide	n.d	n.d	n.d
5	Sous vide	n.d	n.d	n.d
10	Sous vide	n.d	n.d	n.d
15	Sous vide	n.d	n.d	n.d
21	Sous vide	n.d	n.d	n.d

Values are presented as means ± standard deviations (n = 3). n.d: not detected.

4. Conclusions

Sous vide cooking is gaining more and more attention from catering, restaurants, ready-to-eat industries, and homes recently mainly due to the improvement in eating quality characteristics, extended shelf lives, and reduced risk of post-cooking contamination compared to other cooking methods. Temperature and time are two critical parameters in sous vide cooking that directly affect eating quality and safety. The finding of this study showed that cooking temperature played a major role in the moisture content, cooking loss, shear force, TBARS, a*, and pH value. Increasing cooking time from 60 min to 150 min caused a reduction in moisture content and a* value while cooking loss increased. Chicken breast fillets cooked at 60 °C revealed less cooking loss, lipid oxidation, shear force, and a more intense red color compared to those cooked at 70 and 80 °C. Total mesophilic aerobic bacteria, *Psychrotrophic* bacteria, and *Enterobacteriaceae* were not detected during storage at 4 °C for 21 days, ensuring microbiological safety for consumers. Overall, the optimum condition obtained in this study for chicken breast fillets was cooking at 60 °C for 60 min. Future studies need to be carried out to assess the sensory quality parameters and palatability of sous vide chicken breast fillets during the storage time to determine shelf life and consumer acceptability. Besides, it is necessary to perform inoculum studies targeting specific pathogenic and spoilage microorganisms to assess the effectiveness of selected temperature and time combinations on microbiological quality.

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International Fire Code & NFPA Standards References

IFC, Section 903.5 (from 2000 to the current 2021 edition) requires the inspection, testing and maintenance of fire sprinklers to be per NFPA 25.

For example, this section states, "Sprinkler systems shall be tested and maintained in accordance with Section 901." Section 901.6 states, "Fire protection and life safety systems shall be maintained…and shall be replaced or repaired or defective…"

NFPA 1 *Fire Code,* Section 13.3.3.4.1.1. (from the 1997 to 2021 edition) requires the inspection, testing and maintenance of fire sprinklers to be per NFPA 25.

For example, this section states, "Inspection, testing, maintenance, and impairment procedures shall be implemented in accordance those established in this document and in accordance with the manufacturer's instructions."

NFPA 25, Section 5.2 (beginning in the 2002 Version), requires leaking fire sprinkler heads, as well as other leaking equipment, piping, etc. to be replaced.

For example, this section states, "Any sprinkler that shows signs of any of the following shall be replaced:

(1) Leakage
(2) Corrosion detrimental to sprinkler performance
(3) Physical damage
…"

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State of Maine Health Inspection Program

Refilling Returnables Policy

The Health Inspection Program (HIP) has provided the following guidance for licensees when establishments choose to refill returnable containers in their operations. The current 2013 Maine Food Code section 3-304.17 prohibits this however, HIP recently adopted, as policy, the requirements for the reusable packaging section 3-304.17 of the 2017 FDA Food Code for retail food establishments, which will replace sections 3-304.17 and 4-603.17 of the Maine Food Code.

This policy provides guidance for HIP inspections, including a variance approval process for HIP establishments that are refilling returnable food containers.

For more information, please contact your Health Inspector or the HIP main line at 207-287-5671.

I. 3-304.17 Refilling Returnables. (2017 FDA Food Code)

3-304.17 Refilling Returnables.
(A) Except as specified in ¶¶ (B) - (E) of this section, empty containers returned to an eating establishment for cleaning and refilling with food shall be cleaned and refilled in a regulated Food Processing Plant.
(B) A take-home food container returned to an eating establishment may be refilled at an eating establishment with food if the food container is:
(1) Designed and constructed for reuse and in accordance with the requirements specified under Part 4-1 and 4-201.11, 4-202.11 of the Maine Food Code.
(2) One that was initially provided by the eating establishment to the consumer, either empty or filled with food by the eating establishment, for the purpose of being returned for reuse.
(3) Returned to the eating establishment by the consumer after use.
(4) Subject to the following steps before being refilled with food:
(a) Cleaned as specified under Part 4-6 of the Maine Food Code,
(b) Sanitized as specified under Part 4-7 of the Maine Food Code; and
(c) Visually inspected by a food employee to verify that the container, as returned, meets the requirements specified under Part 4-1, 4-201.11, and 4-202.11; *and*
(d) Stored and handled in accordance with Part 4-9 of the Maine Food Code.
(C) A take-home food container returned to an eating establishment may be refilled at an eating establishment with beverage if:
(1) The beverage is not a Potentially Hazardous Food (PHF) Time/Temperature Control for Safety Food (TCS) as defined in the Maine Food Code,
(2) The design of the container and of the rinsing equipment and the nature of the beverage, when considered together, allow effective cleaning at home or in the eating establishment,
(3) Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system,
(4) The consumer-owned container returned to the eating establishment for refilling is refilled for sale or service only to the same consumer; and
(5) The container is refilled by:

Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
Commissioner

Maine Department of Health and Human Services
Maine Center for Disease Control and Prevention
11 State House Station
286 Water Street
Augusta, Maine 04333-0011
Tel; (207) 287-8016; Fax (207) 287-9058
TTY: Dial 711 (Maine Relay)

(a) An employee of the eating establishment, or
(b) The owner of the container if the beverage system includes a contamination-free transfer process as specified under ¶¶ 4-204.13(A), (B), and (D) of the Maine Food Code that cannot be bypassed by the container owner.

(D) Consumer-owned, personal take-out beverage containers, such as thermally insulated bottles, non-spill coffee cups, and promotional beverage glasses, may be refilled by employees or the consumer if refilling is a contamination-free process as specified under ¶¶ 4-204.13(A), (B), and (D) of the Maine Food Code.

(E) CONSUMER-owned containers that are not food-specific may be filled at a water vending machine or system.

II. Variance and Approval Process

(A) All eating establishments that provide refilling returnable services per this policy, must first submit a completed variance form for HIP's review and approval.

(B) Once HIP receives the variance form, the inspector will conduct an inspection of the eating establishment to review policies and procedures to ensure proper ware-washing techniques for cleaning, rinsing, sanitizing and storage of reusable takeout containers.

(C) If a third-party system of reusable containers is used by the establishment, the establishment must have a contract with the third-party company that allows inspection by HIP of the third-party facility and any remote drop-off locations utilized for the temporary storage of the used reusable containers to ensure sanitary conditions. A copy of the contract with the third-party company is to be submitted to HIP at the time the variance is submitted. The contract must specify that the third-party company agrees to inspection of its facility and any remote drop off locations. The inspector will inspect the third-party facility to review their policies and procedures to ensure proper ware-washing, rinsing, and sanitizing, in addition to the cleanliness of facility and the storage of the reusable takeout containers. If remote locations are utilized by the third-party company for the drop off of used reusable containers, the drop off locations must be kept clean and be protected from pests.

(1) The eating establishment will bear the additional inspection fee cost, if over two inspections occur within the establishment's annual license year.

(2) If the third-party inspection is a failed inspection or does not comply with the Maine Food Code, and the eating establishment and third party are unwilling to correct the violations, then HIP will inform the establishment that they will not be approved to use the third-party refillable returnable services.

(3) The inspector will note all Maine Food Code violations for the third-party facility on the licensed eating establishments inspection report and provide the inspection report to the owner or person in charge.

(D) The inspector will provide the inspection report to the owner and inform HIP management of their recommendations.

(E) HIP management will review the inspector's recommendations. The variance form will be approved or disapproved by signature and provided to the inspector and the licensed eating establishment.

THE TOWN OF PLYMOUTH

26 Court Street
Plymouth, Massachusetts 02360

Department of Public Health
(508) 747-1620 ext 10118

June 25, 2019

FROM: Dr. Nate Horwitz-Willis, Plymouth Department of Public Health

TO: All Plymouth Food Establishments to include: Restaurants, Retail Facilities, and Other Establishments Serving Food to the Public with Plastics or Styrofoam

RE: Mitigating Use of Plastics and Styrofoam through Voluntary Use of Consumer Reusable Containers

This memorandum serves as official guidance to allow for the voluntary use and acceptance of reusable containers by your consumers/patrons for food and/or drink consumption. This guidance is applicable for all those identified in the 'TO' field and for those who are in receipt of this document. The intent of this guidance is to assist with limiting or eliminating the use of single use plastics and Styrofoam containers as they are known to negatively impact human health over time and our natural environment to include our waterways. Rapid climate change also contributes to the leaching of contaminants from the containers into our environment. This guidance enables you an opportunity to help mitigate the negative impacts mentioned in this paragraph within the Town of Plymouth.

This guidance is in line with *Massachusetts General Law, Chapter 111, Public Health, Section 127A: State Sanitary Code*. Also, this guidance complements the *105 Code of Massachusetts Regulations 590 Chapter 4, Equipment, Utensils, and Linens, 4-101 Multiuse and 4-202 Cleanability*. Further, the following specific criteria must be met in order to remain in compliance with the laws and regulations mentioned in this paragraph:

1) The reusable containers can be either metal, glass, food grade silicon, bamboo, or any other plant fiber material. These materials are generally non-toxic and are easy to sanitize and generally are reliably constructed.
2) All consumers/patrons presenting the use of reusable containers in a food establishment must have them originate from a commercial vendor and they must not be damaged.
3) All consumers/patrons desiring to use a reusable container in a food establishment must wash and clean it before each use and present it in a sanitary condition deemed acceptable by food establishment personnel.
4) Food containers must be brought into an establishment to allow for an appropriate visual inspection of the container by food establishment personnel.
5) Consumers/Patrons must always check in with food establishment personnel to ensure they are able to use their reusable container.
6) Consumers/Patrons are responsible for the sanitary and constructed condition of their reusable container if an establishment opts into voluntary use for reusable containers.
7) Food establishments may voluntarily place signage, to make aware to consumers/patrons, that they accept reusable containers (based on item #1 in this paragraph) that are claimed to be and appear sanitary per a consumer/patron.

Food establishments are not required to provide reusable containers for consumers/patrons to use as a result of this guidance. All consumers/patrons are responsible for complying with the guidance described in this document when a food establishment chooses to engage in this voluntary guidance. This voluntary guidance is effective immediately this day of June 25, 2019.

Nate Horwitz-Willis

Dr. Nate Horwitz-Willis, DrPH, MPH, MPA
Director of Public Health
26 Court Street
Plymouth, MA 02360

Town of Plymouth
Public Health
Prevent. Promote. Protect.

AB 619

Bring Your Own Container & Reusables Act

SUMMARY

California statewide bill that allows temporary food facilities at events to serve customers in reusable containers rather than single-use disposables. This bill also clarifies existing health code laws ensuring that the public can bring reusable containers to restaurants for take-out.

WHAT THIS MEANS FOR FOOD VENDORS

AB 619 clarifies that reusables, including customer-owned containers that are constructed for reuse, can be used and filled at festivals, food trucks, farmers' markets, school cafeterias, and more! A physical barrier should be placed down or the surface sanitized after filling. This should be clearly outlined and documented. Besides allowing approved reusables to be filled, other ways to support the bill are:

DISCOUNT

Encourage customers to bring their own reusables by providing a small discount when they fill them up!

SELL

Sell approved reusables (with brand name if desired) for customers to purchase and use at the event!

RENT

Hire a service to rent out reusables through a deposit-refund program and wash them once returned!

SOURCE: LEGINFO.LEGISLATURE.CA.GOV

ZERO WASTE GUIDE

FOR FOODSERVICE ESTABLISHMENTS IN THE CITY OF PHILADELPHIA

UPDATED 08/25/2021

City of Philadelphia

Fels Institute of Government
University of Pennsylvania

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INTRODUCTION

Foodservice establishments generate a significant amount of wasted food and packaging. Between 4 and 10% of food purchased by foodservice operations in the U.S. is thrown out before reaching the plate. By reducing the amount of food and packaging discarded, foodservice establishments can significantly reduce the volume of their waste stream and save money (EPA, pg. 1). Packaging also makes up a majority of the litter that ends up in waterways, harming fish, birds, and other aquatic wildlife that ingest plastic bags and other debris from packaging (EPA, pg. 3).

The City of Philadelphia aims to become a "Zero Waste" city, wherein the city diverts at least 90% of its waste away from the landfill and commercial incinerators. Much of the waste currently produced in the city stems from eating and drinking, like single-use hot beverage cups from coffee shops and Styrofoam takeout containers from food trucks. Best practices for reduction and reuse in the foodservice industry are a critical component of Philadelphia becoming a zero waste city. **This guide aims to educate both employees in and customers of the foodservice industry on how to implement zero waste practices while still complying with local and national health and safety regulations.**

WHAT DOES THE FDA FOOD CODE SAY?

Reusable Food Containers

Empty containers returned to a food establishment for cleaning and refilling with food shall be cleaned and refilled in a regulated food processing plant, except:

A take-home food container returned to a food establishment may be refilled at a food establishment with food if the food container is:

1. Designed and constructed for reuse and in accordance with the requirements specified under Part 4-1 (Materials for Construction and Repair) and Part 4-2 (Design and Construction) of the FDA Food Code;
2. One that was initially provided by the food establishment to the consumer, either empty or filled with food by the food establishment, for the purpose of being returned for reuse;
3. Returned to the food establishment by the consumer after use;
4. Subject to the following steps before being refilled with food:
    a. Cleaned as specified under Part 4-6 (Cleaning of Equipment and Utensils) of the FDA Food Code
    b. Sanitized as specified under Part 4-7 (Sanitization of Equipment and Utensils) of the FDA Food Code; and
    c. Visually inspected by a food employee to verify that the container, as returned, meets the requirements specified under Part 4-1 (Materials for Construction and Repair) and Part 4-2 (Design and Construction) of the FDA Food Code.

Want to learn more about reusable containers? Find guidance for choosing a compliant container, proper sanitization and storage in the Appendix.

WHAT DOES THE FDA FOOD CODE SAY?

Reusable Drink Containers

Empty containers returned to a food establishment for cleaning and refilling with food shall be cleaned and refilled in a regulated food processing plant, except:

A take-home food container returned to a food establishment may be refilled with beverage if:

1. The beverage is not a time/temperature control for safety food;
2. The design of the container and of the rinsing equipment and the nature of the beverage, when considered together, allow effective cleaning at home or in the food establishment;
3. Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;
4. The consumer-owned container returned to the food establishment for refilling is refilled for sale or service only to the same consumer; and
5. The container is refilled by:
    a. An employee of the food establishment, or
    b. The owner of the container of the beverage system includes a contamination-free transfer process as specified under Section 4-204.13(A), (B), and (D).

Consumer-owned, personal beverage containers, such as thermally insulated bottles, non-spill cups, and promotional glasses, may be refilled by employees or the consumer if refilling is contamination-free as specified under Section 4-204.13(A), (B), and (D).

WHAT DOES THE PHILADELPHIA FOOD CODE SAY?

All existing foodservice establishments in Philadelphia may offer reusable containers effective July 2021.
Inspections will occur at the next regularly scheduled annual Department of Health Food Establishment Inspection. All new businesses will be required to check off that they are using reusable containers on their Food Establishment Plan Review and will be inspected during the first inspection. All food establishments will be expected to follow the FDA guidelines for container types, sanitizing, and storage. **Full guidelines are available & linked in the Appendix.**

Local Case Study: Parks on Tap

Since 2019, the City of Philadelphia's Parks on Tap program has offered reusable plastic and silicone pint cups. Guests who reuse the cups receive $1 off their drink each refill. The team at Philadelphia Parks and Recreation came to PDPH with the idea and worked with PDPH staff to address all stages of the refill process to ensure safety and sanitation.

Local Case Study: Tiffin Indian Cuisine

In 2021, after a long search for a more sustainable to-go container, Tiffin launched the *Return 2 Tiffin* program. The restaurant gives its customers the option to select durable, reusable plastic containers with each to-go order, and uses an electronic tagging system to keep track of the containers. With most customers returning their boxes on time, Tiffin has not often needed to charge customers for using their returnable containers.

REUSABLE WARES

Oftentimes, foodservice establishments assume that customers want their food to-go or default to packaging food to-go. Be sure to train your staff to ask the question "for here or to-go?" with each order placed.

For Here

For customers who are eating in, reduce the amount of single-use disposable waste produced by serving them in reusable wares, including:

- Ceramic mugs and glass drinkware
- Reusable dishes and bowls
- Metal silverware and straws

Not only does providing reusable wares reduce the amount of waste your establishment produces, but they also give your establishment a more upscale feel that customers will notice and appreciate.

To-Go

Guests who bring reusable containers for to-go orders or for packing their leftovers can save you money on disposables and waste. If a staff member is filling a reusable container, they should either place a physical barrier down or sanitize the surface after filling.

DID YOU KNOW?

Customers cannot transfer food directly to their reusable plate/container from shared food sources like buffets. This must be done by a trained staff member. Make sure the kitchen utensils you use to make the transfer do not touch the customer's container.

MINIMIZING SINGLE-USE DISPOSABLES

Reduction and Reuse

- Use a reusable lid on food storage containers on your food prep line instead of disposable plastic wrap (ex. invest in stainless steel food containers with lids for storing and preparing food)
- Use health department-approved refillable condiment dispensers instead of individual packets
- Implement a reusable to-go container program that allows customers to take and bring back durable containers to be sanitized and reused
- Don’t automatically put to-go food in a bag or give customers single-use items like coffee sleeves or straws; rather, have these items available upon request
- Use a sneeze guard display case for customers to see baked goods while protecting the food instead of baked goods individually wrapped in disposable plastic wrap

Single-Use Disposable Alternatives

- In general, paper wares are preferable to plastics and "compostable bioplastic" wares. Packaging materials labeled "compostable" or "biodegradable" must go in the landfill stream unless your compost hauler allows otherwise; they cannot be disposed of in single stream recycling
- Use butcher, waxed, and parchment paper when possible in place of plastic wrap

DID YOU KNOW?

One $5 reusable container can be used over 1,000 times, while a business might spend hundreds of dollars on 1000 single-use plastic containers. Many of these single-use containers will display the universal recycling symbol, but this doesn't mean they can be recycled everywhere. In 2020, the U.S. produced 14.5 million tons of plastic packaging, and only 14% was actually recycled! (EPA)

LEFTOVER FOOD AND ORGANIC WASTE

In Philadelphia, nearly 17% of trash sent to the landfill is wasted food. To encourage recycling and composting, Ordinance 10-722 was amended to state that grindable food waste (such as produce scraps, small bones, and leftovers) **cannot** be disposed of in refuse/waste dumpsters. Here are some steps you can take to comply with the ordinance and reduce wasted food:

- **Reduce** wasted food before it's created. You can do this by measuring wasted food, rethinking your purchasing practices, reducing consumption, and repurposing extra food.
- **Donate** leftover food to local organizations. A variety of foods are eligible for donation, including those that are not readily marketable. Work with a local food rescue organization to learn what they accept.
- **Compost** food scraps and opened food that cannot be donated. Composting turns organic waste into rich fertilizer.
- When there are no other options for reducing or diverting food waste from the landfill, grindable food waste must be disposed of **using an in-sink garbage disposal.**

Want to learn more about sustainable food waste management? Find the Food Waste Management Guide for Commercial Properties in the Appendix.

RESOURCES

Resources: Regulatory (click to follow link)

City of Philadelphia Department of Public Health Regulations Governing Food Establishments

FDA Food Code 2017

Resources: Tools & Guidance (click to follow link)

Philadelphia Disposal, Recycling, and Donation Finder

Food Waste Management Guide for Commercial Properties

Reusable To-Go Container Program Guidance *by Circular Philadelphia and ECHO Systems*

City of Philadelphia Zero Waste Initiatives Page

Sources

"Reducing Wasted Food & Packaging: A Guide for Food Services and Restaurants." United States Environmental Protection Agency (EPA), 2015, www.epa.gov/sites/production/files/2015-08/documents/

Disclaimer: Reference in this guide to any specific commercial product or service, or the use of any trade, firm or corporation name is for the information and convenience of readers, and does not constitute endorsement, recommendation, or favoring by the City of Philadelphia.

This guide was authored by Elizabeth Main, MPA student at the University of Pennsylvania's *Fels Institute of Government* under the guidance of Claire Robertson-Kraft, Nic Esposito, Haley Jordan, and Helena Rudoff.
Created 8/20/20. Last updated 8/25/2021.

Washington State Retail Food Code

Chapter 246-215
Washington Administrative Code (WAC)

Effective March 1, 2022

Washington State Department of Health

April 2021

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.

Washington State Department of Health Food Safety Program • www.doh.wa.gov/foodsafety • 360-236-3330

03348 Preventing contamination from equipment, utensils, and linens--Refilling returnables (FDA Food Code 3-304.17).

(1) Except as specified in subsections (2) through (6) of this section, empty containers returned to a FOOD ESTABLISHMENT for cleaning and refilling with FOOD shall be cleaned and refilled in a regulated FOOD PROCESSING PLANT.

(2) A take-home FOOD container returned to a FOOD ESTABLISHMENT may be refilled at a FOOD ESTABLISHMENT with FOOD if the FOOD container is:

(a) Designed and constructed for reuse and in accordance with the requirements specified in Part 4, Subparts A and B of this chapter;

(b) One that was initially provided by the FOOD ESTABLISHMENT to the CONSUMER, either empty or filled with FOOD by the FOOD ESTABLISHMENT, for the purpose of being returned for reuse;

(c) Returned to the FOOD ESTABLISHMENT by the CONSUMER after use;

(d) Subject to the following steps before being refilled with FOOD:

(i) Cleaned as specified under Part 4, Subpart F of this chapter;

(ii) Sanitized as specified under Part 4, Subpart G of this chapter; and

(iii) Visually inspected by a FOOD EMPLOYEE to verify that the container, as returned, meets the requirements specified under Part 4, Subparts A and B of this chapter.

(3) A take-home FOOD container returned to a FOOD ESTABLISHMENT may be refilled at a FOOD ESTABLISHMENT with a BEVERAGE if:

(a) The BEVERAGE is not a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD;

(b) The design of the container and of the rinsing EQUIPMENT and the nature of the BEVERAGE, when considered together, allow effective cleaning at home or in the FOOD ESTABLISHMENT;

(c) Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;

(d) The CONSUMER-owned container returned to the FOOD ESTABLISHMENT for refilling is refilled for sale or service only to the same CONSUMER; and

(e) The container is refilled by:

(i) An EMPLOYEE of the FOOD ESTABLISHMENT; or

(ii) The owner of the container if the BEVERAGE system includes a contamination-free transfer process as specified under 04230 (1), (2), and (4) that cannot be bypassed by the container owner.

(4) Consumer-owned multiuse BEVERAGE containers may be refilled, including TIME/TEMPERATURE CONTROL FOR SAFETY FOOD beverages, by EMPLOYEES or the CONSUMER if refilling is a contamination-free process as specified in 04230 (1), (2), and (4).

(5) CONSUMER-owned containers that are not FOOD-specific may be filled at a water VENDING MACHINE or system.

(6) A FOOD ESTABLISHMENT under an APPROVED plan may allow CONSUMERS to:

(a) Refill a visibly clean CONSUMER-owned container with nonREADY-TO-EAT FOOD, bulk FOOD, and PACKAGED FOOD;

(b) Refill a visibly clean CONSUMER-owned container with READY-TO-EAT FOOD when dispensed from equipment, such as a gravity-flow unit, meeting standards for liquid food and ice in 04230; and

(c) Request a FOOD EMPLOYEE of the FOOD ESTABLISHMENT to refill a visually clean CONSUMER-owned container with FOOD using a contamination-free process.

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Breaking news for everyone's consumption

Beach Beat: We need food safety boots on the ground and we need them right now

By Coral Beach on March 17, 2022

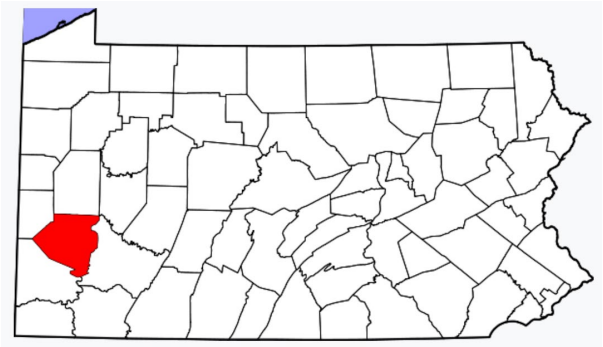
– OPINION –

Budget woes are part of so-called normal life right now, especially for individuals and small businesses. Public entities such as school districts are also having trouble making ends meet. In addition to keeping the lights on, finding enough

employees to fill open positions is another challenge related to budget constraints, with wages figuring in the equation with increasing frequency.

Public health departments are no exception and restricted budgets mean less money for their services, including crucial food safety efforts.

Consider the situation in Allegheny County, PA. With a population of 1.25 million as of the 2020 Census, the county is second only to Philadelphia County in terms of residents. The county seat of Allegheny County is the metropolis of Pittsburgh.



Allegheny County, PA

The county's food safety program monitors and regulates more than 8,500 permanent food businesses with inspections of each business required at least once per year. Some facilities, which distribute only pre-packaged food, can be inspected once every two years. The food safety employees also conduct additional inspections in response to consumer complaints and to follow up after violations are found. They also investigate a fluctuating number of reports of operations that are not working under proper permits.

The food safety program in Allegheny County is representative of most county programs across the county. Such programs are generally housed within public health departments and handle inspections and other regulatory issues for localities within the county. Most county health departments rely on their food safety programs to cover consumer education, emergency preparedness, certification of food handlers, and education programs for businesses.

That's a lot of public safety responsibility.

That requires a lot of boots on the ground.

Right now there are enough empty boots out there to open a chain of shoe stores. Much of the problem can be found if you follow the money, or rather the

lack thereof.

“Overall there are several challenges facing all food safety programs,” said Steven Mandernach, executive director of the Association of Food and Drug Officials (AFDO).

Steven Mandernach

The organization Mandernach heads include members from the city, county, and state health departments across the country as well as people from federal entities such as the Center for Food Safety and Applied Nutrition and the Food and Drug Administration. Funding for food safety programs at all levels has never been up to par with responsibilities laid out in government policies at all levels. The number of food operations and other food safety issues to address has outpaced budget allocations.

“Overall, the attractiveness of government employment is not the same as it once was, pensions and health insurance have been diminished and now pay is quite low compared to industry,” Mandernach said.

“Some (food safety) programs are experiencing a 20 percent year-over-year turnover. Programs report not getting qualified candidates and frequent reposting of the positions multiple times to fill.”

In Allegheny County, the food safety program is operating at half capacity with only 14 of its 30 inspector positions currently filled, according to data published by the county.

When you consider the amount of responsibility and stress on public food safety inspectors at all levels of government it’s easy to understand why there is a hiring crisis. Mandernach said the numbers from Allegheny County are not

unusual. He said national numbers show a typical county public health inspector is assigned to review operations of between 200 and 600 establishments per year.

With only 260 weekdays per year — including holidays — it's easy to do the math. Inspectors can't possibly meet the expectations of their job descriptions effectively.

"It takes close to two years to train a candidate to be effective and many new hires will stay 5 years or less," Mandernach said.

The problem could be solved with an infusion of funds for public health inspectors, but a general mood among much of the public, and therefore elected officials, is blocking the path.

"Funding to maintain positions is always challenging," Mandernach said. "The legislative will at the state and local level for any type of regulation is a bit challenging currently with anti-regulation tendency."

The current situation is flat-out unacceptable.

It is time to allocate enough money for enough food safety staff at all levels of government — but especially at state, county, and city levels — to make sure our food is safe to eat.

If we had enough boots on the ground at state and local levels we would catch food safety problems sooner and reduce the need for federal intervention. More people inspecting more food operations at the state and local levels is a state and local control issue.

The public needs to lobby state and local lawmakers to provide adequate funding for food safety programs. If the elected officials won't step up, send them stepping on their way next time they ask for your vote.

(To sign up for a free subscription to Food Safety News, click here.)

Tags: AFDO, Allegheny County, Association of Food and Drug Officials, food inspections,

food safety funding, restaurant inspections, Steven Mandernach

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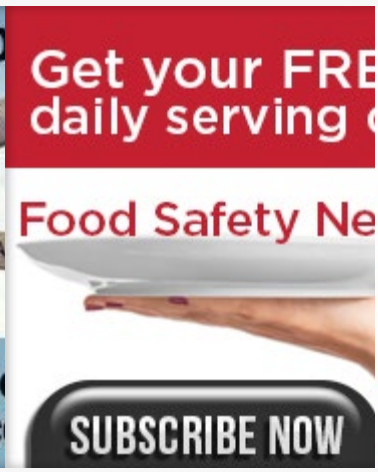

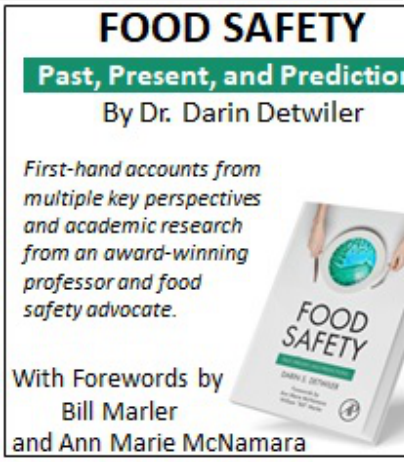

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Environmental Health Regulatory Food Safety Program Capacity Assessment

Initial Assessment Results
April 2011

Assessment report compiled by the National Environmental Health Association (NEHA).

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1.0 Introduction

NEHA and AFDO have been asked to conduct an EH regulatory food safety program capacity assessment by CIFOR. CIFOR members are interested in knowing what impacts budget cuts may be having on the capacity of local and state regulatory food safety programs—and specifically on those programs that conduct environmental investigations during foodborne disease outbreaks. Having completed workforce capacity assessments for epidemiology and laboratories, there was a remaining need to do an assessment for EH personnel. Additionally, with state and local EH programs experiencing drastic budget reductions in the current economic climate, there was consensus about the urgency of completing this remaining assessment. This assessment is intended for EH and regulatory food safety managers and directors who oversee regulatory food safety programs within local, tribal, and state departments that conduct environmental investigations during foodborne disease outbreaks.

Because of the urgency to have basic information quickly, an initial assessment was created using Zoomerang. The assessment was both anecdotal and qualitative and addressed EH foodborne illness investigation capacity issues such as fewer staff/resources, less training, less capacity. NEHA, AFDO, and NACCHO disseminated the assessment to EH and food safety managers and directors. The assessment was launched March 24, 2011, and closed April 8, 2011.

NEHA announced the assessment through e-mail to its state and regional affiliates, Certified Professional in Food Safety credentialed list, CDC's EH listserv, NEHA's e-News electronic membership newsletter, and on its Web site, Facebook page, and through Twitter. AFDO directly e-mailed the assessment to its list of state food safety program managers and are encouraging everyone to complete it. NACCHO shared the assessment with its food safety distribution list, EH distribution lists, and EH advisory groups. It was also included in their EH newsletter that went out the week of April 4.

At the close of the survey, 457 individuals visited the Zoomerang assessment link with 157 completing and 30 partially completing the assessment. The following information is the feedback received through the assessment. This data is broken down into results for all assessment participants, as well as for local and state agency assessment participants. Throughout this report, data for all participants will be represented in red, whereas data for local agency participants is in blue and state agency participants is in green.

1.1 Assessment Results Overview

Provided below is an overview of results intended to highlight some main points, information, and trends obtained through the assessment.

Assessment Participant Characteristics

- 75% of assessment participants indicated working at a local government agency and 25% indicated working at a state government agency.
- Feedback was received from 78% of U.S. states, along with feedback from two U.S. territories.
- 66% of assessment participants indicated a job title that can be readily classified as management level.

Administrative Capacity Impacts

- In terms of staff size, staff salaries, and grant funding, about 50% of assessment participants indicated no change over the past two years.
- Assessment participants indicated the following decreases:
    - 45% indicated a decrease in staff size
        - 5% indicated a decrease of over half
        - 12% indicated a decrease between 25 and 49%
    - 53% indicated a decrease in training budgets
        - 32% indicated a decrease between 1 and 24%
    - 58% indicated a decrease in overall budgets
        - 49% indicated a decrease between 1 and 24%
    - 59% indicated a decrease in travel budgets
        - 15% indicated a decrease of over half
- Assessment participants indicated the following increases:
    - 19% indicated some percentage of staff salary increases
    - 14% indicated a 1–24% increase in overall budget
- Comparing local and state agency results:
    - For the most part, the percentages for administrative capacity impacts were similar among local and state agencies.
    - Areas where percentages differed by 10% or more were:
        - Staff salaries: 10% of state agencies indicated an increase between 1 and 24%, compared to 21% of local agencies.
        - Training budgets: 5% of state agencies indicated a decrease between 25 and 49%, compared to 17% of local agencies.

Programmatic Capacity Impacts

- 48% or more of assessment participants indicated no change for all of the programmatic capacities listed with the highest capacities not affect being:
    - Ability to conduct environmental assessments/investigations in response to outbreaks (68%)
    - Ability to respond to food recalls (68%)
    - Ability to respond/investigate consumer foodborne illness complaints (78%)
- 40% indicated some level of decreased ability to support government mandated services

- Furthermore, 33% indicated a decrease in services offered to retail food facilities, 32% indicated a decrease in services offered to other government programs and departments, and 37% indicated a decrease in services offered to the general public.
- Comparing local and state agency results:
  - For the most part, the percentages for programmatic capacity impacts were similar among local and state agencies.
  - Areas where percentages differed by 10% or more were:
    - Ability to support government mandated services: 30% of local agencies indicated a decrease between 1 and 24%, compared to 44% of state agencies.
    - Inspection fees: 62% of local agencies indicated no change, compared to 49% of state agencies.
    - Ability to conduct environmental assessments/investigations in response to outbreaks: 15% of state agencies indicated an increase between 1 and 24%, compared to 5% of local agencies.
    - Ability to respond/investigate consumer foodborne illness complaints: 17% of state agencies indicated an increase between 1 and 24%, compared to 4% of local agencies.

Trends in Program Effects

- Local agencies indicated a decrease in the frequency of inspections, staff sizes, and training/outreach provided to retail food facilities and the general public.
- Local agencies indicated an increase in inspection fees, in-house training of staff, and workloads.
- State agencies indicated a decrease in the frequency of inspections and staff size.

Regulatory Food Safety Program Inspection Impacts

- 25% indicated that they were conducting more inspections while 31% indicated that they were conducting fewer inspections.
- 20% claim they are unable to meet routine regulatory inspection requirements.
- Comparing local and state agency results:
  - For the most part, the percentages for regulatory food safety program inspection impacts were similar among local and state agencies.
  - Areas where percentages differed by 10% or more were:
    - No change to the number of inspections required: 40% of local agencies indicated no change, compared to 22% of state agencies.
    - Fewer inspections conducted: 26% of local agencies indicated conducting fewer inspections, compared to 44% of state agencies.
    - Increased backlog of inspections: 19% of local agencies indicated an increased backlog of inspections, compared to 32% of state agencies.
    - Unable to meet routine regulatory inspection requirements: 16% of local agencies indicated being unable to meet routine regulatory inspection requirements, compared to 32% of state agencies.

Regulatory Food Safety Program Capacity to Investigate and Respond to Foodborne Illness Outbreaks

- In terms of program funding, staff size, qualifications and competency of staff, and other food safety workload expectations, over 50% of assessment participants indicated no change over the past two years.
- 41% indicated an increase in workloads from programs besides food safety.
- 22% indicated an increase in staff qualifications and competency.
- 37% indicated a decrease in staff size.
- 35% indicated a decrease in training for staff.
- 27% indicated a decrease in program funding.
- Comparing local and state agency results:
    - For the most part, the percentages for impacts to regulatory food safety program capacities to investigate and respond to foodborne illness outbreaks were similar among local and state agencies.
    - Areas where percentages differed by 10% or more were:
        - Program funding: 4% of local agencies indicated a decrease between 25 and 49%, compared to 17% of state agencies. Conversely, 3% of local agencies indicated an increase between 1 and 24%, compared to 15% of state agencies.
        - Training for staff: 26% of local agencies indicated a decrease between 1 and 24%, compared to 7% of state agencies. Furthermore, 9% of local agencies indicated an increase between 1 and 24%, compared to 22% of state agencies.
        - Increased backlog of inspections: 19% of local agencies indicated an increased backlog of inspections, compared to 32% of state agencies.

Anecdotal Impact Trends

- Staff morale is low due to increased workloads and decreased salaries.
- There is less focus on educating food workers when conducting inspections. There is also less time spent providing public education and outreach.
- Most haven't experienced any major negative public health impacts due to decreased food safety program capacity, but feel that the potential for increased foodborne illness outbreaks is very likely.
- There is a sense of agencies turning inward to survive, such as trying to stay afloat by focusing on mandated work and trying to compensate for decreased training budgets by focusing on providing in-house training.

2.0 Please provide the following information: State, Name of jurisdiction or organization, and Job title.

Assessment participants were required to indicate the state they work in, the jurisdiction or organization they work for, and their job title.

2.1 State

Overall, feedback was received from 78% of U.S. states, plus two U.S. Territories (Northern Marianas Islands and Puerto Rico). Colorado, Iowa, Massachusetts, Michigan, and Ohio had 10 or more individuals participating in this assessment. Table 1.1 shows the state breakdown of assessment participants. The table also shows the level of government each state's participants work within.

Table 2.1.1 U.S. State Participation

U.S. States / Territories	Local Agency Assessment Participants	State Agency Assessment Participants	Total Assessment Participants	% of Total Assessment Participants
Alabama	1	0	**1**	< 1%
Alaska	0	0	**0**	0%
Arizona	2	0	**2**	1%
Arkansas	2	2	**2**	1%
California	3	1	**4**	2%
Colorado	10	1	**11**	6%
Connecticut	3	1	**4**	2%
Delaware	0	0	**0**	0%
District of Columbia	0	0	**0**	0%
Florida	2	6	**8**	4%
Georgia	1	2	**3**	2%
Hawaii	0	0	**0**	0%
Idaho	0	1	**1**	< 1%
Illinois	5	0	**5**	3%
Indiana	5	0	**5**	3%
Iowa	17	1	**18**	10%
Kansas	0	1	**1**	< 1%
Kentucky	0	0	**0**	0%
Louisiana	0	0	**0**	0%
Maine	1	1	**2**	1%
Maryland	2	0	**2**	1%
Massachusetts	15	2	**17**	9%
Michigan	10	1	**11**	6%
Minnesota	2	2	**4**	2%
Mississippi	0	1	**1**	< 1%
Missouri	4	0	**4**	2%
Montana	0	0	0	0%

Table 2.1.1 U.S. State Participation (Continued)

U.S. States / Territories	Local Agency Assessment Participants	State Agency Assessment Participants	Total Assessment Participants	% of Total Assessment Participants
Nebraska	4	1	5	3%
Nevada	3	1	4	2%
New Hampshire	0	0	1	< 1%
New Jersey	0	1	1	< 1%
New Mexico	2	1	3	2%
New York	1	0	1	< 1%
North Carolina	4	1	5	3%
North Dakota	0	0	0	0%
Northern Marianas Islands	0	1	1	< 1%
Ohio	17	2	19	10%
Oklahoma	0	0	0	0%
Oregon	3	2	5	3%
Pennsylvania	3	0	3	2%
Puerto Rico	0	1	1	< 1%
Rhode Island	0	2	2	1%
South Carolina	0	1	1	< 1%
South Dakota	0	0	0	0%
Tennessee	1	0	1	< 1%
Texas	5	0	5	3%
Utah	0	0	0	0%
Vermont	0	0	0	0%
Virginia	2	4	6	3%
Washington	3	0	3	2%
West Virginia	0	1	1	< 1%
Wisconsin	2	3	5	3%
Wyoming	6	2	8	4%

2.2 Jurisdiction/Organization

Assessment participants came from state and local agencies (see Section 3.0 and Graph 3.0.1 for a local versus state agency breakdown of assessment participants). Below is a list of these agencies for each state. If more than one person indicated the same agency, that number is indicated in parentheses.

Table 2.2.1 Assessment Participant Local and State Agency Breakdown by State

State	Local Agency	State Agency
Alabama	• Jefferson County Health Dept	
Arizona	• Mohave County • Yuma County	
Arkansas		• Arkansas Department of Health (2)
California	• City and County of San Francisco • Glenn County Environmental Health • Public Health, Env Health	• California Public Health, Food and Drug Branch
Colorado	• Broomfield Public Health and Environment • Colorado State University • El Paso County Public Health • Larimer County Department of Health & Environment • Las Animas/Huerfano County Health Department • Park County • Pueblo City-County Health Department • Summit County • Weld County • Weld County Department of Public Health and Environment	• Colorado Department of Public Health and Environment
Connecticut	• Franklin, Lebanon & Salem (2) • Town of Manchester	• Consumer Protection
Florida	• Charlotte/DeSoto Counties • Volusia County – Department of Health	• Department of Agriculture and Consumer Services (2) • Department of Health (3) • Florida Department of Health – Broward County
Georgia	• Forsyth County Health Department	• Georgia Department of Agriculture • Georgia Department of Community Health
Illinois	• Hoffman Estates • Lake County Health Department (2) • McDonough County • Vermilion County Health Dept	

Table 2.2.1 Assessment Participant Local and State Agency Breakdown by State (Continued)

State	Local Agency	State Agency
Indiana	• Cass County • Dearborn County • Hamilton County Health Department - Noblesville • Hendricks County Health Department • Tipton County	
Iowa	• ADLM Counties, Environmental Public Health • Black Hawk County Health (2) • Buena Vista • Carroll County Environmental Health • Cedar County Environmental Health & Zoning Department • Cerro Gordo County Department of Public Health • City of Ames • City of Dubuque Health Department • City of Ottumwa • Dubuque Health Services • Iowa Environmental Health Association • Lee County Health Department • Linn County Public Health • Scott County Health Department • Taylor County Environmental Health • Webster County Health Department	• Iowa Department of Inspections and Appeals
Kansas		• Health Department
Maine	• City of Bangor	• Department of Agriculture, Division of Quality Assurance and Regulations
Maryland	• Baltimore County Public Schools • Prince George's County Health Department	

Table 2.2.1 Assessment Participant Local and State Agency Breakdown by State (Continued)

State	Local Agency	State Agency
Massachusetts	• Ashland • Brookline Public Health Department • City of Newton Health and Human Services Department (2) • Fairhaven Board of Health • LBOH • Merrimac Board of Health • Reading Health Division • Town of Burlington Board of Health • Town of Danvers Board of Health • Town of Harwich • Town of Natick Health Department • Town of Topsfield • Town of West Springfield • Weymouth Health Department	• Department of Public Health, Food and Drugs • Food Protection Program
Michigan	• Barry-Eaton Health District • Berrien County Health Department • District Health Department #4 • District Health Department #10 • Genesee County Health • Ingham County Health Department • Jackson County Health Department • Kalamazoo County • Livingston County Department of Public Health • Tuscola County Health Department	• Michigan Department of Agriculture and Rural Development
Minnesota	• City of St. Cloud • Olmsted County Public Health Services	• Department of Agriculture • Minnesota Department of Health
Mississippi		• Mississippi Department of Health
Missouri	• City of Joplin • St. Louis County (2) • St. Louis City Department of Health	
Nebraska	• Lincoln-Lancaster County Health Department (2) • Central District Health Department (2)	• Nebraska Department of Agriculture
Nevada	• Southern Nevada Health District (3)	• Nevada State Health Division, Office of Epidemiology
New Hampshire	• Manchester Health Department	
New Jersey		• New Jersey Department of Health

Table 2.2.1 Assessment Participant Local and State Agency Breakdown by State (Continued)

State	Local Agency	State Agency
New Mexico	• Bernalillo County • Environment Department, Environmental Health Division	• New Mexico Environment Department
New York	• Madison County Health Department	
North Carolina	• Alamance County Health Department • Cabarrus County • Craven County Health Department • New Hanover County Health Department	• Department of Environment and Natural Resources
Northern Marianas Islands (U.S. Territory)		• Department of Public Health
Ohio	• Cincinnati Health Department • City of Springdale • Cuyahoga County Board of Health • Delaware County • Elyria City Health District • Henry County Health Department • Hocking County Health Department • Lake County General Health District • Mahoning County District Board of Health (2) • Marion Public Health • Pickaway County Health Department • Sidney-Shelby County Health Department • Stark County Health Department • Warren City Health Department • Warren County Combined Health District • Wayne County General Combined Health District	• Department of Agriculture • Ohio Department of Health
Oregon	• Hood River County Health Department • Marion County Health Department • Multnomah County Health Department	• Oregon Health Authority • Public Health Division
Pennsylvania	• Allegheny County Health Dept (2) • Allentown Health Bureau	
Puerto Rico (U.S. Territory)		• Department of Health
Rhode Island		• Department of Health (2)

Table 2.2.1 Assessment Participant Local and State Agency Breakdown by State (Continued)

State	Local Agency	State Agency
South Carolina		• Department of Health and Environmental Control
Tennessee	• Metro Nashville Public Health Department	
Texas	• City of Burleson • City of Garland Health Department • City of Longview • City of Plano • Harris County Public Health & Environmental Services	
Virginia	• Alexandria Health Department • Arlington County Public Health	• Virginia Department of Agriculture and Consumer Services (2) • Virginia Department of Health • Virginia State Health Department – Office of Environmental Health Services
Washington	• Clallam County • Kitsap County Health District • Mason County Public Health	
West Virginia		• Bureau for Public Health
Wisconsin	• Outagamie Count Public Health • Tri-County Environmental Health	• Department of Agriculture, Trade & Consumer Protection • State Department of Health Services (2)
Wyoming	• Cheyenne-Laramie County Environmental Health • Cheyenne-Laramie County Health Department • City of Casper-Natrona County Health Department (3) • City of Laramie	• State of Wyoming Consumer Health Services (2)

2.3 Job Titles

The assessment targeted management level professionals within environmental health regulatory food safety programs. Table 2.3.1 organizes job titles by position (e.g., director, manager, supervisor, etc.) and the descriptors listed for the position title. If more than one person indicated the same position and title descriptor, that number is indicated in parentheses.

Overall, 186 assessment participants provided job titles. Sixty-six percent of job titles fall under the classification of management level—administrator, chief, commissioner, director, head, leader, manager, and supervisor. The other job titles, such as sanitarian, specialist, and officer, don't clearly indicate management level. However, that does not mean these individuals do not manage the food safety programs within their jurisdiction. It is just not clear as to the level of responsibility they have based solely upon their job title.

Table 2.3.1 Assessment Participant Job Titles

Position Title	Title Descriptor
Administrator (7)	Environmental (2) Environmental Health Food Division Food Safety Program Public Health (2)
Agent (4)	Health (4)
Analyst (1)	Community Health
Chief (10)	Division of Food Safety Environmental Health (2) Environmental Health Services Bureau Food and Consumer Safety Bureau Food Protection (3) Food Safety Section Program
Commissioner (2)	Health (2)
Consultant (1)	Environmental Health Program
Dietician (1)	-
Director (49)	Bureau Code Enforcement Division, Acting Division of Food Safety, Acting (2) Environmental Health (23) Environmental Health, Interim Environmental Health Regulatory Environmental Programs Food Protection (3) Health Department (4) Health (5) Health, Inspections, and Solid Waste Neighborhood Services Public Health (2) Public Health, Deputy Public Health Services, Associate

Table 2.3.1 Assessment Participant Job Titles (Continued)

Position Title	Title Descriptor
Environmentalist (1)	Assistant
Epidemiologist (2)	Environmental
	Regional Environmental
Head (1)	Branch
Inspector (5)	Environmental Health
	Food
	Health
	Public Health
	Senior Food, II
Leader (1)	Foods Team
Manager (39)	No descriptor (3)
	Consumer Health Services
	Consumer Protection
	Division
	Environmental
	Environmental Field Services
	Environmental Health (8)
	Environmental Health Services (4)
	Environmental Public Health
	Epidemiology
	Food and Neighborhood Nuisances
	Food Processing Program
	Food Program (3)
	Food Protection Program
	Food Safety Program
	Outbreak
	Preparedness
	Program (5)
	Section (2)
	Unit
Representative (2)	Field
Sanitarian (12)	No descriptor (2)
	City (2)
	Environmental Health
	Environmental (2)
	Registered (2)
	Registered, III (2)
	Senior
Scientist (1)	Environmental
Specialist (20)	Environmental Health (15)
	Environmental Health, III
	Environmental
	Food
	Senior Environmental Health (2)

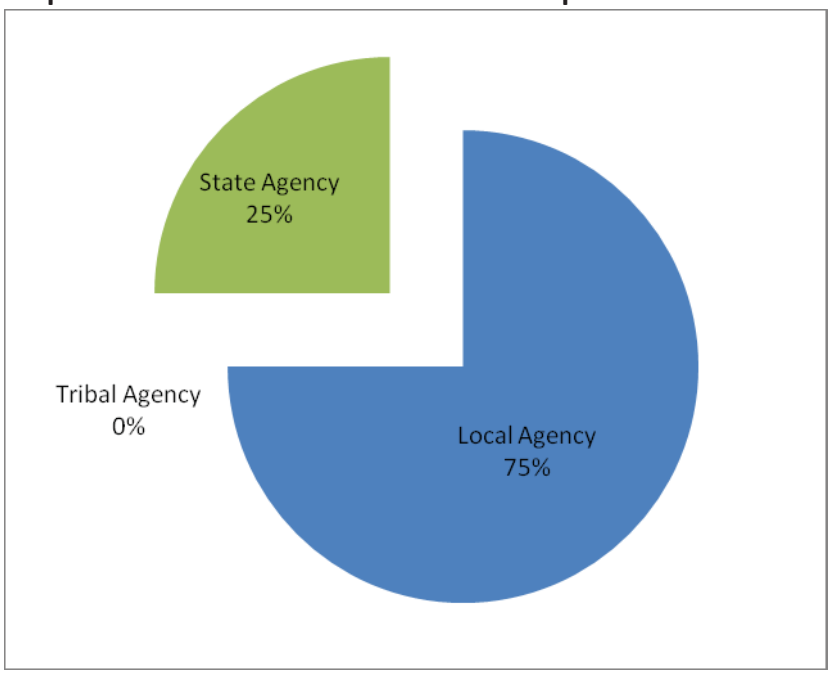
Table 2.3.1 Assessment Participant Job Titles (Continued)

Position Title	Title Descriptor
Supervisor (14)	No descriptor (2) Community Services Environmental Health (6) Environmental Food Safety Program Health Department Program Inspection Services Inspection
Surveyor (1)	Food, Drug, and Lodging

3.0 Please indicate the level of government in which you work.

Assessment participants were asked to indicate if they work at a local, tribal, or state government agency. Those indicating none of the above were bounced to a screen-out page informing them that the survey was specifically for those working at a local, tribal, or state government agency, and thanked them for their interest in participating. Graph 3.0.1 shows the percentage of assessment participants coming from the different government agency levels.

Graph 3.0.1 Percent of Assessment Participants from the Different Levels of Government



4.0 For your regulatory food safety program, please indicate the degree to which the following administrative capacities have been impacted over the past two years.

Assessment participants were asked to indicate the degree of increase, decrease, or no change to certain administrative capacities using a likert scale. Table 4.0.1 shows the administrative capacities and the degrees of impact indicated by all assessment participants. The number in each box is the percent of the total participants selecting that option. The next two tables show this information specific to local and state agency assessment participants.

Table 4.0.1 Indicated Degrees of Impact to Administrative Capacities for all Assessment Participants

Administrative Capacity	>50% decrease	25-49% decrease	1-24% decrease	No change	1-24% increase	25-49% increase	>50% increase	N/A
Staff size	5%	12%	28%	46%	4%	0%	0%	4%
Staff salaries	2%	2%	20%	55%	18%	1%	0%	2%
Overall budget	2%	7%	49%	26%	14%	0%	0%	2%
Training budget	7%	14%	32%	36%	4%	1%	1%	6%
Travel budget	15%	14%	30%	32%	2%	1%	0%	6%
Technology/ equipment budget	4%	12%	29%	43%	7%	1%	0%	5%
Grant funding	4%	4%	16%	47%	4%	1%	1%	23%

Table 4.0.2 Indicated Degrees of Impact to Administrative Capacities for Local Agency Assessment Participants

Administrative Capacity	>50% decrease	25-49% decrease	1-24% decrease	No change	1-24% increase	25-49% increase	>50% increase	N/A
Staff size	5%	12%	29%	48%	3%	0%	0%	3%
Staff salaries	2%	2%	18%	54%	21%	0%	0%	2%
Overall budget	2%	6%	49%	25%	16%	0%	0%	2%
Training budget	6%	17%	32%	35%	3%	1%	1%	6%
Travel budget	15%	16%	30%	31%	2%	1%	0%	5%
Technology/ equipment budget	3%	12%	29%	43%	7%	1%	0%	6%
Grant funding	3%	5%	17%	45%	3%	0%	1%	25%

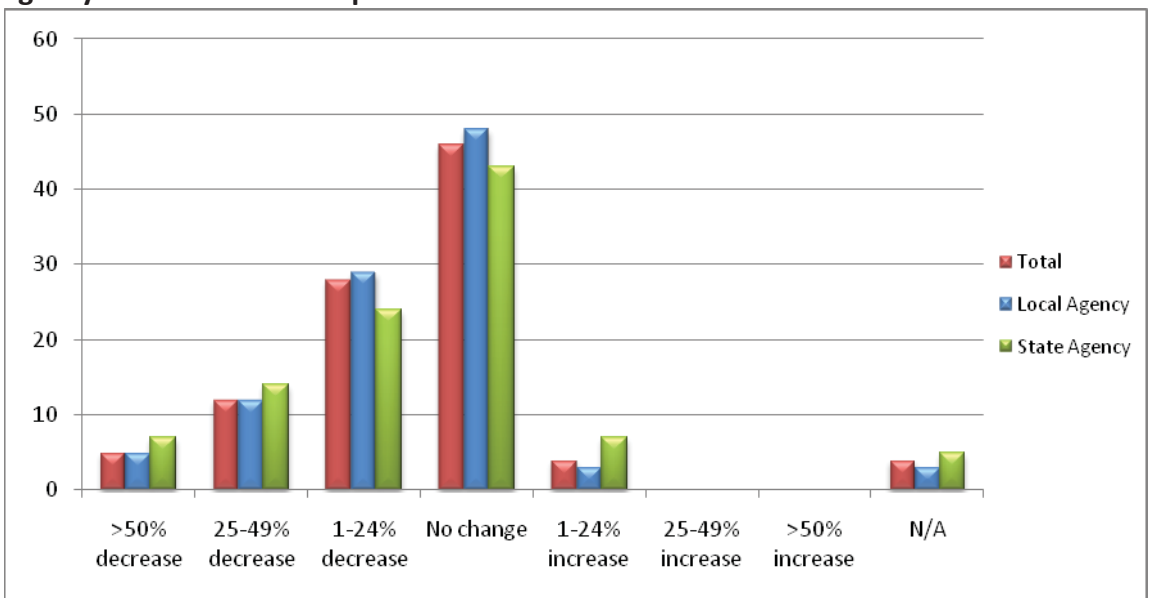
Table 4.0.3 Indicated Degrees of Impact to Administrative Capacities for State Agency Assessment Participants

Administrative Capacity	>50% decrease	25-49% decrease	1-24% decrease	No change	1-24% increase	25-49% increase	>50% increase	N/A
Staff size	7%	14%	24%	43%	7%	0%	0%	5%
Staff salaries	2%	0%	24%	57%	10%	5%	0%	2%
Overall budget	5%	7%	48%	31%	7%	0%	0%	2%
Training budget	7%	5%	33%	40%	5%	2%	0%	7%
Travel budget	17%	10%	29%	33%	2%	0%	0%	10%
Technology/ equipment budget	5%	12%	29%	43%	7%	0%	0%	5%
Grant funding	5%	2%	12%	52%	7%	2%	2%	17%

4.1 Comparison of Total and Local and State Agency Percentages

The next set of charts (4.1.1 –4.1.7) show the percentages of assessment participants indicating the different levels of change for each administrative capacity. Following the charts are comments made for each specific degree of impact. The charts also compare responses for all participants to responses from local and state agency participants.

Chart 4.1.1 Staff Sizes: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

>50% decrease

Local Agency

- 4 hour food inspector budget eliminated in 2010.
- Effective July 1, administrative will be reduced 50%
- Not enough staff to effectively perform job duties.
- We share a secretary with Planning, Conservation and about 14 other small non-regulatory Boards and Commissions. Additionally we were recently given duties for Veterans' Affairs with no staff increase.

State Agency

- Bureau of Environmental Health office was fully staffed @ 21 staff down to incumbent 11 staffs.

25–49% decrease

Local Agency

- Personnel retiring or leaving the department have not been replaced.
- Loss of senior staff person and increased demand on Env Director related to other programs and initiatives has effected administrative capacity
- Lost an EH Director to budget cuts and EH Coordinator retired and was not replaced.
- One full time inspector was laid off

State Agency

- No vacancies are filled.
- We have lost an Administrative Assistant 1 position and program manager position. We have reconfigured to try to minimize the impact to the actual inspection program.

- There are more establishments and less inspectors to achieve the goal of inspecting at least 80% of the establishments.

1–24% decrease

Local Agency

- We still have the same staff of one. He has been assigned additional duties in emergency response for 4 hours per week.
- De-regionalized because food licensing fees were inadequate to maintain region. Staff reduction occurred.
- The county had a workforce reduction and one full time inspector position was lost.
- Permanently lost 1 of 8 field EHS positions in our Food Program (12.5%). Funding for the position was eliminated after the position became vacant.
- Reduction based on Budgets

State Agency

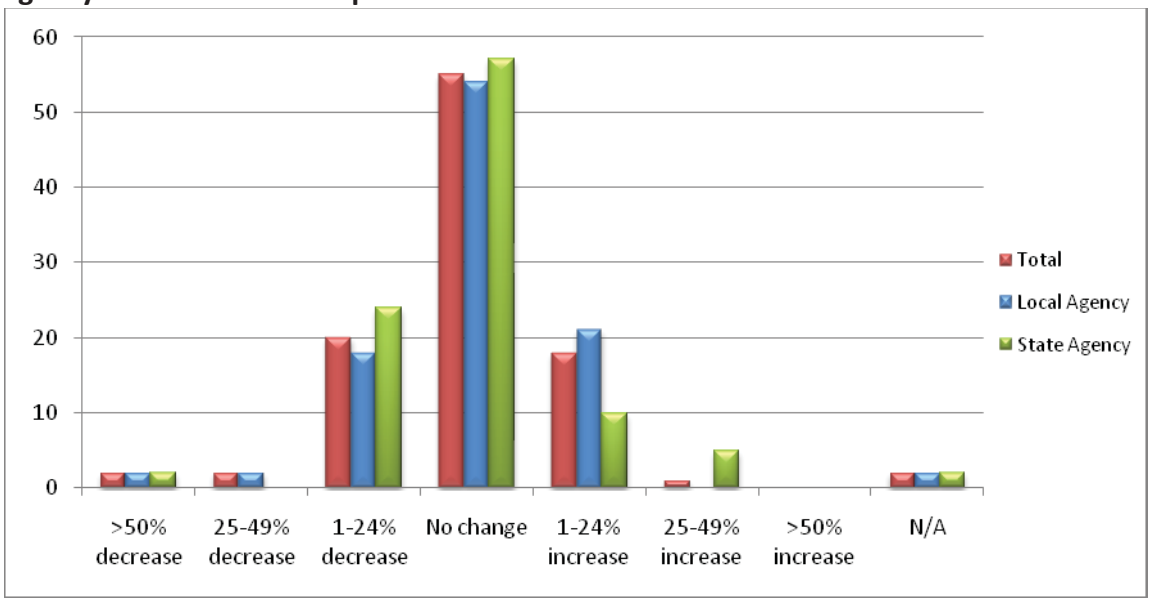
- Loss of assistant director position and delay in filling director position for 8 months

No change

Local Agency

- Increase in facilities - same staff level.
- In Fiscal year 2012 I expect a 25% reduction
- Two years ago we lost 1.0 FTE but we should get it back

Chart 4.1.2 Staff Salaries: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

>50% decrease

Local Agency

- Cut 100 percent
- We are currently on a budget freeze for salaries

1–24% decrease

Local Agency

- 401K contributions have been eliminated
- Furlough & Health Insurance Premiums
- Wages frozen but increased employee share of Health Insurance
- Replacement of Sr staff person and freeze on management salary has decreased total salary costs
- Staff received a one merit step raise this fiscal year along with a 2% bonus. However, beginning July 1 they will have to contribute 5% to their retirement. For most it will be a slight (<3%) negative impact.
- We had to implement a salary freeze for 2009 and 2010 to avoid any layoffs.

State Agency

- Fourteen mandatory furlough days equal roughly a 5% pay decrease.
- Staff salaries were impacted by 5% over the past 2 years by furloughs and decrease of employer paid benefits.

No change

Local Agency

- I personally have only received a $0.50 raise in the two years that I have been here.
- This is the 3rd year of frozen salaries in our county.
- ACTUAL salaries have remained unchanged for the past two years, and we expect them to stay flat for the coming Fiscal Year (2011/2012) However, as noted below, in order to achieve this, we left one position unfilled, creating a 25% reduction in Professional Field staff, and we were forced to eliminate one position in another Division.
- We had no raises in 2010 or 2011.
- Budgetary woes
- Salaries frozen for current fy 2011 and fy 2012
- No increases for 6 years
- No increase in Staff salaries for two consecutive years
- We are about to enter our second year of wage freeze

State Agency

- For the past 4 yrs, no increases. Had 10 day furlough in 2010.
- Cost of life is higher and salaries are the same, all salary raise were put on hold.
- There were 12 furlough days without pay last year and one furlough day every two weeks this year through March. This was followed by a 3% salary increase.

1–24% increase

Local Agency

- Salaries increased by 2% for those staff still remaining.
- Cost of living and planned step increases only.

25–49% increase

Local Agency

- Contractually obligated increase through FY12
- 07/01/10, union represented staff [Environmental Health Specialists (EHS) and Office Assistants] received step

State Agency

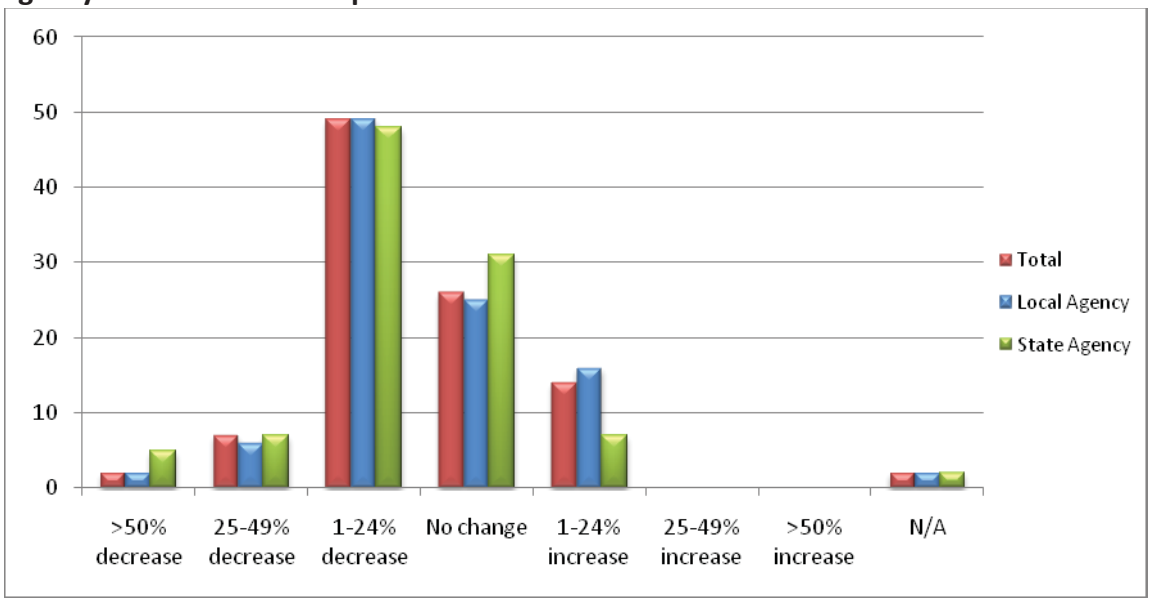
- Base salary means average $15,000 per annual
- Field staff given 2% increase but had to take 2 days furlough.

N/A

Local Agency

- 2009 hours reduced by 20% (worked 32 hr week). Staff 1 clerk, 1 Director, 2 RS. 2010 40 hour week, same staff. 2011 37.5 hr. work week Staff 1 RS/Dir. EH & 1 clerk. No increase in salary.

Chart 4.1.3 Overall Budget: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

>50% decrease

Local Agency

- $8,000 per year, food inspector conduct

State Agency

- State's had austerity measures since 2005. All vacated FTEs are zero out, all expenditures are slashed since 2005. Daily operational costs barely cover expected incurred operation cost.

25–49% decrease

State Agency

- Agency wide cuts have been greater than 40% to date. Expecting at least another 6-10% cut in July.
- We were taken away the first permits given to an establishment decreasing the budget in more than a million

1–24% decrease

Local Agency

- Revenues are down. Some long time businesses are closing routine inspections
- Reduced total revenues by $250,000.
- We experienced a 7% reduction in both total budget and revenues (includes state aid) since last year
- In addition to small cuts in staff compensation, money for training and travel has been sharply curtailed.

State Agency

- 2% reduction.

No change

Local Agency

- Over 125,000 dollars were returned to the county from our program alone
- budget kept same
- Level funded from FY11 to FY12

1–24% increase

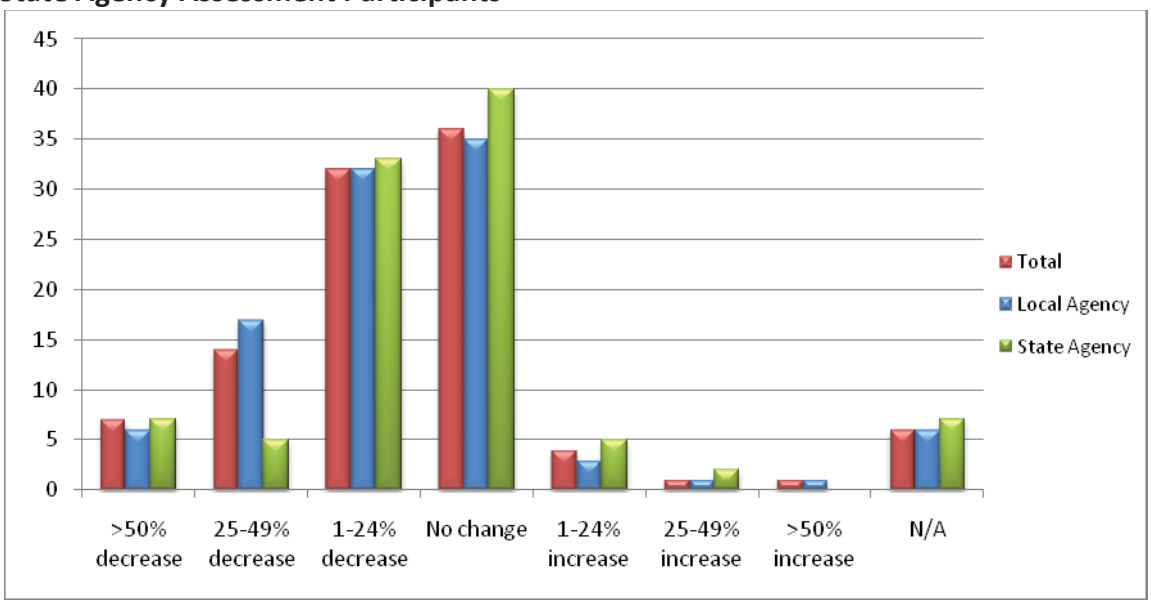
Local Agency

- Number of licensed facilities continues to grow slightly

State Agency

- 3 year grant for rapid emergency response team has supported positions within our agency

Chart 4.1.4 Training Budget: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

>50% decrease

Local Agency

- It has been eliminated.
- Our training budget was decreased from $2,800 for 2009 to $1,000 in 2010 & 2011
- Eliminated for FY12

State Agency

- We have almost no training budget now. Instate training only.

25–49% decrease

Local Agency

- It is hard to get time to attend a conference now even if one pays one's own way. To attend this year's NEHA conference as a speaker I will have to take vacation days.
- Training got cut down to only CEU's required for maintaining your Sanitarian registration. Any additional training in food safety had to be put on hold.

1–24% decrease

Local Agency

- Training limited to local (in state or surrounding states within driving distances.

State Agency

- ALL TRAINING WERE PUT ON HOLD.

No change

Local Agency

- EHS required to obtain CEUs to meet health licensing agency registration criteria

State Agency

- NO actual food safety training carry out since 2005. CNMI relies on the BT program (federally funded) to assist and cover cost of preparedness training.

25–49% increase

State Agency

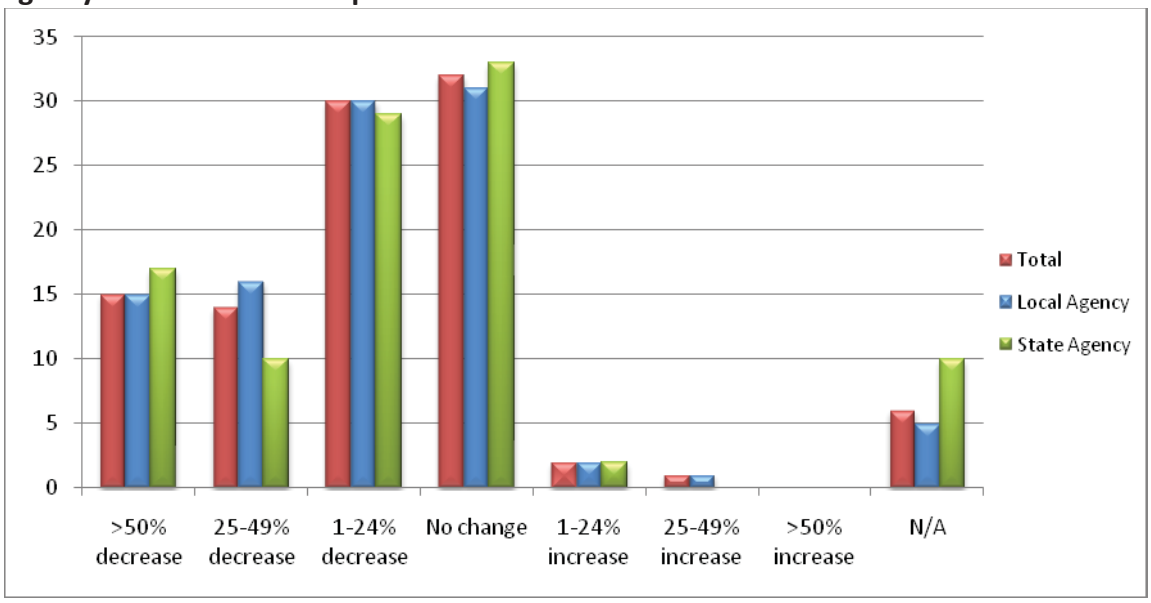
- A fee increase has allowed for increased training to allow for uniformity.

N/A

Local Agency

- Don't have a training budget, only allowed to attend free training that does not involve overnight stays.
- Have no designated training budget. Free or web-based training promoted.

Chart 4.1.5 Travel Budget: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

>50% decrease

Local Agency

- No travel has been permitted unless covered by grant monies.
- Out of town travel is not approved unless it is required by contract or fees paid by the sponsor
- It has been eliminated.
- There is no travel budget
- No out of county travel was approved.
- Eliminated for FY12
- No out of state travel to Natl. Conferences which was strongly encouraged in the past.

State Agency

- Travel restriction to all locally funded TAs.

25–49% decrease

Local Agency

- Since the travel and training budget was cut, I am unable to send staff to quality training events such as NEHA's AEC
- Our travel and conference budget was decreased from $1,500 in 2009 to <$1,000 in 2010 / 2011

1–24% decrease

Local Agency

- No out of state traveled allowed
- Training limited to local (in state or surrounding states within driving distances). Also limited to training forums conducted by Federal Agencies or those that offer inexpensive enrollment.

State Agency

- Only task related travel allowed, no out of state travel unless paid by someone else.

No change

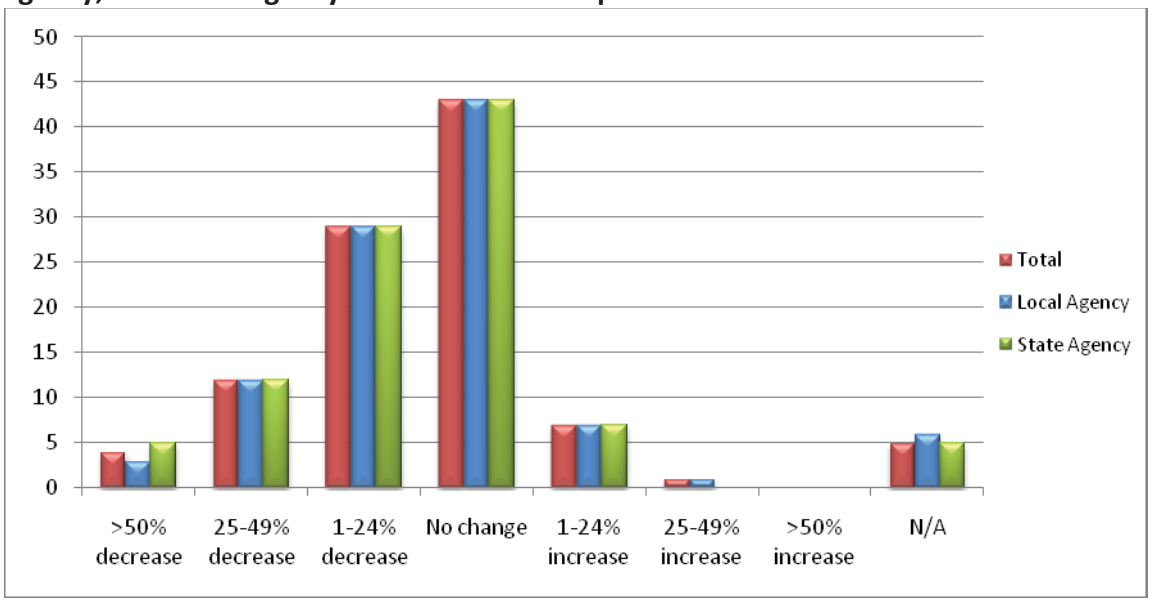
Local Agency

- Travel budget remains the same but we try to provide training on-site to reduce travel

State Agency

- While the travel budget has not been reduced, travel expenditures are less due to travel restrictions.
- While travel budget has not been reduced, travel expenditures have been less due to travel restrictions.

Chart 4.1.6 Technology/Equipment Budget: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

>50% decrease

Local Agency

- Our budget for equipment and technology was eliminated in the 2010 budget year.

State Agency

- Only replaced when essential to completing priority task, with cheapest possible replacement item.

25–49% decrease

State Agency

- 2000 operating computer window would be the latest norm. Basically, ICT equipments are neither from FDA used inventory or "hand-me down" from other federally funded program within department

1–24% decrease

State Agency

- No equipment has been given to the inspectors in many years

No change

Local Agency

- Using what we have, no upgrades or additions of new technology.

1–24% increase

Local Agency

- Replacement of hardware preparing for EH software implementation for Food program.

State Agency

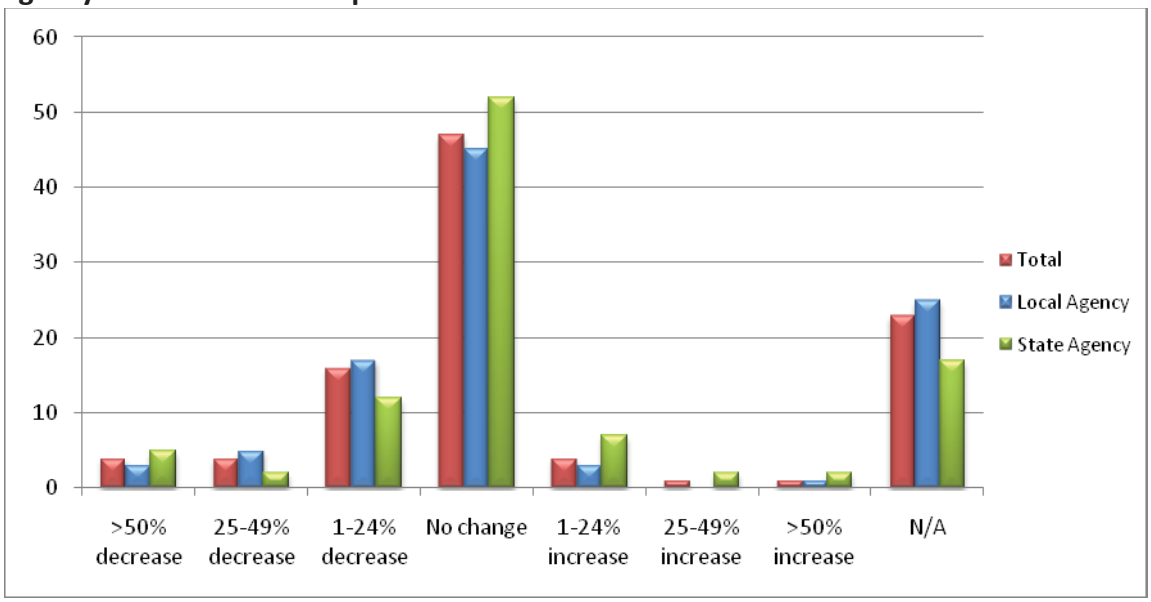
- The same fee increase has impacted our ability to update equipment.
- grant monies from FDA

25–49% increase

Local Agency

- Our IT provider, Northrop Grumman, has sharply raised the seats charges for the IT hardware and software services they provide.

Chart 4.1.7 Grant Funding: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

>50% decrease

Local Agency

- No grant funding

State Agency

- WHO and SPC (regional NGOs partners) sometimes provides technical assistance and funded training in disease surveillance.

25–49% decrease

Local Agency

- 1 FTE may be lost in FY12 due to Federal Funds Reductions

1–24% decrease

Local Agency

- Our Grant & State Aid funding was reduced in the range of 1.1% to >5%

No change

Local Agency

- We receive no grant funding.
- We apply for no grants in the food safety program. All funding is from license fees.
- Did not have any grant funding for food program.
- Summer Feeding program

State Agency

- Able to maintain all levels of grant participation.

N/A

Local Agency

- We do not and have not had grant funding in our food program.

5.0 For your regulatory food safety program, please indicate the degree to which the following programmatic capacities have been impacted over the past two years.

Assessment participants were asked to indicate the degree of increase, decrease, or no change to certain programmatic capacities using a likert scale. Table 5.0.1 shows the programmatic capacities and the degrees of impact indicated by all assessment participants. The number in each box is the percent of the total participants selecting that option. The next two tables show this information specific to local and state agency assessment participants.

Table 5.0.1 Indicated Degrees of Impact to Programmatic Capacities for all Assessment Participants

Programmatic Capacity	>50% decrease	25-49% decrease	1-24% decrease	No change	1-24% increase	25-49% increase	>50% increase	N/A
Ability to support government mandated services	4%	3%	33%	49%	7%	1%	0%	3%
Services offered to retail food facilities	2%	4%	27%	52%	8%	2%	1%	4%
Services offered to other government programs and departments	2%	2%	28%	56%	6%	1%	0%	4%
Services offered to the general public	3%	6%	28%	48%	9%	1%	0%	4%
Partnerships with other groups and organizations	1%	7%	15%	58%	15%	1%	0%	4%
Quality of inspections conducted	1%	3%	19%	54%	14%	3%	2%	3%
Inspection fees	0%	2%	6%	59%	22%	2%	2%	8%
Ability to conduct environmental assessments/ investigations in response to outbreaks	1%	1%	17%	68%	7%	2%	0%	2%
Ability to respond/ investigate consumer foodborne illness complaints	1%	2%	10%	74%	7%	2%	0%	2%
Ability to respond to food recalls	2%	4%	14%	68%	4%	1%	0%	7%
Number of programs supported by your jurisdiction	2%	1%	13%	59%	15%	1%	1%	9%
Outsourcing of programs	0%	0%	2%	67%	3%	1%	1%	27%

Table 5.0.2 Indicated Degrees of Impact to Programmatic Capacities for Local Agency Assessment Participants

Programmatic Capacity	>50% decrease	25-49% decrease	1-24% decrease	No change	1-24% increase	25-49% increase	>50% increase	N/A
Ability to support government mandated services	3%	3%	30%	54%	7%	0%	0%	3%
Services offered to retail food facilities	2%	3%	27%	53%	7%	2%	1%	3%
Services offered to other government programs and departments	2%	2%	26%	58%	7%	1%	0%	5%
Services offered to the general public	3%	4%	27%	50%	9%	1%	0%	5%
Partnerships with other groups and organizations	1%	5%	16%	60%	14%	0%	0%	5%
Quality of inspections conducted	2%	3%	17%	56%	14%	3%	2%	2%
Inspection fees	0%	1%	6%	62%	20%	3%	2%	7%
Ability to conduct environmental assessments/ investigations in response to outbreaks	1%	2%	17%	70%	5%	2%	0%	2%
Ability to respond/ investigate consumer foodborne illness complaints	0%	3%	9%	79%	4%	2%	0%	2%
Ability to respond to food recalls	2%	6%	14%	67%	3%	1%	0%	7%
Number of programs supported by your jurisdiction	2%	0%	16%	57%	15%	1%	1%	9%
Outsourcing of programs	0%	0%	2%	67%	2%	0%	0%	28%

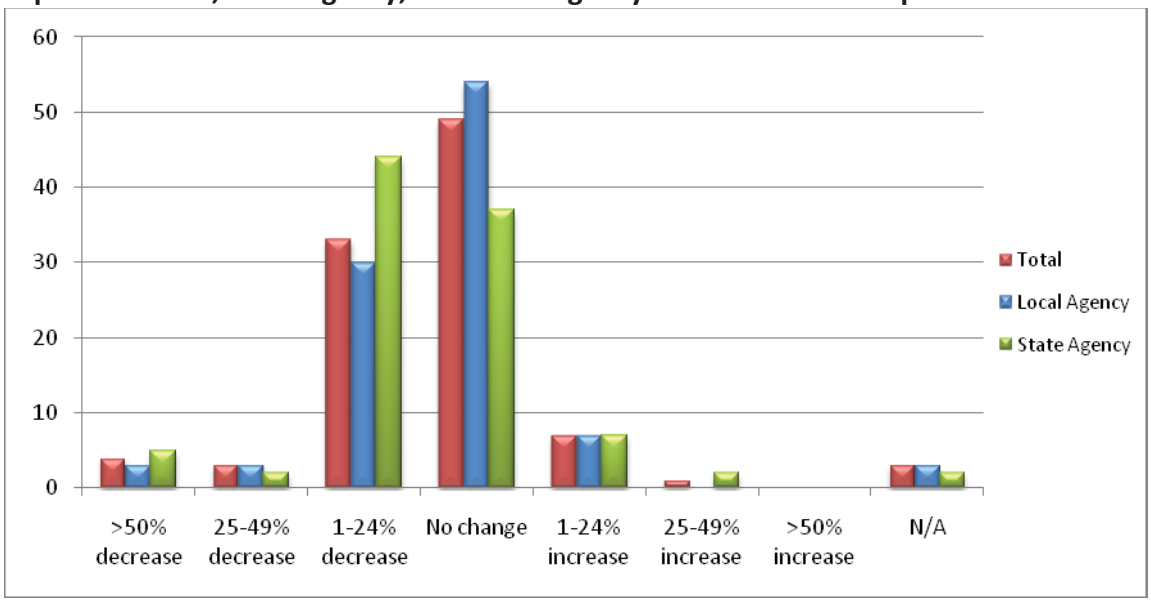
Table 5.0.3 Indicated Degrees of Impact to Programmatic Capacities for State Agency Assessment Participants

Programmatic Capacity	>50% decrease	25-49% decrease	1-24% decrease	No change	1-24% increase	25-49% increase	>50% increase	N/A
Ability to support government mandated services	5%	2%	44%	37%	7%	2%	0%	2%
Services offered to retail food facilities	2%	5%	27%	51%	10%	0%	0%	5%
Services offered to other government programs and departments	2%	5%	34%	51%	5%	0%	0%	2%
Services offered to the general public	2%	12%	32%	41%	10%	0%	0%	2%
Partnerships with other groups and organizations	0%	12%	12%	54%	17%	2%	0%	2%
Quality of inspections conducted	0%	2%	27%	49%	15%	2%	0%	5%
Inspection fees	0%	5%	5%	49%	27%	0%	2%	10%
Ability to conduct environmental assessments/ investigations in response to outbreaks	0%	2%	17%	61%	15%	2%	0%	2%
Ability to respond/ investigate consumer foodborne illness complaints	5%	2%	12%	61%	17%	2%	0%	0%
Ability to respond to food recalls	2%	0%	12%	71%	7%	2%	0%	5%
Number of programs supported by your jurisdiction	2%	2%	5%	63%	15%	2%	2%	7%
Outsourcing of programs	0%	0%	0%	68%	5%	5%	5%	22%

5.1 Comparison of Total and Local and State Agency Percentages

The next set of charts (5.1.1 –5.1.12) show the percentages of assessment participants indicating the different levels of change for each programmatic capacity. Following the charts are comments made for each specific degree of impact. The charts also compare responses for all participants to responses from local and state agency participants.

Chart 5.1.1 Ability to Support Government Mandated Services: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

>50% decrease

State Agency

- CNMI prioritized food safety mandated retail outlets establishment food safety inspection. Other mandated program are not regularly schedule

1–24% decrease

Local Agency

- Staff has been reduced to 90% time in the food program.
- Loss of personnel increase work load on remaining personnel.
- We have reduced food safety program inspection frequencies slightly and dropped non-mandated programs.
- Reduced personnel resulted in prioritizing activities to offer optimum levels of support based on availability.

State Agency

- This will continue to decrease.
- Regulatory inspection program has experienced reduction in available work force due to both hiring restrictions and economic attrition with staff leaving for better pay opportunities.
- Due to 3 furlough days/month. No position losses

No change

Local Agency

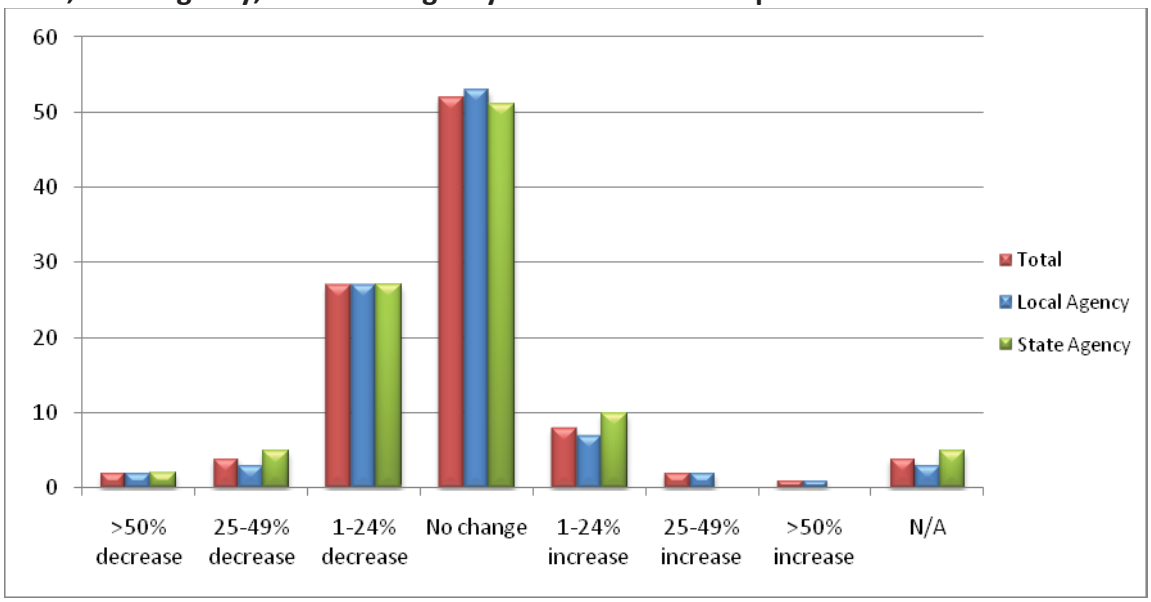
- Continues to be an area of concern.
- Our major program cuts were 5 years ago- program cut by 50%

1–24% increase

Local Agency

- Fewer staff, small geographical area to cover, more time to meet requirements

Chart 5.1.2 Services Offered to Retail Food Facilities: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

>50% decrease

State Agency

- Very little is offered other than some group training classes.

1–24% decrease

Local Agency

- Ability time wise to be interactive with industry people for comprehensive education regarding food safety.

No change

Local Agency

- We increased permit fees
- Have worked hard to maintain services to the food establishments since we have not reduced their fees. Have not increased fees either.
- In NY, retail food services and regulation are provided by Ag & Markets, DOH responsible for commercial food service establishments
- 50% cut 5 years ago

1–24% increase

Local Agency

- We are doing more food safety outreach and education with industry.
- We have increased our educational opportunities for food operations by providing food safety education (ServSafe) at a minimum price and free one on one training.

State Agency

- Annual basic food safety training for retail outlet (food handlers). Bi-annual establishment inspections.

>50% increase

Local Agency

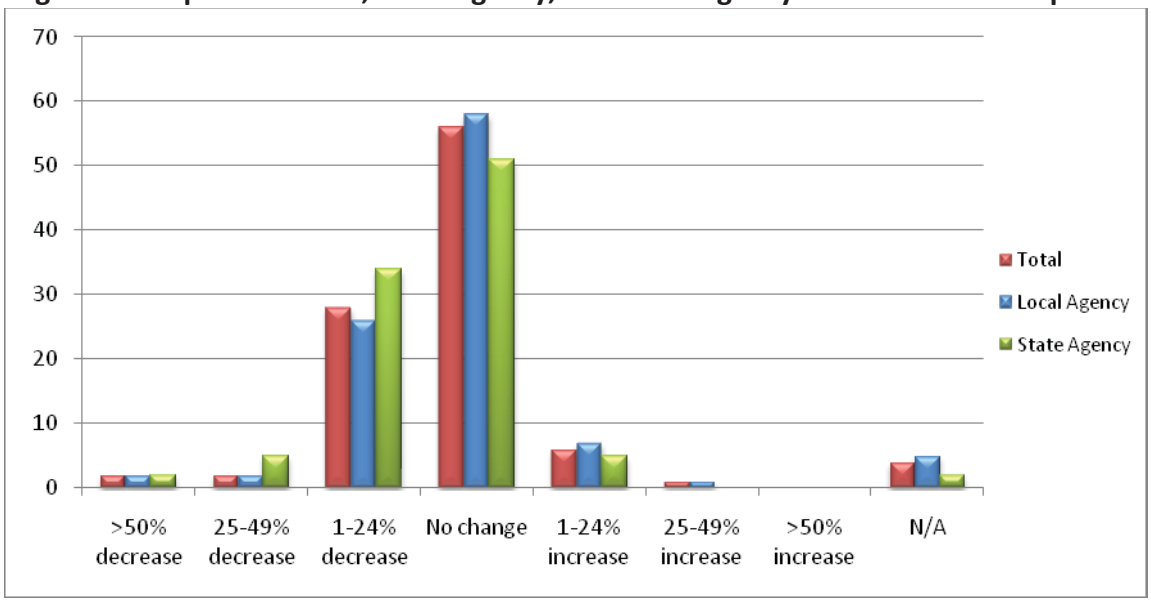
- Increased # of certified manager classes 2x

N/A

State Agency

- Handled by Local Health Departments

Chart 5.1.3 Services Offered to Other Government Programs and Departments: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

>50% decrease

State Agency

- Very little is offered other than some group training classes.

1–24% decrease

Local Agency

- Consultation and collaboration with others. Building, planning, local gov'ts is diminished due to time constraints. Demanded service only.

No change

Local Agency

- We continue to do more with less
- 50% cut 5 years ago

State Agency

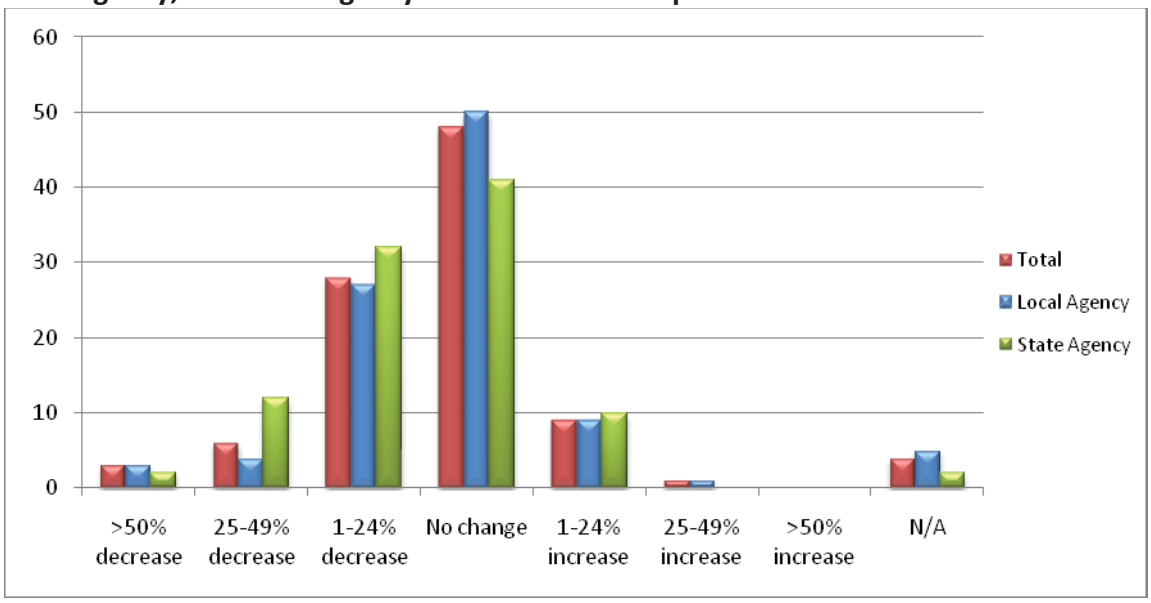
- Promotion and presentation of personal hygiene, NCDs program such as tobacco cessation, proper diet and better choices to improve lifestyle at respective gov'tal department

1–24% increase

Local Agency

- Additional inspections at schools
- The food inspection program works very close with the Stark Co. Plumbing Program during the food service plan review process to ensure operations are properly plumbed. In addition, the food inspection program works with the 9 sewer districts in our health jurisdiction to ensure proper grease trap size, installation, and maintenance.

Chart 5.1.4 Services Offered to the General Public: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

1–24% decrease

Local Agency

- Reduce the number and level of non- mandated services (complaint investigations, on-site investigations etc.) based on available personnel.

State Agency

- We no longer provide certified food protection manager courses. Iowa State University has filled this gap.
- Decrease due to 3 furlough days/month.

No change

Local Agency

- Our department has a "dilemma" person who fields walk-ins and phone calls so we have coverage even when the food staff person is not in the office for whatever reason.
- These services were already somewhat limited.
- Trying to keep this level of involvement in check.

1–24% increase

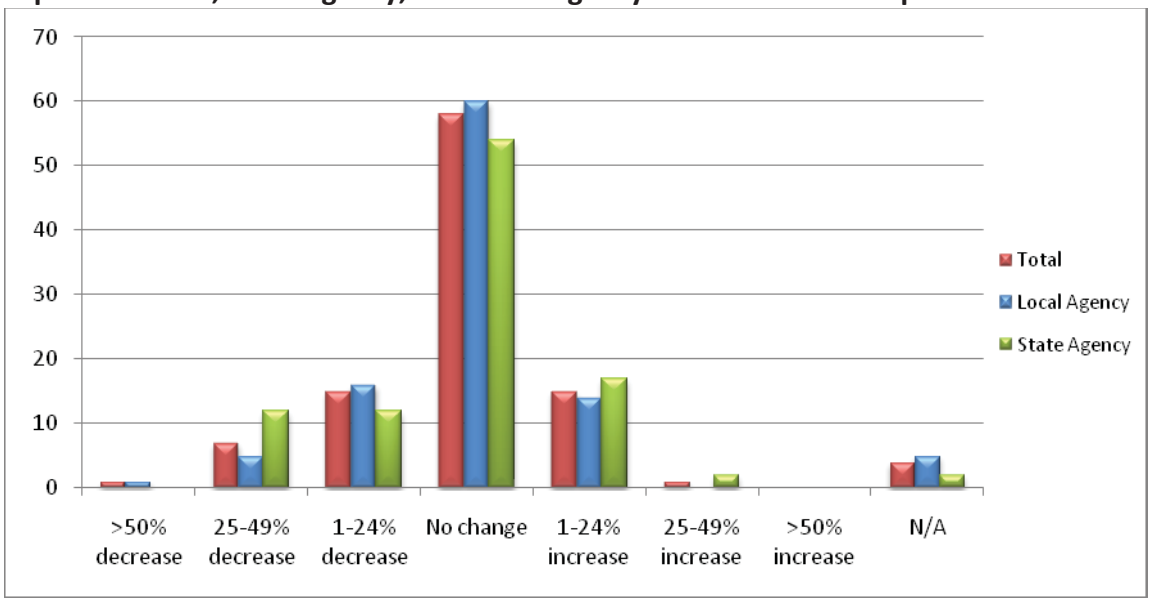
Local Agency

- The Environmental Division of the Stark County Health Department Food Inspection Program provides the following services to the public:
    - Inspects and regulates every type of food service and food establishment - restaurants, caterers, institutions, retail markets, mobile vendors, temporary and seasonal food facilities.
    - Investigates citizen complaints about unsafe or unsanitary conditions in food service and food establishments.
    - Investigates allegations of contaminated food and food-borne illness.
    - Provides food safety certification course and exam for basic food safety training to anyone willing to learn.
    - Offers food safety information to the public.
- Added health education component

State Agency

- Health advisory press releases on disease outbreaks, environmental issues affecting food sources and zoonotic issues affecting for food chain.

Chart 5.1.5 Partnerships with Other Groups and Organizations: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

1–24% decrease

Local Agency

- Diminished due to limited staff and time constraints. Difficult to be proactive with limited staffing.

State Agency

- due to 3 furlough days/month.

No change

Local Agency

- They don't have any more money than we do and are unwilling to share responsibilities.....

State Agency

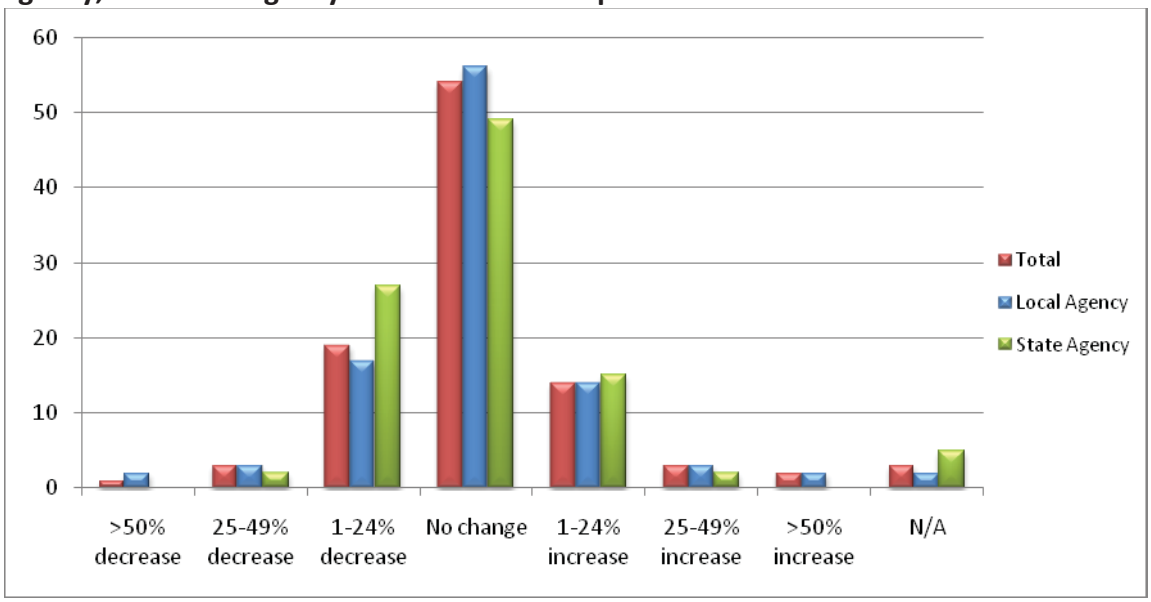
- Environmental Health program is integrated partner in promotion of NCDs programs with community. Partnership, includes Public School system, community coalitions such as Diabetes, Cancer, hotel associations.

1–24% increase

Local Agency

- re; training and strategic planning, increased engagements with other organizations
- We are seeking more partnerships in order to stretch our resources farther.
- Partnerships include: Stark Co. Plumbing Department, Stark Co. Building Department, 17 local fire departments, 9 local sewer districts, Stark Co. Fire Inspector Assoc., Community Harvest of Stark Co., Stark Co. Board of Education, Tri-County Restaurant Assoc., Ohio Environmental Health Assoc., Assoc. of Ohio Health Commissioners, Ohio Grocers Assoc., Ohio Retail Food Safety Advisory Council
- Conducting a community health assessment

Chart 5.1.6 Quality of Inspections Conducted: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

No change

Local Agency

- Working hard to maintain quality inspections. Results are posted in the local newspaper.
- We strive to be consistent and that all inspections are conducted at high level
- Public health risk reduction is a priority
- We will continue to inspect according to MI law and Federal food code.
- Only in frequency of inspections conducted however quality of services have not changed
- We maintain our standards of quality--just reach less establishments

State Agency

- We are stressing that no matter what the frequency, quality of inspections must be maintained.
- Most of the Environmental inspections are sanitary condition assessment and NOT risk base inspection.

1–24% increase

Local Agency

- Our QA program has improved under the leadership of a new supervisor.
- We have implemented a Quality Assurance Program for field inspections and administration.
- Always striving to increase quality of inspections, difficult to accomplish when trying to meet state intergovernmental agreement

State Agency

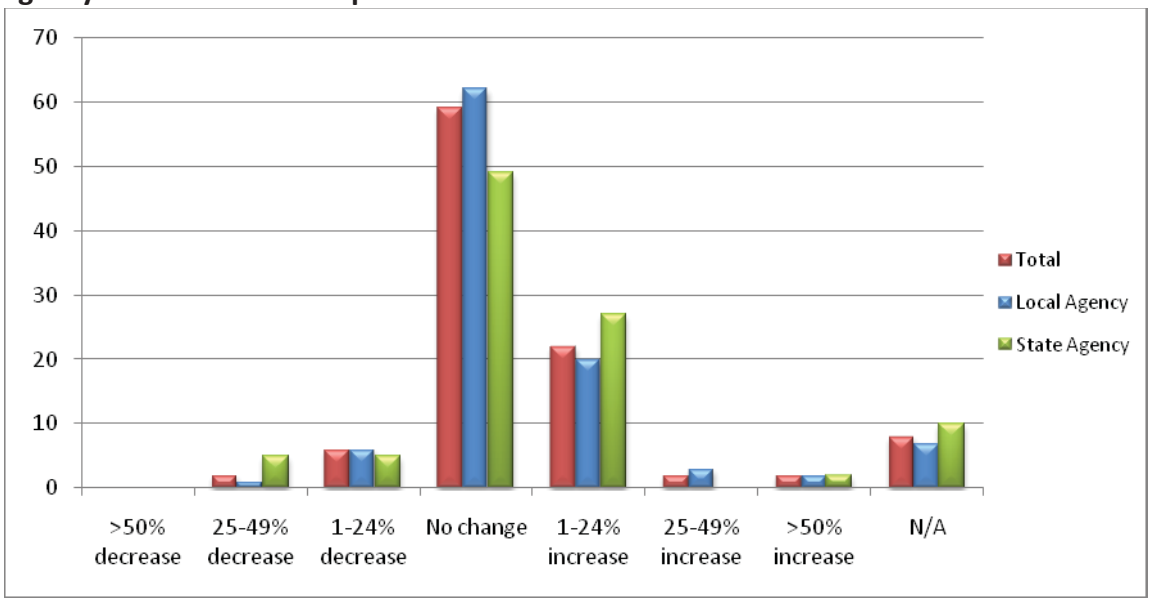
- We have great inspectors

25–49% increase

Local Agency

- Significant changes allow more time to spend with each facility. We can focus on quality of inspections over quantity of inspections.

Chart 5.1.7 Inspection Fees: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

25–49% decrease

State Agency

- Inspection fee are nominal at best. Average permit fees is $50. per establishment, renewal yearly basis

1–24% decrease

Local Agency

- Since 2008 state fees went from $100 to $285 and back down to $40. City fees went from $0 to $50.

No change

Local Agency

- In NC there is no fee established at the local level
- Have remained the same for 3 years.
- Fees in Iowa are set by legislature. Fees severely inadequate.
- With a down economy, unable to increase fees to make up for lost revenue.
- There will be an increase in fees soon.
- Last increase in fee's was 5 years ago, fee's will increase in 2012
- These have stayed the same due to the salary freeze.
- There has been no increase in fees while costs continue to increase so we are operating the program at a loss each year.
- Pending increases of 10% (last increase was in 2006)
- Using the state cost methodology the fees change slightly either up or down but overall revenue has been stable
- No changes to food service license fees (restaurants, mobile food units, commissaries, vending machines, temporary restaurants) - mobile food units increased a little but commissary fee decreased.

State Agency

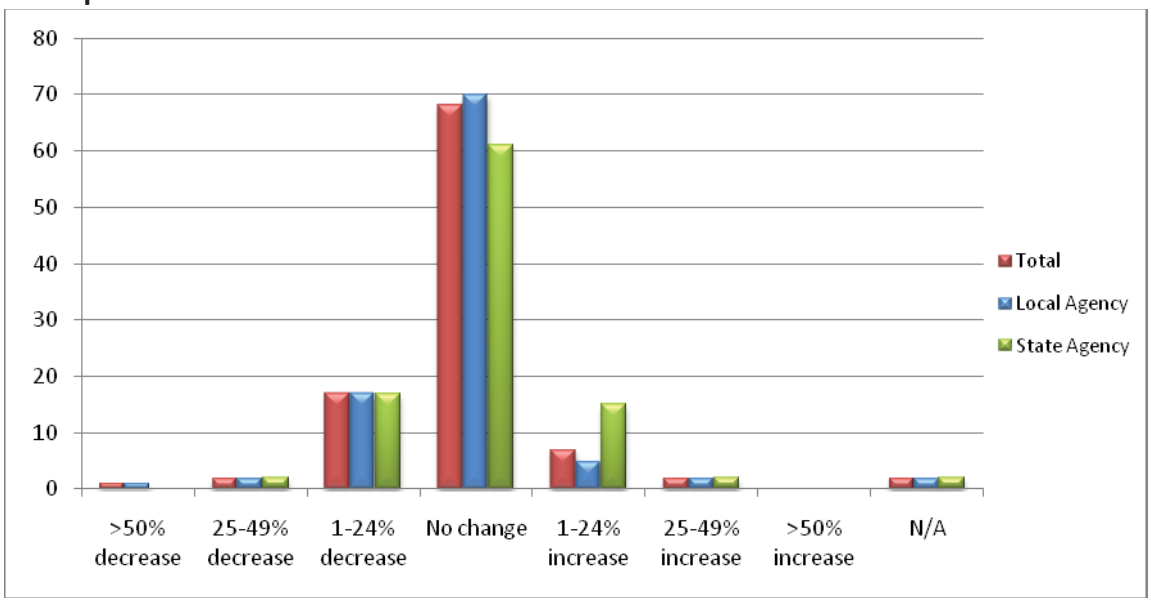
- No change and no hope of getting them changed.
- Proposed bill in 2010-11 to increase fees, governor would not allow.

N/A

Local Agency

- No inspection fees, however we now issue citations for repeat offenses with a $50 fine--no longer have the luxury of handholding and repeat visits

Chart 5.1.8 Ability to Conduct Environmental Assessments/Investigations in Response to Outbreaks: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

1–24% decrease

Local Agency

- There has been a 25% decrease in staffing in the Office of Epidemiology due to unfilled vacancies.
- I think our capacity is reduced. We have lost 4 sanitarians, a coordinator and a director in one year. If we had a full blown outbreak, we would not be getting any regular work done, inspections would go over due to spend time on investigation. I only have bare minimum staff to complete inspections.
- Smaller foodborne illness complaints or institutionally associated diseases (daycares) are still investigated by our Dept. Larger events are relegated to the State
- We contract with a VNA to do disease investigations. Sometimes coordination with environmental assessment is weak

No change

Local Agency

- Primary public health function, given top priority.
- EPI training continues to be emphasized
- We have not reduced staffing/commitment to this high priority item.
- All of the food inspectors have the ability to investigate outbreaks. I did not mark a change here because we have not added any additional personnel.
- Public health risk reduction is a priority
- no change, we continue to prioritize environmental assessments/investigations - budget for investigations were reduced minimally

State Agency

- This is job one, we will drop everything to follow up on outbreak responses.

1–24% increase

Local Agency

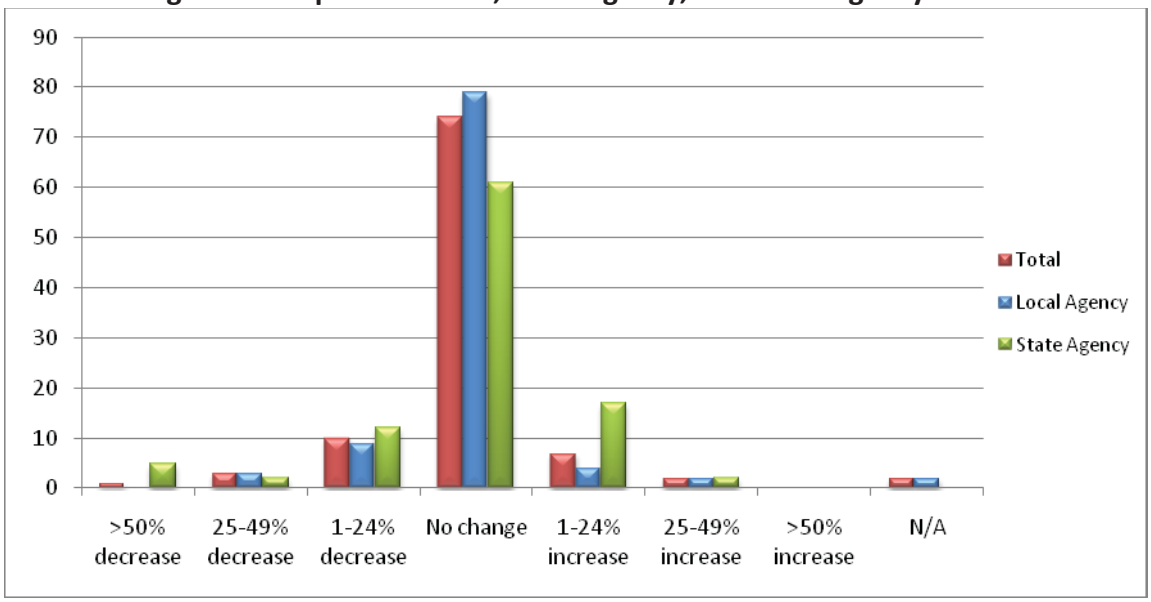
- In the event of an outbreak, our county public health, env. health and the county who handles our food inspections would work together.
- Reviewed CIFOR guidelines, updated all policies, included CIFOR guidance on env assessments, achieved compliance with FDA Standard # 5 on foodborne outbreak response

- Using the services of the epidemiologist to assist the sanitarian and nursing staff

State Agency

- Increased due to in house training.
- Staff are well trained respondents to environmental, disease and/or food/water/vectorborne outbreaks. CNMI is located in the tropics and geographical located within tropical disease environment and situated between mainland Asia and continental USA.

Chart 5.1.9 Ability to Respond/Investigate Consumer Foodborne Illness Complaints: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

>50% decrease

State Agency

- Most follow up is done by phone now, however thanks to a grant position we are attempting to conduct enteric questionnaires with all illness complainants.
- Environmental staff are well-train to respond to Health emergency, such as disease outbreaks and/or environmental disaster

No change

Local Agency

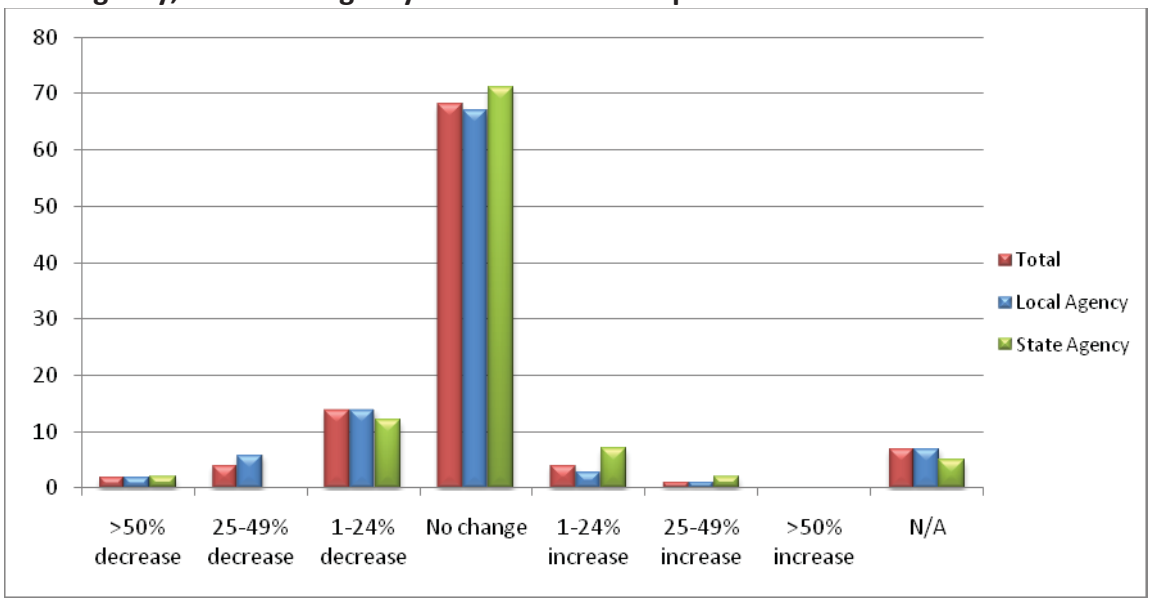
- Public health nurses assist.
- We still begin investigation within 24 hrs of receiving complaint.
- We have not reduced staffing/commitment to this high priority item.
- Public health risk reduction is a priority
- Depending on magnitude of the event.
- no change, we continue to prioritize investigation of foodborne illness complaints - budget for investigations were reduced minimally
- 50% cut 5 years ago

1–24% increase

State Agency

- Increased due to in house training.
- We have focused resources leveraging some homeland security funds to improve this system dramatically.

Chart 5.1.10 Ability to Respond to Food Recalls: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

>50% decrease

State Agency

- CNMI comprises of 3 inhabited islands. All food sources are either locally grown-produced or imported. Environmental staff network (email & phone) with each offices and other food regulating gov'tal agencies are in are members of the recall team and in the loop on notification of recall neither from FDA, USDA or WHO.

1–24% decrease

Local Agency

- We would not be able to respond to our State's request for local help.
- This area could be done better, but it would require additional personnel.
- change in response to notification-- electronically-no longer do site visits unless specifically requested
- Too many coming in to address all especially with reduction in staff. Do a risk assessment and address most critical.

No change

Local Agency

- In this state most of the recall work is done by the state Department of Health.
- Recall effectiveness checks are rarely conducted; only when requested by the state health dept.
- Ag & Mkt responsibility
- Public health risk reduction is a priority
- RE: all of above. We are operating at minimum staff to deliver present service level. If anyone gets sick, we are understaffed.
- majority of food recalls are performed by state department of agriculture

State Agency

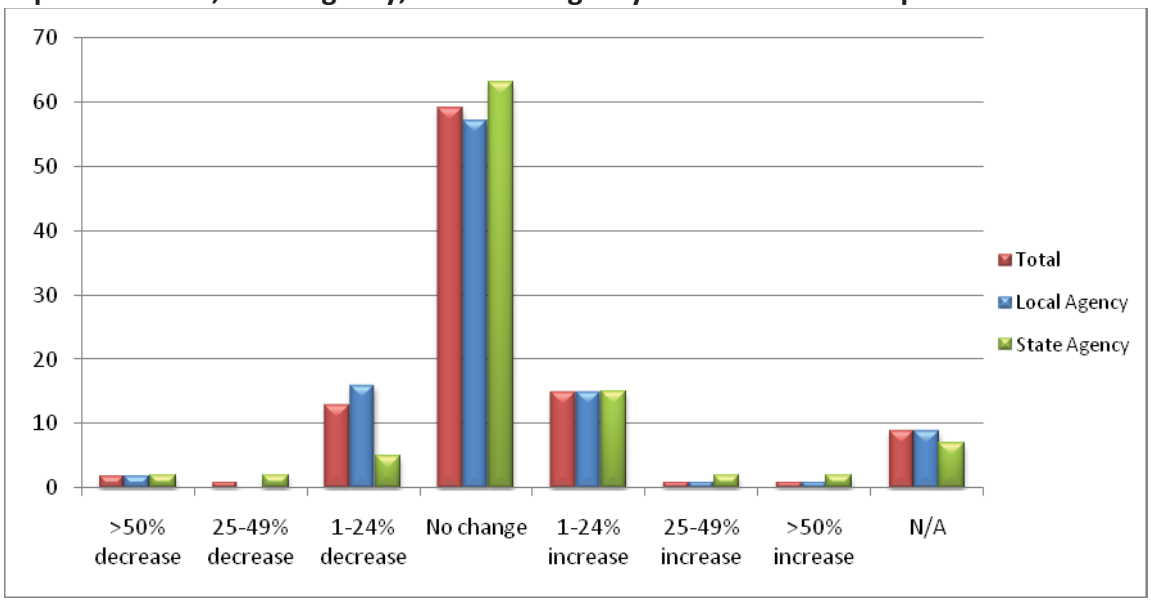
- We have never had this ability and have no mandate by law to do so.

N/A

Local Agency

- The Dept. of Agriculture handles food recalls in Virginia.

Chart 5.1.11 Number of Programs Supported by Your Jurisdiction: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

>50% decrease

State Agency

- All potential issues that have adverse affect on health and wellbeing of general public, visa vi environmental issues, man-made issues, biological or chemical issues.

1–24% decrease

Local Agency

- We have eliminated inspection of health clubs and laundromats, reduced inspection of hotels, and begun inspecting massage therapy and personal grooming establishments only if there is a complaint.

No change

Local Agency

- Continues to be a struggle to maintain.
- restaurants, mobile food units, mobile unit commissaries, vending machines, food service at bed and breakfast accommodations and temporary restaurants
- Working more hours with less staff.

1–24% increase

Local Agency

- We are generalists. We work with septics, wells, complaints, food establishments, and to a lesser degree lead risk assessments.
- Added Tanning facilities and responding to gas drilling complaints are added programs, increased workloads in aquatic recreation and public water supply programs.
- 26 Environmental Health Programs

>50% increase

Local Agency

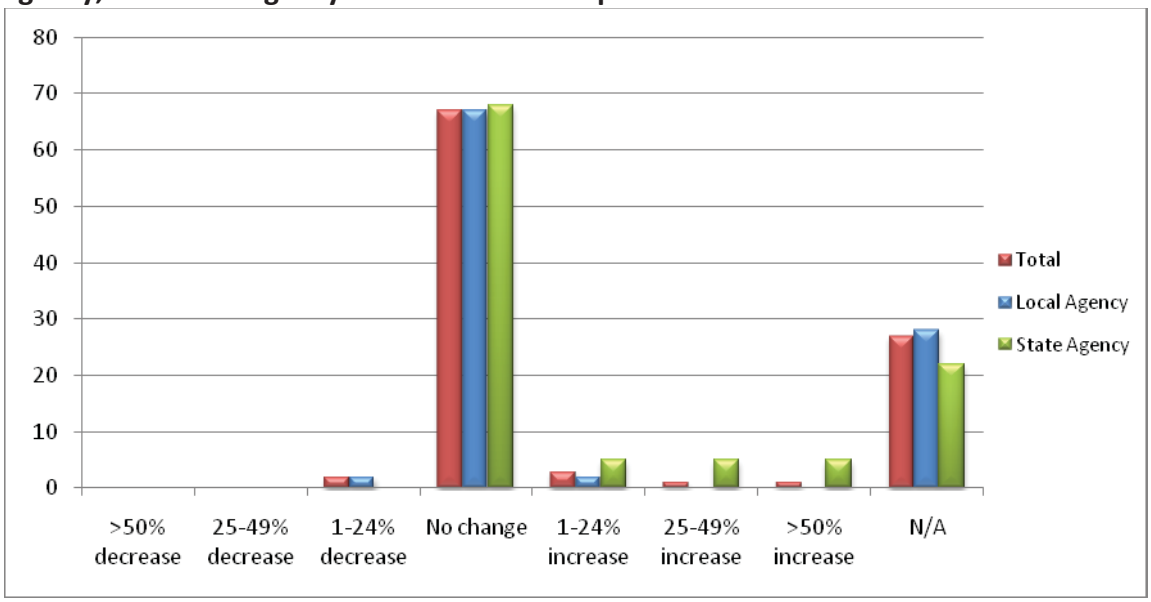
- 'do more with less', new regs and programs in all areas of EH continue to land in our jurisdiction--not just food

N/A

State Agency

- We are the statewide program

Chart 5.1.12 Outsourcing of Programs: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

No change

Local Agency

- Have discussed this possibility, but no change at this time.
- No one to outsource to, other than privatizing our Home Care Program, which will decrease overall PH staff by >50% by end 2011, and further diminish our capacity to respond to outbreaks due to loss of nursing staff

1–24% increase

Local Agency

- With limited staff any program function necessary like continuing education for industry is outsourced.

>50% increase

State Agency

- Appropriate funding is strictly for personnel. All others had been suspended during the austerity measure taken by the State gov't.

6.0 If you indicated in the question above that programs have been decreased, increased, or outsourced, please identify these programs and the extent to which they have been affected.

6.1 Program Effects at the Local Agency Level

6.1.1 Decreases

Inspections

- frequency of food inspections;
- Fewer itinerant food inspections
- DOH no longer inspect child care, hospitals, not for profit/churches or nursing home food service operations, now no inspections are made or are made by non-health entity.
- We have eliminated inspection of health clubs and laundromats, reduced inspection of hotels, and begun inspecting massage therapy and personal grooming establishments only if there is a complaint. We have used the current financial crisis to eliminate or reduce programs with low public health impact.
- Frequency of inspections will also be diminished.
- THE NUMBER OF FOOD SERVICE INSPECTIONS ARE DOWN HOWEVER WE HAVE NOT LOST OR LOWERED THE QUALITY OF THE INSPECTIONS THAT WE PERFORM

Programs/Capacity

- Reduction in quality assurance.
- Encephalitis monitoring program funding has been removed. It was a financially losing program in the past now made worse.
- Mosquito collections for west nile virus surveillance has been stopped. 16 hr servesafe training has been replaced with a 4 hour person in charge class. Changes have been made in our temporary food licensing program. Less flexibility in all programs in attempt to maintain as many services as possible with fewer people
- Programs Decreased: "Nuisance" complaints such as backyard trash complaints;
- The state mandated programs have been a challenge to fund at the same level due to budget cuts.
- Food Safety support will decrease additionally negatively impacting our ability to effectively respond to complaints, recalls and food borne illnesses
- Food, Lodging and Institutions inspections
- Food Program - quality and timeliness has decreased as staff members have decreased.
- Air Quality - response time has dramatically decreased due to low staff and equipment and supplies decrease.
- have quit inspecting mobile home parks.
- Our Mobile Home Park Program was eliminated in the last two years.
- Decrease in programs is to the extent that public health risk is not compromised but the program is lacking some elements that would make it better and more comprehensive (ie industry education, formal or one on one, staff training, and slowing of the internal quality improvement process)

- Decreases have occurred in areas that were additional activities we performed ie additional training to food establishments Dept considered signing onto the FDA retail standards program but due to resource limitations and additional department tasks
- generally across the board---we haven't necessarily eliminated factions (town political machine will not allow that to necessarily happen) we just take much longer to achieve results or required intervals are not met. Also, adopt new ways to get the job done--notify businesses by fax and email of minor patron complaints and request remediation and written response; 'empower' residents to try to find solutions by communicating to others of their complaints i.e. trash; minor housing concerns; etc before filing formal complaints with the Dept. Not outlined or condoned anywhere in the regs but you have to find different solutions and approaches in order to maintain some sort of public/env health priorities for the community as a whole. " Should I work on implementing the new beach regulations for my 30+ beaches or chase after an overflowing dumpster?" Resource allocation and community priorities.

Staff Size

- Reduction in clerical staff
- program field staff decreased by 60% and frozen/non-funding of positions.
- privatizing our Home Care Program, which will decrease overall PH staff by >50% by end 2011, and further diminish our capacity to respond to outbreaks due to loss of nursing staff
- Staff in program has decreased. We have not reduced our program. Same amount of work exists. :-)
- In 2007 there were 3 staff RS, 1 Director, 1 clerk. 2011 there is 1 RS/Dir. & 1 clerk. This has affected all environmental health programs. Our dept. has 18 EH programs, Animal bites to Water, etc.
- It is anticipated that if we have staff reductions in FY 12 we will scale back our services which are not statutorily required, such as in-service food safety training.
- We laid off one full time inspector. We have hired a per diem inspector. We only Have 1 full time inspector therefore our response time to emergencies have been diminished.

Staff Time

- Employees required to furlough.

Training/Outreach

- Reduced or eliminated various educational events.
- training classes, both presented and attended.
- Food Safety Classes are not going to be offered as often as planned.
- The food manager's training program has been discontinued.
- no food service classes offered, no school consumer protection in-services offered, Public information meetings
- Not be able to offer free educational material to general public
- lost ability to offer Spanish ServSafe courses

Travel

- Eliminated all travel for employee training.

- have to cut the travel cost to obtain and offer trainings

Response
- Reduction in ability to respond to recalls.

6.1.2 Increases

Fees
- Food Program fees increase as indicated in cost methodology used. Takes into account increasing overhead costs such as fuel, utilities, employees health insurance premium increases
- Fees went up with the consumer price index for the 2011 year
- License and inspection fees increase a small percentage annually.
- Increase in permit fees.

Training/Outreach
- As the public becomes more educated in Food Safety, their demand for services has only increased every year since I have been here. I have work for Stark Co. for 18 years.
- increased certified manager classes temporarily to meet demand. Self supporting program
- Most program increases have resulted from increased training for me. I have been in charge of the food safety program for 1.5years and had no job-related experience before taking the position.

Workload
- With existing staff we have taken on a major role with stormwater regulations.
- More areas of responsibility/inspections have been acquired.

Inspections
- We enrolled in the FDA Program Standards, and as a result, we have increase inspection frequency of more complex restaurants (better service to the public)and has improved the training and uniformity of inspections among inspectors (better inspection quality)

Other
- increase in customer waiting time and response to phone calls.
- The number of food facilities in the county has increased [but one inspector position has been eliminated.]
- There has been an increase in grant application to retain current staff.
- mobile food facilities increased significantly, caterers increased significantly

6.1.3 Outsourcing

- Outsource of work is done by obtaining part time people to conduct work in program areas that cannot be taken on by current overloaded remaining staff. Mainly in the area of formal education to industry.
- Total food inspection program removed and workload sent to 1.0 FTE who handles all health related matters for municipality

- Our food borne investigations have been reassigned to our epidemiology program. If they determine that there is an outbreak we are then dispatched to investigate (with lag time)
- Have stayed the same but we are seriously looking at outsourcing some of our food inspections to a consultant on an inspectional fee paid basis w/out benefits.

6.2 Program Effects at the State Agency Level

6.2.1 Decreases

Funding

- funding

Inspections

- We have had to limit the number of state inspected meat plants that want to come under inspection due to not being able to increase staffing numbers.
- mandated inspections of none prioritized sectors
- Reduced routine inspections of state licensed facilities.
- Inability to fill vacant positions has resulted in a decrease in food inspections in most areas (milk, shellfish and contract inspections are still conducted according to mandates).

Programs/Capacity

- food safety, recreational programs (campgrounds, pools, tourist rooming houses)
- food defense/emergency preparedness eliminated, shellfish reduced
- Outbreak response capacity. no ability to implement system wide capacity
- Mandated work and complaints are priorities. All other work has been affected adversely to some extent.
- Furlough days impact the quantity of services rendered

Resources

- resources

Staff Size

- retirements w/o filling programmatic slots
- personnel
- Lost 1 compliance manager, 1 regional manager in the dairy program, 1 regional manager in the food program, lost 3 inspectors in the food program, quality of inspection remains the same, however, service level related to frequency has decreased significantly,

6.2.2 Increases

Complaints

- Increased: Frequency of environmental & sanitary residual complaints.

Fees

- WV has started charging permit fees for the Retail Est. that are owned/operated by the State and inspected by State staff.

Training

- Increased due to in house training. We now have an Enteric Disease Epidemiologist on staff who is conducting training.

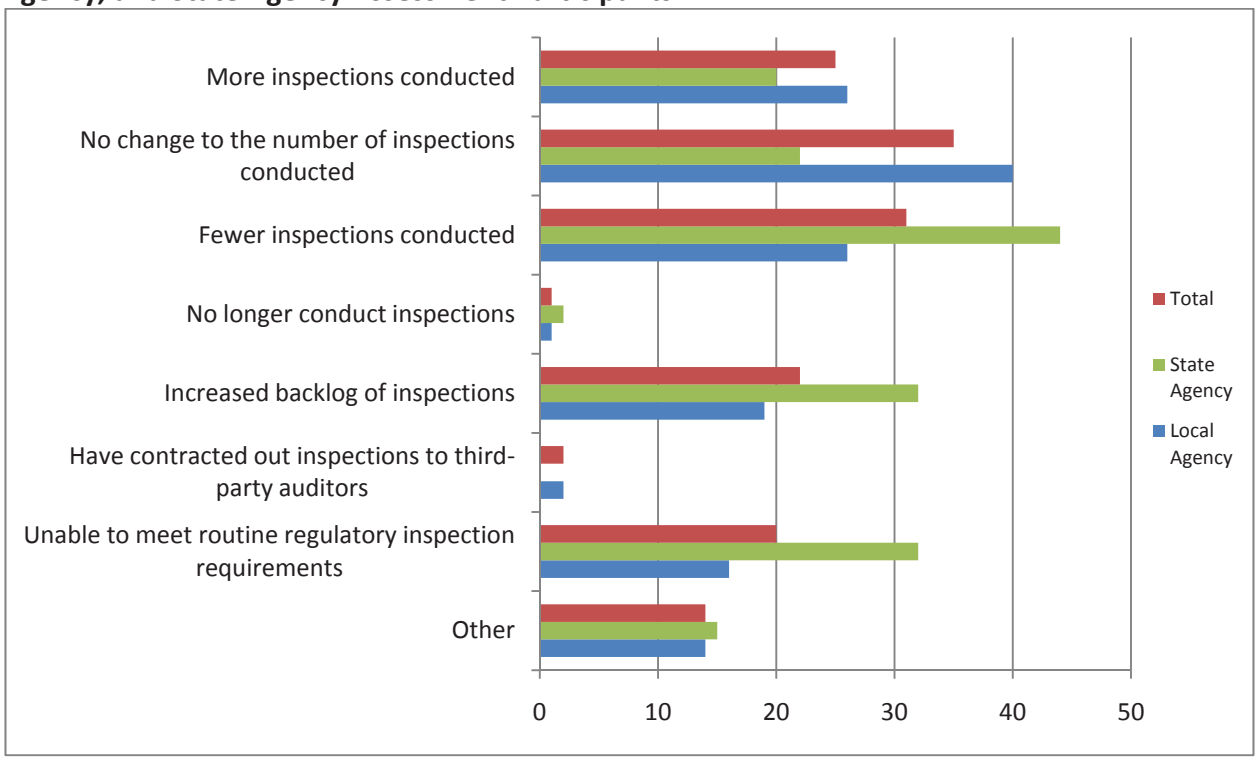
6.2.3 Outsourcing

- Two counties have received delegation to conduct program activities for the retail food program.

7.0 Please indicate any impacts experienced in your regulatory food safety program's inspections over the last two years. Check all that apply.

Assessment participants were asked to indicate any impacts experienced in their regulatory food safety program's inspections over the last two years. They were allowed to check all options that applied to their program.

Chart 7.0.1 Percent of Regulatory Food Safety Program Inspection Impacts Indicated by Total, Local Agency, and State Agency Assessment Participants



Other Responses

Local Agency

- Inspections handled by another county; local public health & EH assist with investigation of outbreaks
- Only change has been more tem event weekend inspections
- We have applied new technology (dashboard tools) to help staff better identify what inspections are due
- We are not doing some of the extra things we like, such as education and outreach. Just performing the basics.
- Decrease in quality of inspections, less time/inspection
- No response/investigation to "nuisance" complaints
- More facilities to regulate
- Director has changed regs to favor industry and increased threats to public health
- Increase in food recalls
- Additional tasks within the dept are required
- Unable to meet inspection frequency timely
- Fewer inspections conducted because of fewer food facilities
- Decrease in quality inspections due to reduced staffing
- We are seeing more temporary food service activities
- Charge for additional inspections

State Agency

- Prioritizing workload has become more acceptable
- Fewer inspections conducted because there was a field sanitarian vacancy for 2 months
- Increase in # of FDA contracts conducted
- ODH does not conduct the inspections
- Third parties are conducting school inspections since 2006

8.0 Specific to your regulatory food safety program's capacity to investigate and respond to foodborne illness outbreaks, please indicate the degree to which the following have been impacted over the past two years.

Assessment participants were asked to indicate the degree of increase, decrease, or no change to their regulatory food safety program's capacity to investigate and respond to foodborne illness outbreaks using a likert scale. The following table shows all of the capacities and the degrees of impact indicated by assessment participants. The number in each box is the percent of the total participants selecting that option. The next two tables show this information specific to local and state agency assessment participants.

Table 8.0.1 Indicated Degrees of Impact to Regulatory Food Safety Program Capacity to Investigate and Respond to Foodborne Illness Outbreaks for all Assessment Participants

Regulatory Food Safety Program Capacity	>50% decrease	25-49% decrease	1-24% decrease	No change	1-24% increase	25-49% increase	>50% increase	N/A
Program funding	1%	4%	22%	61%	6%	1%	0%	5%
Staff size	3%	5%	29%	53%	5%	1%	0%	4%
Training for staff	3%	11%	21%	47%	12%	1%	1%	4%
Qualifications and competency of staff	1%	1%	8%	65%	20%	2%	0%	3%
Other food safety workload expectations	1%	3%	8%	53%	28%	3%	1%	4%
Other workload expectations	3%	3%	8%	43%	34%	7%	0%	4%

Table 8.0.2 Indicated Degrees of Impact to Regulatory Food Safety Program Capacity to Investigate and Respond to Foodborne Illness Outbreaks for Local Agency Assessment Participants

Regulatory Food Safety Program Capacity	>50% decrease	25-49% decrease	1-24% decrease	No change	1-24% increase	25-49% increase	>50% increase	N/A
Program funding	1%	4%	23%	64%	3%	1%	0%	4%
Staff size	3%	4%	31%	54%	3%	1%	0%	3%
Training for staff	3%	11%	26%	47%	9%	1%	0%	3%
Qualifications and competency of staff	2%	2%	8%	66%	18%	2%	0%	3%
Other food safety workload expectations	1%	2%	9%	52%	29%	3%	0%	4%
Other workload expectations	3%	3%	9%	44%	31%	9%	0%	3%

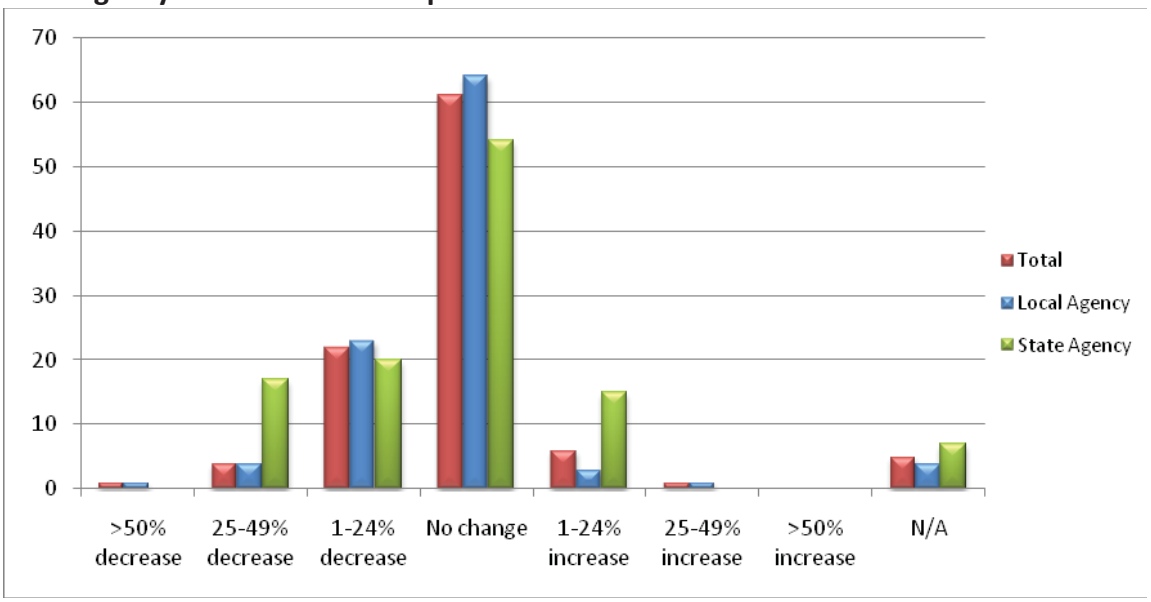
Table 8.0.3 Indicated Degrees of Impact to Regulatory Food Safety Program Capacity to Investigate and Respond to Foodborne Illness Outbreaks for State Agency Assessment Participants

Regulatory Food Safety Program Capacity	>50% decrease	25-49% decrease	1-24% decrease	No change	1-24% increase	25-49% increase	>50% increase	N/A
Program funding	0%	17%	20%	54%	15%	0%	0%	7%
Staff size	0%	7%	24%	51%	10%	2%	0%	5%
Training for staff	2%	10%	7%	49%	22%	2%	2%	5%
Qualifications and competency of staff	0%	0%	7%	63%	24%	2%	0%	2%
Other food safety workload expectations	0%	7%	2%	56%	24%	2%	2%	5%
Other workload expectations	2%	2%	5%	41%	41%	2%	0%	5%

8.1 Comparison of Total and Local and State Agency Percentages

The next set of charts (8.1.1–8.1.6) show the percentages of assessment participants indicating the different levels of change for each capacity. Following the charts are comments made for each specific degree of impact. The charts also compare responses for all participants to responses from local and state agency participants.

Chart 8.1.1 Program Funding: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

1–24% decrease

Local Agency

- budget for foodborne illness was slightly reduced
- Costs go up, but license fees stayed the same.
- One less field EHS in the food program.
- In training funds only

No change

Local Agency

- 50% cut 5 years ago
- Revenue stays the same and costs continue to increase.
- no funding

1–24% increase

State Agency

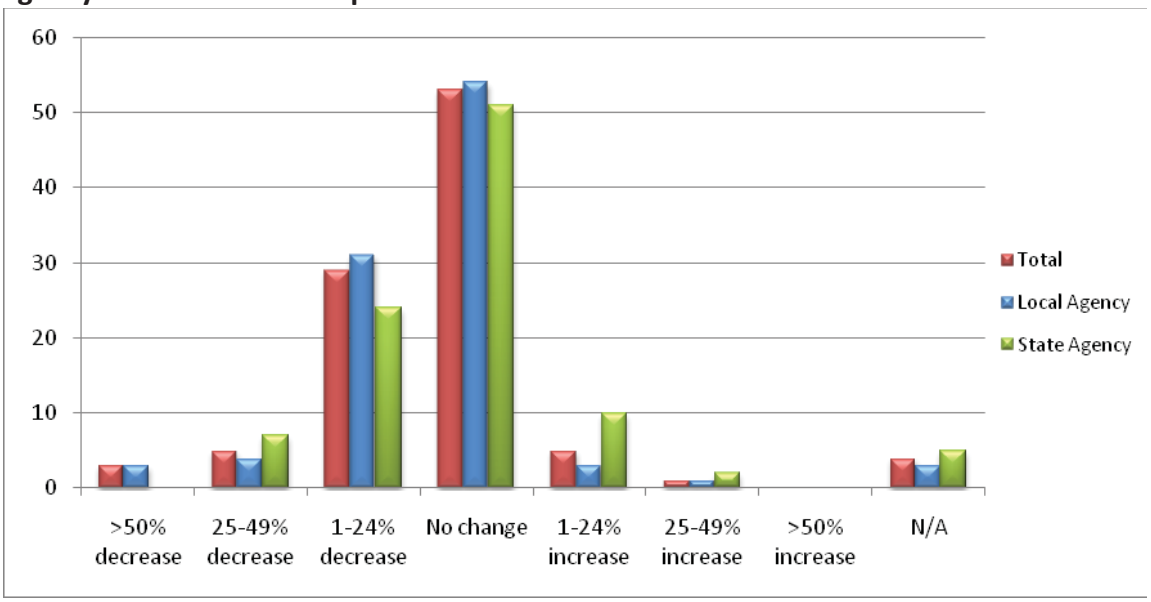
- received an FDA RRT grant. State funding has decreased significantly.

N/A

Local Agency

- We still respond to all complaints regarding possible food borne illnesses. Detailed interview with person ill, inspection of facility, collect food for testing is possible.

Chart 8.1.2 Staff Size: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

25–49% decrease

Local Agency

- Staff size reduced but geographical region reduced - 2200 facilities down to 350.

1–24% decrease

Local Agency

- We lost one full time inspector and a part-time inspector that worked with swimming pools and wells.
- One less field EHS in the food program.
- chronic turnover due to low wages.
- Less staff same amount program requirements.

No change

Local Agency

- Same staff #'s, experience diminished due to loss of sr sanitarian
- 50% cut 5 years ago

State Agency

- there will be four retirements this year out of a staff of 15. The ability to fill all these positions may prove difficult, although have so far been able to replace all positions, so are hopeful

1–24% increase

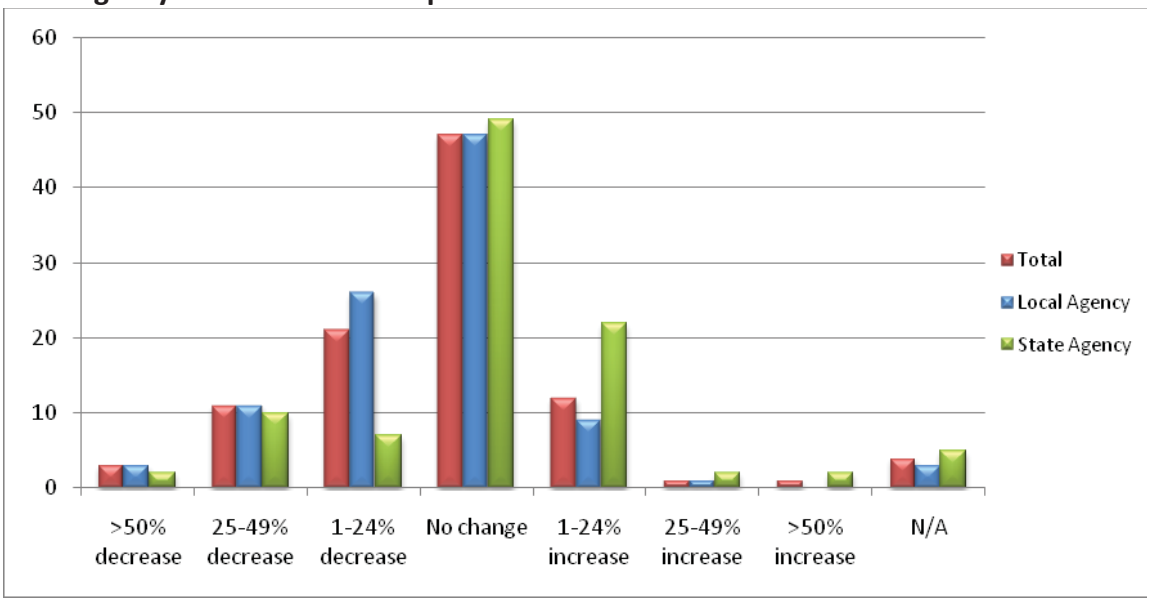
Local Agency

- The staff included a full time sanitarian with a contracted part time food inspector from another county originally. Then the county hired me as a part-time assistant sanitarian and gave me the entire food program. Now I am full time, so even though the staff number stayed the same, the time commitment to the program increased.

State Agency

- Hired 3 rapid response team members. However, managers for the food program have decreased.

Chart 8.1.3 Training for Staff: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

>50% decrease

Local Agency

- there has been no training for new employees in how to respond to a food borne investigation

25–49% decrease

Local Agency

- Cannot afford to accommodate the need.

1–24% decrease

Local Agency

- No training budget, can still attend free training.
- Funding for continuing education is very scarce.

No change

Local Agency

- Able to take advantage of State training, but local training budget diminished

State Agency

- training has actually increased not by us but by the increased opportunities for free training offered by FDA

1–24% increase

Local Agency

- Several very recent trainings, including EPI Ready and a DHS course on food preparedness have helped.
- Planned
- Most of it is on the job.

State Agency

- In house training.

>50% increase

State Agency

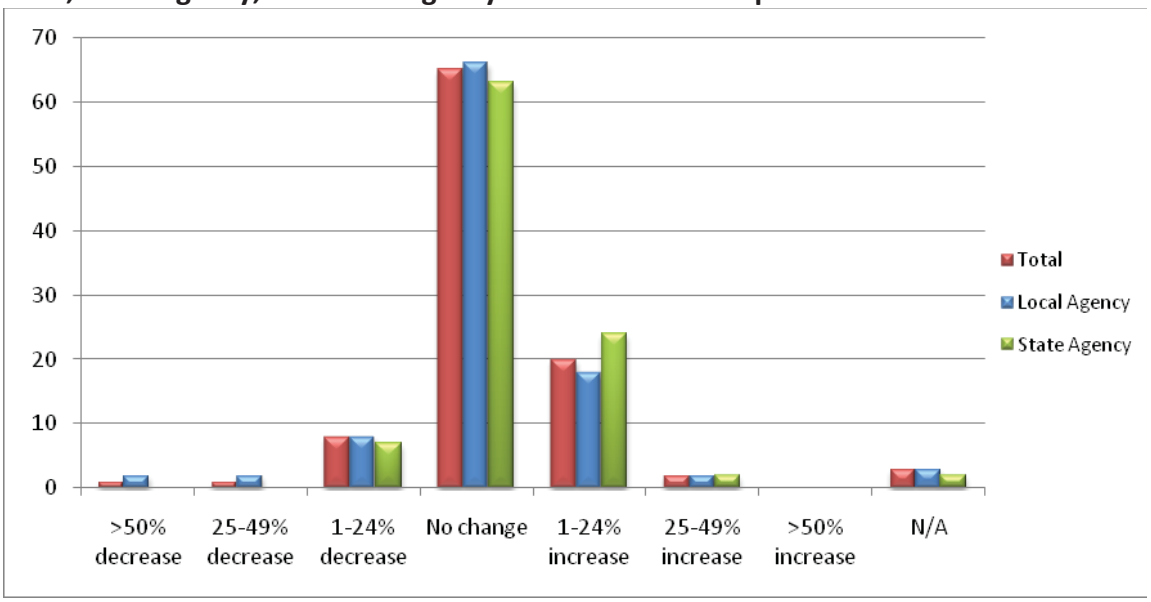
- Due to an increase in licensing fees and an increased focus on training we have been able to increase the training provided to inspectors.

N/A

State Agency

- Training aside from Federal sources all has to be in-house

Chart 8.1.4 Qualifications and Competency of Staff: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

25–49% decrease

Local Agency

- There is a huge turnaround of inspectors. Of 17 inspectors 8 have under 3 yrs of experience. Of those 8, 4 have under 1 yr of experience

1–24% decrease

Local Agency

- New staff hired to replace exiting staff

State Agency

- with four of our Senior staff retiring, including Director of Program, we will be losing a lot of our experienced staff. Difficult to replace with highly trained staff due to small salary increase for the higher level positions.
- Not all the current staff has attended an Epi-Ready course or Managing Retail Food Safety course.

No change

Local Agency

- no significant change
- Had to fight to get NEHA certification. We trained ourselves.
- Public Health risk reduction is a priority

1–24% increase

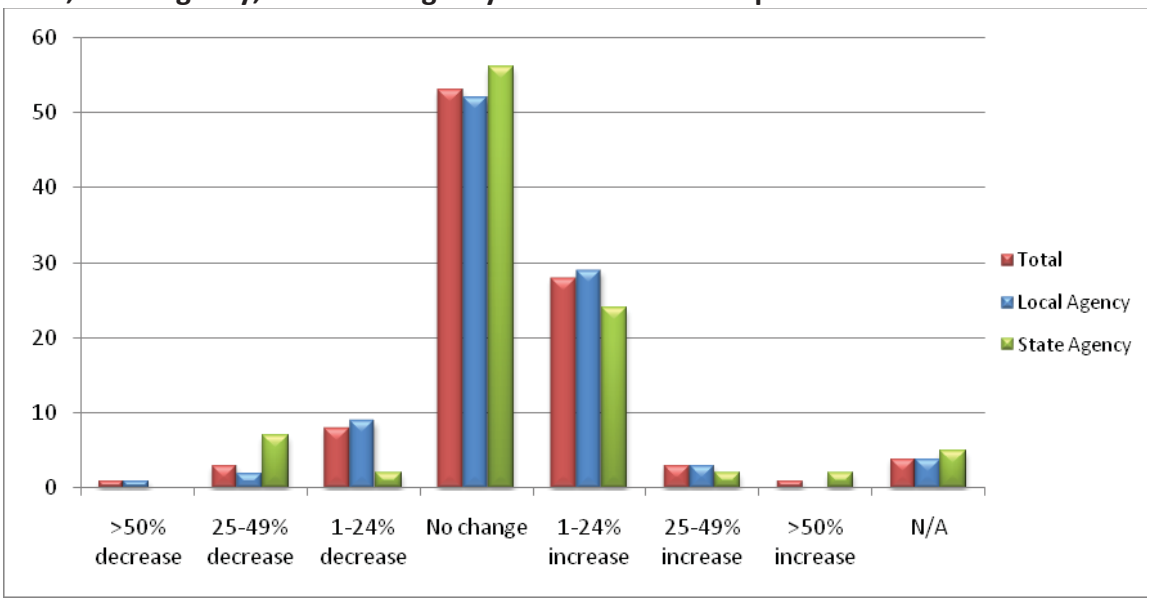
Local Agency

- change of personnel with more advanced qualifications

State Agency

- In house training

Chart 8.1.5 Other Food Safety Workload Expectations: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

>50% decrease

Local Agency

- Newly enacted Law prohibits inspection of any non-profit food operation.:

1–24% decrease

Local Agency

- State added new Food Safety laws, no funding, but regulatory requirement to enforce
- Reduced inspection frequency by approximately 17%.
- Reduction in the number of temporary food safety inspections due to legislative laws enacted to reduce govt. involvement.
- meet minimum inspection requirements, sacrifice quality time in facility.

1–24% increase

Local Agency

- Increase in the public demand for food safety training. Good for the department as it increases revenues.
- increase in recalls
- Expectations always increase, especially related to quality control. Our goal is to conduct investigations rapidly and accurately.
- Doing more ServSafe training
- Expected to do more with less.
- Increased involvement with temporary food service events due to expanding farmers markets and less Ag & Mkt involvement
- Expanded food safety education, which requires extra time.
- Demand from the public to assure food is safe
- Not every food establishment was being inspected 2x/yr before I was hired. Now they are and I am trying to provide more food safety training to managers and employees.
- Added new regulations: Trans Fat restrictions, Allergy notification - training requirements

State Agency

- With the new Food Bill as well as requirements for Manufactured Food Program standards, workload my increase
- In some areas of the state, facility workloads assigned to staff are exceeding 300 facilities per person.

25–49% increase

Local Agency

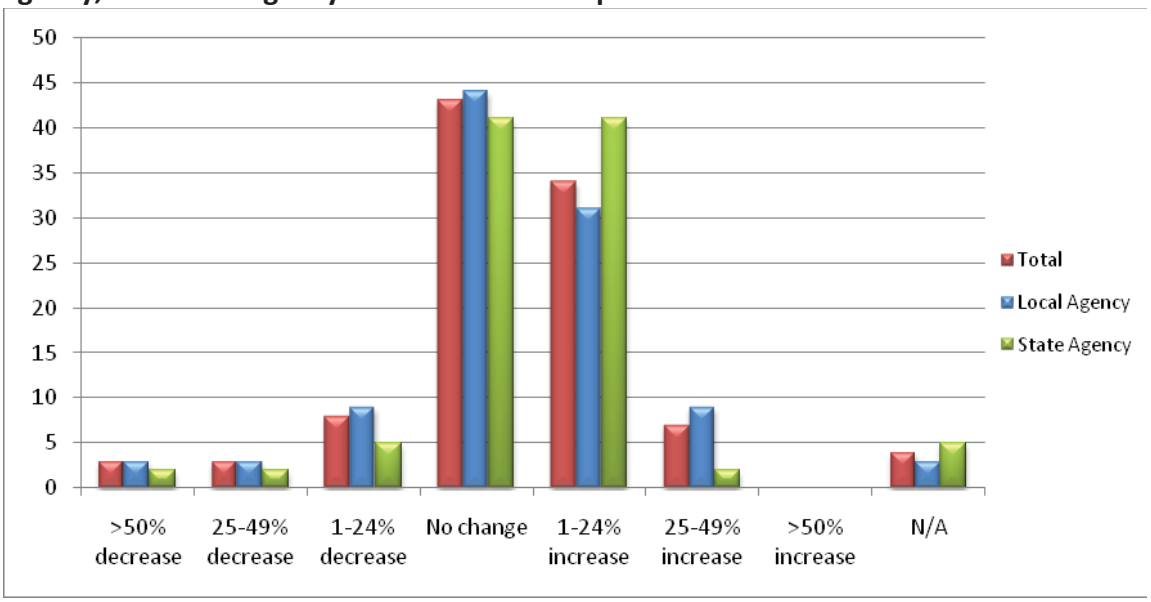
- It has been made clear to the inspectors that numbers of inspections conducted in a day are far more important than conducting a quality inspection. We are expected to conduct 4 inspections a day, regardless of the size or scope of the facility

N/A

Local Agency

- I don't oversee other food safety work

Chart 8.1.6 Other Workload Expectations: Percent of Indicated Degrees of Impact for Total, Local Agency, and State Agency Assessment Participants



Additional Comments

No change

Local Agency

- No change at this time, may look at outsourcing weekend and temp event inspections that are out of the regular work time.
- workload expectations remain the same because we have reduced # of staff as we have lost inspection programs.

State Agency

- We have instituted a renewed emphasis in quality over quantity.

1–24% increase

Local Agency

- Enforcement of the Non-smokers Protection Act and the Dogs of Pation Act.
- Charged with enforcing new unfunded NC smoking in public places prohibition.
- Stormwater, lead paint, universal waste...
- Additional programs that are contributing to increased workloads include public water supply, tanning facilities, radiological programs, emergency response program mandates, gas well development

State Agency

- More staff are cross trained for Onsite Wastewater and Vector control. More are working in multiple counties so travel time is increasing, productivity is dropping.

25–49% increase

Local Agency

- 50% cut 5 years ago

>50% increase

Local Agency

- Acceptance of federal grants for Emergency Preparedness have greatly increased required staff training, drills and exercises, which in turn reduces staff availability for traditional work.
- Addition of community wellness program and changes in other rules require additional involvement by staff away from food

9.0 Please describe any anecdotal examples in your community of negative health impacts or consequences resulting from budget cuts.

9.1 Local Agency Comments

Budgetary Impacts

- Additional tax dollars provided to local food inspection program. By deregionalizing, allows to local tax investment into the food program. Where in the past, local tax dollars could NOT be used for regional program.
- Budgeting and staffing have been flat the last 3 years, but we have had a steady increase in the number of food operations. The EH Division has lost 1 FTE, but was not in our food program. 2011 EH Budget decreased ~4.0%, 2012 budget to decrease another ~4%.
- Our food licensing fees have increased at a very high rate to an almost preposterously expensive level.

Continuing Education

- Cut's in training budgets impede our ability to secure even basic training need's of staff

No Impacts

- Unlike other divisions in the department, my division has been spared cuts.
- have not cut budget at this time, although currently there is potential for cuts in near future
- We haven't had any significant budget cuts for most EH programs. They are fee driven and if costs go up or down, so do fees.
- none, gratefully

Potential Impacts

- increase potential for food borne illnesses, reduction in ability to respond to emergencies
- Consequences are related to potential foodborne illness events may increase.

Program/Capacity Impacts

- Considering inspections every 2 years for low risk establishments
- Less inspections
- The number of mandatory inspections are not being completed in a timely manner.
- Increases in number of Food establishments and reduction in management capacity reduces the capacity of the Department to work with Food Establishments to address violations and
- develop strategies to reduce the factors that influence food borne illnesses
- Reduced inspection frequencies, increased complaints
- decreased availability and equipment necessary to perform essential job functions and inspections
- Hospitals, child care and nursing homes are basically self inspecting since the agencies responsible have little to no training in food hygiene and foodborne illness investigation. Churches and not-for-profits are not inspected by anyone anymore so it is the wild, wild west for temporary events.
- Fewer itinerant food inspections and less opportunities for training of employees working at itinerant events.

- When frequency of inspections decreases, performance decreases (especially when the time between inspections exceedes 6 months).
- ESTABLISHMENTS HAVE ACTUALLY CALLED OUR OFFICE WONDERING WHY THEY HAVE NOT BEEN INSPECTED LATELY-----ALSO INSPECTIONS HAVE SHOWN SLIPPAGE IN SANITARY STANDARDS ON SOME OF THE ESTABLISHMENTS

Staff Impacts

- Moral is week and discouraging.
- Our staff person is stretched to the maximum. We have no additional capacity to cover vacations or other time off. When auditing the work of the food program I am finding mistakes like I have never seen before. I am very concerned about staff burn out in all of our programs. We have been told to do more with less for so long. We are starting to see the results of our attempts to keep doing everything without the necessary resources, fortunately it has not been in the form of an illness outbreak yet.
- We are experiencing a hiring freeze. All request to fill have to be submitted to the County Executive's Office for approval. Strong justifications have to be provided before an approval is granted. While we are waiting for approval, inspections fall behind.
- Staff morale reduced due to lower raises than desired; they work harder to pick up work due to reduced size of work force
- To date, none but each year the increase in temporary events, mostly nights and weekends, is straining staff.
- Dedicated clerical staff hours have been cut from 18 to 14 per week. As a result, availability for citizen assistance and records maintenance are reduced exponentially.

Training/Outreach Impacts

- Resources for training and outreach programs have been cut.
- We have been fortunate that illnesses have not increased, as we are spending less time in each operation. In addition, it is not really possible to provide as much general information to the community on not only food safety issues but for all programs
- We cannot spend time educating food workers during inspections. In and out. With less time we see more violations. We focus more on civil penalties earlier w/ lack of time to educate.
- Unable to provide public, school cafateria worker and food service facility food safety education at previous levels.
- lack of public outreach programs to educate local business owners related to food safety.
- Less public services
- WE used to offer training courses for food handlers and certified managers. We no longer have the staff for training endeavors.
- Trained workers do not know sage temps.

9.2 State Agency Comments

Budgetary Impacts

- We have not experienced budget cuts, however our local public health partners that conduct the majority of retail food inspections are experiencing a number of budgetary impacts that have resulted in measurable consequences.

Legislation Impacts

- The legislature keeps re-introducing a raw milk bill.

No Impacts

- Thus far none has shown up because the impacts hasn't taken effect. Too early to determine
- we have not seen extreme cuts as of yet. We have had to be more careful in our justfications of out of state travel, but have been able to utilize contract funds for this with proper justification

Program/Capacity Impacts

- As the result of a recent salmonellosis outbreak, it was found pastry shells were being stored in used egg boxes. Bakeries have been a lower priority for inspections due to staffing and the relative risk for outbreaks. Serious hazards were identified as a result of this investigation. Lower risk facilities can become high risk when they are not evaluated on a regular basis.
- We now no longer inspection Food events such as cook-offs.
- Some counties now have no permanently assigned staff. Service delivery in those counties are on a once or twice a week basis. Complaints that do not involve illness are generally investigated at the next routine inspection (sometimes months later).
- Bureau had to suspend all inspection and community education activities and events pertaiining to promotion of good environmental practices and prevention of vectorborne diseases within the community. Reduction of normal workhours from 80 biweekly to 64 h
- Reduced number of inspections in some, not all areas of the state.
- the amount of interventions has decreased making monitoring more difficult.
- Nothing to report at this time. However, inspectional frequency has decreased significantly.

Staff Impacts

- Reduced staff time and availability is responding to and investigating foodborne disease outbreaks. The majority of staff time is in conducting routine inspections.

10.0 If you would like to elaborate on any answers you gave previously in this assessment, please reference the question and add your comment here.

10.1 Local Agency Comments

Budgetary Issues/Funding

- None of these questions dealt with how much the county tax payers are adding to the program. As both our Board of Health and our Board of Supervisors feel this is an important program to keep local, they have allowed us to keep the program as it was suppose to be conducted. The County taxpayer is covering the additional expense of the programs.
- Our inspection and licensing program is 100% fee funded, so effects of budget cut might not directly impact the inspections, however, budget cuts may have an effect on employee salaries and benefits and in the long run, it might have a negative effect due to the quality of employees.
- The direct costs of our program are funded about 75% with local fees and 25% local general fund (city and county taxes).
- Although signs the recession is over are welcome, we are moving into our worst budget in 30 years. This has been a common occurance over my time with local government- the worst budget years are when the private sector is well into recovery.
- We have recently obtained a grant that will pay for addition training to further strengthen our Outbreak Response Team.
- Majority of budget issues at this time has caused for a stagnation of training, services, staffing, and quality. However most services have been able to remain uncut at this time. Last years budget was partially supported by "food staff" conducting H1N1 pandemic work.
- We are extremely concerned that anticipated Federal and State budget cuts will result in staff reductions at the local level and will adversely impact services.

Continuing Education

- it is truly a negative to keep staff from attending traiings that require an overnight stay if that training is really beneficial to the overall program and staff's development. however, that has been a policy here even in non-budget crisis times...the administration is nonsupportive of these types of activities.

Capacity

- Public health needs to be placed as highly as fire and law enforcement in its importance to the citizens we serve. Once people start to die it is too late to adjust. We had to lay off all of our young people, new to the profession, as we took budget cuts. Our food program was not effected because it is supported by fees and the staff person was a long time employee. The support for public health programs has to come from local, state and federal levels. Citizens want us to enforce the rules and they want to be safe when they eat out. We can't provide this protection without resources and support.
- Food Protection in Arkansas has felt little impact from the recession due to the fact that it is under a state umbrella and funded out of General Revenue.
- We have not experienced an outbreak since the reduction in staff.

- It is getting worse with our leaders in Tallahassee being demonstratively anti- regulation so we are on the cutting block for losing many more programs and staff in the next year.

Fees

- We have been increasing our fees about 3% per year over the past six years.

Staff

- The main issue for us is that we are a small department to begin with. At peak we had 3 persons to conduct all programs not just food. When one person was not replaced upon retirement it increased workload on remaining staff by 1/3 each - with two persons there is no depth, no backup if a person calls in ill or on vacation it leaves 1 person - also puts a damper on training
- Due to the poor pay there is a high turnaround in our department. This has resulted in newer, less experienced inspectors that are not as well trained

Training/Outreach

- We have modified our food handler training, providing it online as an option, which has resulted in some freeing up of health educator time to focus on other food safety issues.

Workload

- Due to the increase in workload resulting from decreased staffing, it is very difficult to get outbreak reports written in a timely manner.
- We have added wells and swimming pools to our list on the environmental workload with the part-time inspector leaving.

Other

- In addition to program reductions due to budget cuts, we have been fighting for the past four years against a persistent attempt to allow unregulated sales of home-made foods, including backyard-butchered meats ! This has taken a lot of time that could have been used for other, more traditional activities.
- Not specifically related to any one question- our county is well funded due to increase in oil and gas exploration, so are programs have been relatively stable over the last two years. We had one staff member leave and the position wasn't refilled, but otherwise it has been stable.

10.2 State Agency Comments

Inspections

- Our general approach has been to increase use of risk-based scheduling and inspection approaches, maintain all federally contracted work, emergency response, etc. and take any resource reductions in routine inspection reductions. We currently don't do about 4,000 inspections annually, even though we run a reduced inspection schedule of 6/18/24 mo. for our 3 risk levels.
- WV is enrolled in the Voluntary Retail Food Standards. More frequent inspections are being conducted due to risk ranking of the state owned/operated and inspected factilities.

Staff

- Moral is very low when all the gov't employee pay status is affected.

Other

- In the past Environmental staff, Epidemiology staff and Nursing staff worked individually. We have use CIFOR to develop and train our staff in house.

11.0 Appendix

11.1 Zoomerang Survey Tool

You are currently previewing this survey. No responses will be recorded.

Environmental Health Regulatory Food Safety Program Capacity Assessment

Thank you for taking the time to participate in this assessment.

The National Environmental Health Association, along with the Association of Food and Drug Officials, have been asked to conduct an environmental health (EH) regulatory food safety program capacity assessment by the Council to Improve Foodborne Outbreak Response (CIFOR).

CIFOR members are interested in knowing what impacts budget cuts may be having on the capacity of local and state regulatory food safety programs—and specifically on those programs that conduct environmental investigations during foodborne disease outbreaks. This assessment is intended for EH and regulatory food safety managers and directors who oversee programs within local, tribal, and state government agencies that conduct environmental investigations during foodborne disease outbreaks.

Thank you again for taking the time to participate in this assessment. Your participation is essential and appreciated. The assessment consists of 11 questions that should take about 15-25 minutes to complete. NEHA will be happy to share a summary of the results to those who complete the assessment.

The assessment will close Friday, April 8, 2011.

Start Survey!

Environmental Health Regulatory Food Safety Program Capacity Assessment

1 *** Please provide the following information:**

State

Name of jurisdiction or organization

Job title

2 *** Please indicate the level of government in which you work:**

- Local agency (city, county, district, etc.)
- Tribal agency
- State agency
- None of the above

Submit

Survey Page 1

Environmental Health Regulatory Food Safety Program Capacity Assessment

3 *** For your regulatory food safety program, please indicate the degree to which the following *administrative capacities* have been impacted over the past two years.**

1 >50% decrease	2 25–49% decrease	3 1–24% decrease	4 No change	5 1–24% increase	6 25–49% increase	7 >50% increase	N/A

Staff size

1 2 3 4 5 6 7

Additional Comment

Staff salaries

1 2 3 4 5 6 7

Additional Comment

Overall budget

1 2 3 4 5 6 7

Additional Comment

Training budget

1 2 3 4 5 6 7

Additional Comment

Travel budget

1 2 3 4 5 6 7

Additional Comment

Technology/equipment budget

1 2 3 4 5 6 7

Additional Comment

Grant funding

1 2 3 4 5 6 7

Additional Comment

Submit

Survey Page 2

Environmental Health Regulatory Food Safety Program Capacity Assessment

4 *** For your regulatory food safety program, please indicate the degree to which the following *programmatic capacities* have been impacted over the past two years.**

1 >50% decrease	2 25–49% decrease	3 1–24% decrease	4 No change	5 1–24% increase	6 25–49% increase	7 >50% increase	N/A

Ability to support government mandated services

1 2 3 4 5 6 7

Additional Comment

Services offered to retail food facilities

1 2 3 4 5 6 7

Additional Comment

Services offered to other government programs and departments

1 2 3 4 5 6 7

Additional Comment

Services offered to the general public

1 2 3 4 5 6 7

Additional Comment

Partnerships with other groups and organizations

1 2 3 4 5 6 7

Additional Comment

Quality of inspections conducted

1 2 3 4 5 6 7

Additional Comment

Inspection fees

1 2 3 4 5 6 7

Additional Comment

Ability to conduct environmental assessments/investigations in response to outbreaks

1 2 3 4 5 6 7

Additional Comment

Ability to respond/investigate consumer foodborne illness complaints

1 2 3 4 5 6 7

Additional Comment

Ability to respond to food recalls

1 2 3 4 5 6 7

Additional Comment

Number of programs supported by your jurisdiction

1 2 3 4 5 6 7

Additional Comment

Outsourcing of programs

1 2 3 4 5 6 7

Additional Comment

5 **If you indicated in the question above that programs have been decreased, increased, or outsourced, please identify these programs and the extent in which they have been affected.**

Submit

Survey Page 3

Environmental Health Regulatory Food Safety Program Capacity Assessment

6 *** Please indicate any impacts experienced in your regulatory food safety program's inspections over the last two years. Check all that apply.**

- ○ More inspections conducted
- ○ No change to the number of inspections conducted
- ○ Fewer inspections conducted
- ○ No longer conduct inspections
- ○ Increased backlog of inspections
- ○ Have contracted out inspections to third-party auditors
- ○ Unable to meet routine regulatory inspection requirements
- ○ Other, please specify:

Submit

Survey Page 4

Environmental Health Regulatory Food Safety Program Capacity Assessment

7 *** Specific to your regulatory food safety program's *capacity to investigate and respond to foodborne illness outbreaks*, please indicate the degree to which the following have been impacted over the past two years.**

	1 >50% decrease	2 25–49% decrease	3 1–24% decrease	4 No change	5 1–24% increase	6 25–49% increase	7 >50% increase	N/A
Program funding	1	2	3	4	5	6	7	

Additional Comment

Staff size

1 2 3 4 5 6 7

Additional Comment

Training for staff

1 2 3 4 5 6 7

Additional Comment

Qualifications and competency of staff

1 2 3 4 5 6 7

Additional Comment

Other food safety workload expectations

1 2 3 4 5 6 7

Additional Comment

Other workload expectations

1 2 3 4 5 6 7

Additional Comment

Submit

Survey Page 5

Environmental Health Regulatory Food Safety Program Capacity Assessment

8 **Please describe any anecdotal examples in your community of negative health impacts or consequences resulting from budget cuts.**

9 **If you would like to elaborate on any answer you gave previously in this assessment, please reference the question and add your comment here.**

10 **If you are interested in providing more detailed information regarding your jurisdiction and budget cut impacts, please provide your name and e-mail address below.**

11 **If you are interested in receiving a summary of the results from this assessment, please provide your name and e-mail address below.**

Submit

Survey Page 8

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Food Control

Volume 85, March 2018, Pages 459-465

Differences between official inspections and third party audits of food establishments

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Abstract

Official food control inspections (official inspections) of food establishments and third party audits of food safety management systems (FSMSs) based on international standards both focus on food safety, which has raised discussions on whether FSMSs and their audits could reduce official inspections in food establishments. The aim of this study was to investigate whether the findings of official inspections and third party audits in food establishments are in alignment and to survey the inspectors' and food business operators' (FBOs) perceptions of official inspections and audits. The results can be used in planning the use of audit results as part of official food control. The results show that both inspectors and auditors recognized non-compliances/non-conformities, but significant discrepancies between the findings of official inspections and audits existed, making the utilization of audit results challenging. However, most of the FBOs and inspectors agreed that official inspections and audits overlap, and the majority also agreed that audits of a certified FSMS could under certain circumstances reduce official inspections.

Introduction

Food business operators (FBOs) are responsible for food safety in their establishment (EC, 2002) and are obligated to comply with the general hygiene requirements and Hazard Analysis and Critical Control Point (HACCP) principles stipulated in European Union (EU) regulations (EC, 2004a). FBOs implement self-checking programmes, for example, for sanitation, pest control, traceability and HACCP to fulfil these requirements. The premises and operations, including the self-checking programmes, are regularly inspected by the official food control (food control). In addition to the implementation of the requirements for food safety legislation, many FBOs implement food safety management systems (FSMSs) based on commercial international food safety standards (Lee, 2006, Trienekens and Zuurbier, 2008) such as those of the British Retail Consortium (BRC), the International Organization for Standardizations (ISO 22000) and the Food Safety System Certification (FSSC) 22000 (Mensah and Julien, 2011, Qijun and Batt, 2016) for food safety reasons and customers' requirements (Crandall et al., 2012, Fulponi, 2006). These standard-based FSMSs are audited by third party auditing bodies, which issue a certificate to the food business upon compliance with the standard (BRC, 2017, FSSC, 2016). Both food safety legislation and standards focus on food safety, and the implementation generates costs for FBOs (EC, 2004a, EC, 2004b, Trienekens and Zuurbier, 2008). This has raised discussions on the overlapping of official inspections and audits and on whether third party audits of FSMS could have a role in food control (Anonymous, 2013, CFIA., 2016; Martinez et al., 2013, Räsänen and Vastamäki, 2016, Verbruggen and Havinga, 2015, Wright et al., 2013).

EU legislation states that the food control should take into account the results of quality assurance programmes (EC, 2004b), and some countries have included the possibility to utilize FSMS and the audits of those in food control (Räsänen & Vastamäki, 2016). In EU countries such as Belgium, Denmark, the UK and the Netherlands, the frequency of the official inspections can be reduced according to certain preconditions in food businesses with a certified FSMS (Räsänen & Vastamäki, 2016). In addition, Canada has declared a policy statement including this possibility (CFIA, 2016), and the US has contemplated a role for third party audits (FDA, 2017), showing that there is a wide interest in taking FSMSs into account in food control. Studies, however, on the comparability of official inspection and audit results have not been published according to the knowledge of the authors.

The utilization of FSMSs and their results in food control has raised concerns due to differences in the practices between food control and third party audits (Martinez et al., 2013, Räsänen and Vastamäki, 2016, Wright et al., 2013). Audits are carried out at least annually (FSSC, 2016, GFSI, 2011), and the FBO is usually aware of the audit well in advance, but most of the official inspections must be carried out unannounced. Furthermore, food control is risk based, which means that the risks involved with food operations influence the frequency of the official inspections (EC, 2004b, Evira, 2017). A major difference is that food control is independent from the food businesses, with the primary aim of safeguarding

consumers (EC, 2004b), whereas the certification bodies are part of the market economy (Martinez et al., 2013). Economic interest involved with private standards may cause risks (Martinez et al., 2013) and, for example, has led to speculation on whether non-compliances could go unnoticed (Verbruggen & Havinga, 2015). In slaughterhouses in the Netherlands meat safety was considered to have decreased as a consequence of increasing the responsibility of the FBOs, but decreasing official control (Anonymous, 2014). Because the use of FSMSs and audits of those in food control raises such questions, it is important to investigate the comparability of official inspection and audit results.

The aim of our study is to investigate whether the findings of official inspections and third party audits in food premises are in alignment with the special focus on non-compliances observed in official inspections and non-conformities in audits. Furthermore, we will investigate the perceptions of FBOs and local food control inspectors (inspectors) of official inspections and audits. The results can be used in developing the utilization of audits of FSMSs in food control.

Section snippets

Official inspection and audit reports

Food establishments that were members of the Finnish Food and Drink Industries' Federation were asked to participate in the study. Only food establishments that could provide both official inspection and audit reports from a one-to two-year period were included. Ten food establishments provided the data required (Table 1). The data comprised 66 official inspection and 18 audit reports. The official inspections and audits were conducted between the years 2013 and 2015. Among the 10

Non-compliances/non-conformities observed in official inspections and audits

The frequency of non-compliances/non-conformities varied greatly between the official inspections and audits according to the reports (Fig. 1). The official inspection reports contained significantly more remarks on non-compliance concerning cross-contamination, maintenance, hygienic working methods, sanitation and sampling than the audit reports on non-conformities ($p < 0.05$), (Fig. 1). In some categories, such as HACCP and recall, the frequency of non-conformities was higher in the audits

Discussion

The study reveals differences between official inspections and audits, which are important to take into account when assessing the utilization of audit results in food control. It is especially important to acknowledge that there were significant differences in the observation of non-compliances in official inspections and non-conformities in audits. The differences were observed in important self-checking categories, for example, maintenance of the premises and sanitation, which may have

Acknowledgements

The study was supported by the Agency for Rural Affairs.

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- **Using data mining as a tool for anomaly detection in food safety audit data**

  2022, Food Control

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  The integrity of third-party food safety audits has been constantly challenged by food safety incidents of certified food businesses. Integrity programs have been established for food safety certification program owners (CPOs) to monitor the involved parties' performance and find anomalies in audit data. To find such anomalies in a large amount of data is labour intensive, and no standard approach has been established. This paper explored data mining approaches and leveraged algorithms to automate integrity checks. Furthermore, this paper provides initial validation of a suitable algorithm. Out of three potentially suitable algorithms, the couple-biased random walk (CBRW) algorithm was chosen as the basic algorithm to find anomalies in audit data. This algorithm was adjusted and expanded to show contributing factors for a potential anomaly enabling integrity managers to find the reason for potential anomalies faster. Three experts validated the sample findings of the algorithm and discussed these findings in detail. The validation showed an 80% accuracy of the algorithm and brought up findings that were not known before by the experts. The findings justify further exploration of data mining for anomaly detection in food safety audits.

- **Comparison of official food control results in Finland between food establishments with and without a certified food safety management system**

  2021, Food Control

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  Certified food safety management systems (FSMSs), such as ISO 22000 and BRC, along with official food control, focus on food safety. European Union regulation 2017/625 requires to take FSMSs and their audits into account in official food control. To assess the possibility to decrease official food control frequency due to certified FSMSs the association of certified FSMSs on food business operators' (FBO) compliance was examined. The results of 1484 official inspections of 110 Finnish food establishments representing slaughterhouses, other meat establishments, fish and milk establishments, and bakeries with (n = 59) and without (n = 51) certified FSMS were studied over the period of 2016–2018. Altogether, 14 356 scores were given to 87 different items during the inspections. The comparison of scores between food establishments with and without certified FSMS discovered minor differences: 98.3% and 98.0% of inspected items in food establishments with and without a

certified FSMS, respectively, did not impair food safety. The association between certified FSMSs and food establishments' compliance was inconsistent in different establishment types and among inspected items. Therefore, the results do not support a decrease in the frequency of official food control inspections merely based on the existence of a certified FSMS. Instead, the results advocate for an individual assessment of the FBO's inspection frequency, based on the history of compliance.

- **Evaluating suppliers of spices, casings and packaging to a meat processing plant using food safety audits data gathered during a 13-year period**

  2021, Food Control

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  The aim of this study was to assess the extent to which suppliers of spices, packaging, casings and intestines to a selected meat processing plant achieved the objectives of their food safety management systems, according to the results of audits conducted in the period 2007–2019. The results provide a new perspective on non-compliance by suppliers with food safety standards. The main shortfalls discovered were: the lack of protective clothing and absence of supplier assessment in the plants of casings and intestine producers; low levels of hygiene, poor storage and foreign body management practices in the plants of suppliers of spices, packaging materials and casings. Suppliers of casings and intestines should pay close attention to the evaluation of their suppliers, plant hygiene, and protective clothing. Spice suppliers should strengthen storage, plant hygiene, foreign body and allergen management. Whereas suppliers of packaging materials mainly should pay more attention to storage and plant hygiene. Each category of suppliers showed continuously improving the levels of compliance with requirements during a surveyed 13-year period. Suppliers of spices, packaging materials, casings and intestines should achieve the expected full compliance in 2021 or 2022. The used methodology can be useful not only to monitor the extent to which the suppliers fulfilled food safety requirements, but also to educate auditors. It is important that improvements of food safety and quality management should not be limited to food producers.

- **Antimicrobial resistance of Staphylococcus aureus among cooked food and food handlers associated with their occupational information in Klang Valley, Malaysia**

  2021, Food Control

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  The purpose of the study was to identify the prevalence of *Staphylococcus aureus* and its antimicrobial resistance profile among food handlers and in cooked food in Klang Valley, Malaysia. The correlation between the prevalence of *S. aureus* and the occupational information of the food handlers was also identified. Two hundred hand swab samples and 100 cooked food samples were collected from Grade A, B, and C food premises, whereby the occupational information of food handlers was also recorded. The results showed that the prevalence of *S. aureus* among food handlers and in cooked food was 95.0% and 50.0%, respectively. None of the methicillin-resistant *S. aureus* (MRSA) strains had been isolated from the food handlers, whereas four (8.0%) cooked food samples were detected with the MRSA strains. Antibiotic susceptibility tests showed that 57.9%, 13.7%, 3.2% and 1.1% of the isolates from food handlers' hands were resistant to penicillin-G, erythromycin, clindamycin and mupirocin, respectively. In addition, isolates from food samples showed that 58.0%, 8.0%, 8.0% and 18.0% were resistant to penicillin-G, cefoxitin, erythromycin, and clindamycin, respectively. All of the isolates from cooked food had shown susceptible to mupirocin. Multidrug-resistance *S. aureus* strains were isolated from two non-Malaysian food handlers and two cooked food samples. Furthermore, grading system ($P = 0.000$), grade of food premises ($P = 0.010$), working responsibility ($P = 0.026$), and year of employment ($P = 0.049$) of food handlers were significantly correlated with the prevalence of *S. aureus*. Nonetheless, no correlation was found between multidrug-resistant *S. aureus* with the occupational information of food handlers. This urges for improvements in constructive and sustainable food safety practises among food handlers to reduce the risk of foodborne illness outbreaks.

- **Evaluating food safety management systems in Singapore: A controlled interrupted time-series analysis of foodborne disease outbreak reports**

  2020, Food Control

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  Food catering service establishments are often implicated in foodborne disease outbreaks. We evaluated the effects of implementing Food Safety Management Systems (FSMS) in food catering service establishments in Singapore on two outcome measures: foodborne disease outbreaks and food hygiene violations. Using a controlled interrupted time-series study design, we estimated the change in the average level of these outcome measures following implementation, and compared the pre- and post-intervention trends. There were 42 foodborne disease outbreaks and 521 food hygiene violations associated with catering service establishments from 2012 to 2018. Eighteen months after FSMS implementation, we observed a 78.4% decrease (IRR: 0.216, 95% CI: 0.050 to 0.940, p=0.041) in the average level of foodborne outbreaks in food catering service establishments. There was no significant effect on reported hygiene violations. Our study suggests that the FSMS implementation was successful in reducing foodborne outbreaks.

- **The role of media reporting in food safety governance in China: A dairy case study**

  2019, Food Control

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  Using dairy products as the case study of interest, the aim of the research is to explore the role of the media in food safety governance in China. Thematic content analysis is used to evaluate government and media reports (n = 233) on dairy related food safety incidents in China between 2004 and 2017 with differences identified between government and media reporting. The data is extracted from an online database (Zhichuchuangwai). The results show that the government performs better on exposing incidents earlier within the 14-year period but the news media plays a complementary role in food safety governance exposing a wider coverage of incidents. This study extends the current literature on the role of the news media in food safety governance in China by focusing on a single food sector (dairy), but on a national scale.

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- Research article

  Antifungal and aflatoxin-reducing activity of extracellular compounds produced by soil *Bacillus* strains with potential application in agriculture

  Food Control, Volume 85, 2018, pp. 392-399

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  Toxigenic *Aspergillus flavus* and *A. parasiticus* fungal strains can contaminate a wide variety of food crops with the subsequent production of aflatoxins (AFs) resulting in severe economic losses and public health issues. Biological control is a promising approach to manage AFs contamination in pre- and post-harvested crops. In the present study, the effect of soil-borne *Bacillus* spp. strains on aflatoxigenic *A. parasiticus* growth and AFs production was evaluated and the culture supernatant of the most effective strain was evaluated for the presence of antifungal lipopeptides. Six *Bacillus* spp. strains were able to reduce *A. parasiticus* growth rate significantly ($p < 0.05$). *Bacillus* spp. RC1A was able to inhibit fungal growth almost completely, reducing growth rate to

0.16 mm/h and increasing Lag phase duration (31.72 h) ($p < 0.0001$). RC1A could also reduce AFB_1 concentration produced by *A. parasiticus* ($p < 0.0001$). Organic solvent extraction and chromatographic analysis of RC1A culture supernatant showed the presence of bands corresponding to three of the main groups of lipopeptides (surfactin, iturin A and fengycin) at the expected retention factor (Rf) values; they were also confirmed by MALDI-MS analysis. These fractions were able to inhibit *A. parasiticus* growth and AFB_1 production to non-detectable levels when tested separately in liquid culture media. The further study of the antifungal compounds produced by these strains will determine their potential use to manage AFs contamination in crops and feeds.

- Research article

Rapid ultra-trace determination of Fukushima-derived radionuclides in food

Food Control, Volume 85, 2018, pp. 376-384

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A selection of 35 food samples from Japan (plus one seawater sample and one mushroom sample from Russia) were analyzed by gamma spectrometry and liquid scintillation counting. The analytical protocol included concentration of the sample by lyophilization and/or thermal treatment, resulting in exceptionally low limits of detections (in the low mBq/kg range or even below) for the radionuclides ^{134}Cs, ^{137}Cs, ^{108m}Ag, and ^{110m}Ag, as well as low limits of detection for ^{90}Sr (in the low Bq/kg range). Radiosilver was found in several mussels at low concentrations. Most samples exhibited detectable radiocesium concentrations (below the regulatory limit). An analytical protocol for ^{90}Sr in food was developed and optimized, allowing detection limits in the sub-Bq/kg range. However, despite this high sensitivity, no Japanese food sample exceeded the limit of detection. Only one mushroom sample from Russia revealed detectable traces of ^{90}Sr, but the lack of ^{134}Cs in this sample proves that these radioactive traces did not originate from the Fukushima Daiichi accident. Several moderately time-consuming steps in the analysis of ^{90}Sr increase the sensitivity so far that this radionuclide can be measured directly with high sensitivity, without having to wait for about 2 weeks for the ingrowth of its daughter nuclide ^{90}Y. Our study supports previous studies, which also attested Japanese foods a high level of radiological safety.

- Research article

Assessment of mycotoxins types in some foodstuff consumed in Rwanda

Food Control, Volume 85, 2018, pp. 432-436

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Occurrence and levels of mycotoxins from maize, peanuts and cassava flours consumed in Rwanda were determined. The assessed mycotoxins include aflatoxins, fumonisins, ochratoxin A, deoxynivalenol, zearalenone, T-2 toxin and patulin. Sampling of maize, peanut and cassava flours were randomly drawn from the markets in all four provinces of Rwanda and Kigali City. Mycotoxins occurrence and concentration in flours were assessed using High Performance Liquid Chromatography tandem Mass Spectroscopy (HPLC-MS/MS, Agilent). Results showed that aflatoxins are the most frequent in the analysed foodstuff flours with a frequency of 89%, 100% and 33% in maize, peanut and cassava samples, respectively. The highest total concentrations of mycotoxins in maize flours were 16.8 μg/kg, 48.1 μg/kg and 3.7 μg/kg for aflatoxins, fumonisins and ochratoxin A, respectively. Those quantities reached a total concentration of 126.6 μg/kg, 16.3 μg/kg and 2.8 μg/kg, respectively in peanut flours, while in cassava flours concentrations of 2.7 μg/kg and 3.7 μg/kg for aflatoxins and ochratoxin A, respectively, were detected. Culture of detecting these mycotoxins at regular basis from foods on the markets and increasing awareness amongst consumers and vendors on the toxicity profile of mycotoxins should be instituted by concerned authorities to avoid both human and animal intoxication.

- Research article

Sampling plans for the zero-inflated Poisson distribution in the food industry

Food Control, Volume 85, 2018, pp. 359-368

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Zero-inflated models have been used successfully to describe microbial data with excess of zero-counts. Some sampling plans such as single sampling plan (SSP), resubmitted single sampling plan (RSSP) and quick switching system (QSS) have been developed for the zero-inflated Poisson (ZIP) distribution. Two new plans such as repetitive group sampling (RGS) and multiple dependent state (MDS) sampling are proposed to compare their performance with the existing sampling plans. Additionally, we develop double sampling (DS) and sequential sampling plans for the ZIP data. The plan parameters of the sampling plans are determined by using the unity value approach. The MDS sampling plan is more economical than the other sampling plans, including SSP, RSSP, RGS and QSS, in terms of the required sample size and average sample number in most cases. The probability of a zero in the ZIP data affects the sample size required for all sampling plans. Practical guidance for selecting sampling plans under ZIP is also provided.

- Research article

Compliance in slaughterhouses and control measures applied by official veterinarians

Food Control, Volume 68, 2016, pp. 133-138

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Implementation of well-functioning hazard analysis and critical control point (HACCP)-based self-checking systems (SCSs) is crucial for meat safety in slaughterhouses (SHs). However, if these SCSs fail, control measures used by official veterinarians (OVs) should be efficient enough to secure the safety of the meat. To examine the control measures used by the OVs and the cases of noncompliance in the implementation of SH SCSs, we issued a survey to the chief OVs in high-capacity SHs in Finland during spring 2014. The expertise of the OVs and the quality of guidance they received were also examined. Our results showed that the most common and severe cases of noncompliance in the implementation of high-capacity SH SCSs in Finland were associated with hygiene. Those SHs with high frequencies of noncompliance were all smaller high-capacity units in which written time limits for correction of noncompliance and enforcement measures were less commonly used. Most OVs felt that they did not receive sufficient competent guidance in performing food safety inspections, and in some SHs the expertise of the OVs in administrative procedures and food safety legislation should be improved. To further ensure meat safety, OVs, especially in SHs with high frequencies of noncompliance, should be encouraged to use more effective control measures.

- Research article

Development of water-soluble chitosan powder and its antimicrobial effect against inoculated *Listeria innocua* NRRL B-33016 on shrimp

Food Control, Volume 85, 2018, pp. 453-458

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The objectives of this study were to produce water-soluble chitosan (WSC) powder and to evaluate the effect of WSC on the survival of *Listeria innocua* inoculated onto shrimp surfaces. WSC powder was produced using a combination of enzymatic hydrolysis, ultrafiltration, and freeze drying. WSC solutions of 0.5, 1, 3, and 5 g/100 mL concentrations were prepared by dissolving the WSC powder in water. All concentrations of the WSC

solutions showed anti-*L. innocua* activity *in vitro*, with the 5 g/100 mL WSC solution reducing initial *L. innocua* counts by 7.43 log CFU/mL. Freshly acquired shrimp were inoculated with *L. innocua* to an initial concentration of 7.65 log CFU/g. The inoculated shrimp samples were separately dipped in water (control) and in the WSC solutions for 1 min. After dipping in deionized water and 0.5, 1, 3, and 5 g/100 mL WSC solutions, the *L. innocua* counts were reduced by 1.50, 1.99, 2.25, 3.56, and 5.34 log CFU/g, respectively. For aerobic bacteria loads (8.43 log CFU/g) including *L. innocua* and natural shrimp microflora, dipping in deionized water and 0.5, 1, 3, and 5 g/100 mL WSC solution resulted in 0, 0.69, 3.21, 3.71, and 4.43 log CFU/g reductions, respectively. This study demonstrated that a low viscosity (0.01–0.29 Pa s) WSC solution could be used as an antimicrobial agent to reduce microbial loads on the surface of shrimp.

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Comprehensive Reviews in Food Science and Food Safety

The Role of Auditing, Food Safety, and Food Quality Standards in the Food Industry: A Review

Konstantinos V. Kotsanopoulos, Ioannis S. Arvanitoyannis

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Abstract

Food safety and quality audits are used widely in the food industry for various reasons (to evaluate management systems, obtain certifications to certain food safety and quality standards, assess the condition of premises and products, confirm legal compliance, and so on). Nowadays, the increased interest of consumers on food safety and quality matters, triggered mainly by recent food scandals, has enabled the public and private food sectors to develop a variety of food safety and quality standards. These standards have both advantages and disadvantages and their effectiveness depends on several factors such as the competency and skills of auditors and the standard used in each case. Although the industry continuously invests in developing and improving these systems, the number of foodborne outbreaks per year appears to be quite stable in both Europe and the United States. This may be an indication that additional measures and techniques or a different approach would be required to further improve the effectiveness of the food safety and quality management systems. This article examines the role of audits and food safety and quality assessment systems in the food industry, presenting the results of several studies and briefly describing the main food safety and quality standards currently used in Europe (with particular emphasis on the United Kingdom and Greece), the U.S., Australia–New Zealand, and Asia.

Citing Literature

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The Integrity of Private Third-Party Compliance Monitoring

The Integrity of Private Third-Party Compliance Monitoring

*By Jodi L. Short and Michael W. Toffel**

Government agencies are increasingly turning to private, third-party monitors to inspect and assess regulated entities' compliance with law. Third-party monitors are used to certify compliance with federal standards and other requirements in a wide array of domains, including food safety, pollution control, product safety, medical devices, and financial accounting. For example, third-party monitors assess the compliance of foreign food production facilities with Food and Drug Administration regulations, of children's products with Consumer Product Safety Commission product safety rules, of telecommunication products with Federal Communications Commission regulations, and of registered securities issuers with accounting and internal controls requirements. Several federal agencies rely on third-party monitors to assess adherence to agencies' voluntary product labeling standards, including the Department of Agriculture's National Organic Program, the Environmental Protection Agency (EPA) and Department of Energy's Energy Star Program, and the EPA's WaterSense Program. Many agencies are considering how they might deploy third-party monitoring to enhance their inspection regimes. *See* David Markell & Robert Glicksman, *A Holistic Look at Agency Enforcement*, 93 N.C. L. Rev. 1 (2014).

The integrity of these regulatory regimes rests on the validity of the information third-party monitors provide to regulators. The challenge in designing third-party monitoring regimes is that profit-driven private monitors, typically selected and paid by the firms subject to monitoring, have incentives to downplay problems they observe in order to satisfy and retain their clients. This article discusses the most important factors that can affect the integrity of third-party monitoring and highlights key policy implications for regulators designing third-party monitoring regimes.

Risks to the Integrity of Private Third-Party Monitoring Regimes

Research demonstrates that third-party monitors are strongly influenced by their relationships with the firms they monitor and by economic incentives. A well-designed third-party monitoring program should address several sources of bias shown to influence the likelihood that third-party monitors will accurately and comprehensively identify violations and deficiencies. Below, we focus on five factors associated with auditor leniency.

Finding #1: Third-Party Monitors Tend to Be More Lenient When Monitored Firms Pay Them Directly.

Studies across a range of policy domains have found that third-party monitors face substantial conflicts of interest between attracting and retaining clients and accurately reporting their clients' regulatory compliance. Several studies of pollution-control programs have shown that third-party monitors that exhibit leniency are more likely to retain clients. For instance, when private-sector automobile emissions testing stations conduct smog checks and fail vehicles, those vehicle owners are significantly less likely to continue doing business with those stations. *See, e.g.*, Victor Bennett, Lamar Pierce, Jason Snyder, & Michael Toffel, *Customer-Driven Misconduct: How Competition Corrupts Business Practices*, 59 Mgmt. Sci. 1725 (2013).

An analysis of a pollution-control program that required regulated firms to submit annual pollution readings taken by third-party monitors found that monitors selected and paid by monitored firms frequently reported false pollution readings to regulators. *See* Esther Duflo, Michael Greenstone, Rohini Pande & Nicholas Ryan, *Truth-Telling by Third-Party Auditors and the Response of Polluting Firms: Experimental Evidence from India*, 128 Q. J. Econ. 1499 (2013). In contrast, these monitors reported substantially higher pollution levels, verified to be more accurate in follow-up inspections by regulators, once monitored firms were no longer allowed to select and pay their own auditors, but instead were required to pay into a central government fund that, in turn, assigned and paid the monitors. Similarly, a study of social auditors monitoring supply chains on behalf of global brands concluded that these third-party monitors find and cite fewer violations when they are paid by the audited suppliers than when they are paid by the brand. *See* Jodi Short, Michael Toffel, & Andrea Hugill, *Monitoring Global Supply Chains*, 37 Strategic Management Journal 1878 (2016).

Research has likewise demonstrated that conflicts of interest arising from client payment arrangements shade the assessments of third-party monitors in financial regulation. Several studies have found that credit rating agencies, whose ratings are relied upon by

* Jodi Short is Professor of Law and Bion Gregory Chair in Business Law, University of California, Hastings, shortj@uchastings.edu. Michael Toffel is Professor of Business Administration, Harvard Business School, mtoffel@hbs.edu. A version of this article that includes references to all mentioned studies is available at http://ssrn.com/abstract=2695429. The authors thank Garrett Smith, UC Hastings College of the Law (JD 2017), for invaluable research assistance on this project.

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Identity and Numbers of Bacteria Present on Tabletops and in Dishcloths Used to Wipe Down Tabletops in Public Restaurants and Bars

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SUMMARY

Dishcloths used in restaurants and bars (23 restaurant cloths, 14 bar cloths) were collected, and tabletops (10 restaurants) were swabbed, to determine the occurrence of bacteria. Coliforms were isolated from 89.2% of dishcloths and 70% of tabletops. *Escherichia coli* was isolated from 54.1% of dishcloths and 20% of tabletops. The numbers of heterotrophic plate count bacteria (HPC) and coliforms were significantly higher in bars than in restaurants. The levels of HPC found in dishcloths were 25-fold and coliforms were 60- to 120-fold lower than the levels found in home dishcloths reported in previous studies. The numbers recovered from restaurant tabletops were also lower than those from household kitchen countertops. The most commonly isolated genera from dishcloths in restaurants and bars differed from those in homes. The numbers found for HPC on restaurant tabletops were 45-fold greater after cleaning than prior to cleaning. There were also a 19-fold greater number of coliforms and twice as many *E. coli*. Therefore, although the mandatory use of sanitizers in restaurants and bars may have reduced contamination levels and caused a shift in the microbial populations present in food service establishments, the implication of dishcloths in contamination of tabletops through cleaning suggests that current monitoring of linen sanitation solutions might be inadequate.

A peer-reviewed article

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INTRODUCTION

In the United States each year, an estimated 76 million cases of foodborne gastroenteritis occur, with 325,000 hospitalizations and 5,194 deaths *(10)*. The microbial causes of foodborne illness include viruses, bacteria and parasites, with symptoms ranging from mild gastroenteritis to life-threatening neurologic, hepatic, and renal disease *(10)*. Because food is transported to consumers through long chains of industrial production, processing and distribution, numerous circumstances allow for contamination along the way, and existing regulations may not be sufficient to prevent illness. It is helpful to understand the mechanisms by which such contamination occurs in order to reduce the risk of foodborne illnesses *(16)*.

Epidemiological surveillance is important in determining the types of foods responsible in outbreaks, the populations at risk, the circumstances that lead to food contamination and the growth/survival of foodborne pathogens *(9)*. Data collected by the US Food and Drug Administration (FDA) from nearly 900 institutional food service establishments, restaurants, and retail food stores identified improper holding times and temperatures, contaminated equipment/cross contamination, inad-

equate cooking and poor personal hygiene as risk factors for foodborne disease *(7)*. Between 1988 and 1997, restaurants (2,158) were the most significant sources of foodborne outbreaks, followed by residences (1,032) *(2, 11)*.

When contaminated cloths come into contact with fingers or surfaces, microorganisms are readily transferred. This may represent a risk if there is subsequent contact with food *(13)*. Studies in domestic kitchens indicate that wet cloths are important elements in such cross contamination *(13)*. In one study, cleaning cloths impregnated with a quaternary ammonium disinfectant were compared to cleaning cloths used with a detergent *(14)*. Some of the cloths used with detergent became heavily contaminated within three hours of use. Following use of these cloths for surface cleaning, both the surfaces and the cloths were more heavily contaminated, which suggests that cross contamination had occurred between cloths and surfaces. After the quaternary ammonium-impregnated cloths were used for cleaning, a significant reduction in contamination on food preparation surfaces and cloths was found *(14)*.

Enriquez et al. *(6)* analyzed sponges and dishcloths from household kitchens in the United States. *Pseudomonas* spp. were the most commonly isolated bacteria. Presumptive *Staphylococcus aureus* and *Salmonella* spp. were isolated, with similar frequencies for cellulose sponges and dishcloths. Several other *Enterobacteriaceae* were also isolated. Total and fecal coliform bacteria were present in large numbers in contaminated cleaning materials, sometimes reaching levels greater than 10^8 colony-forming units (CFU)/ml in liquid samples *(6)*. In a similar study of cellulose and natural fiber sponges (loofahs), *S. aureus*, *Aeromonas* spp., *Pseudomonas* spp. *Enterobacteriaceae* and *Serratia* spp. were identified *(3)*. These findings, as well as the recovery of large numbers of enterobacteria from draining boards *(15)*, sinks and dishcloths in household kitchens *(12, 15)*, suggest that dishcloths may act as both reservoirs and disseminators of microbial contamination *(15)*.

In the current study, the occurrence of heterotrophic plate count (HPC) bacteria, total coliforms and *Escherichia coli* on tabletops and dishcloths (used to wipe down tabletops) in public restaurants and bars was determined. In addition, heterotrophic bacterial isolates were identified. The purpose of this study was to determine if current dishcloth sanitation in restaurants and bars is sufficient to prevent environmental cross contamination and thus the spread of foodborne illnesses in public food service establishments. The microbiological results were also used for comparison with results from previously published household kitchen studies.

METHODS

Sample collection

Cleaning dishcloths (2,025 cm^2 total area) were collected from restaurants and bars in the United States and placed in Ziploc™ plastic bags for transport on ice to the laboratory. Restaurants in the study included fast food chains; bar and grills; and pizza, Mexican and Chinese restaurants located in New York City (NY), San Francisco (CA), and Phoenix, Flagstaff, and Tucson (AZ). Restaurant tabletops were also sampled by swabbing (approximately 156 cm^2 total area) with BBL™ CultureSwabs™ (Becton Dickinson, Franklin Lakes, NJ, USA) for subsequent immediate transport on ice to the laboratory. Members of the restaurant staff were unaware of the study and therefore followed their normal cleaning routine.

Sample processing

Dishcloths were wrung to remove any excess liquid; then 75 to 100 ml (depending on the latent moisture content of the cloth) of Letheen neutralizing broth (Difco Laboratories, Detroit, MI, USA) was added to the dishcloths in the Ziploc™ bags. The bags were squeezed to distribute the neutralizer liquid throughout the cloths. After 5 minutes of manual compression, liquid was wrung from the cloths and collected in sterile tubes.

The tabletop culture swabs were vortexed for 30 seconds; then pliers were used to squeeze the liquid from the swab. This resulted in a sample volume of approximately 0.6 ml. An additional 0.5 ml of Tris-Buffered Saline (TBS; Sigma-Aldrich, St. Louis, MO, USA) was added to bring the final sample volume to 1.1 ml. In a separate experiment, tabletops were swabbed, wiped down with a dishcloth (by the restaurant staff) and then swabbed once again to determine if cleaning the table had affected bacterial numbers. As stated previously, members of the restaurant staff were unaware of the study and therefore followed their normal cleaning routine. The swabs were then processed as described previously.

HPC bacterial numbers were determined by plating out appropriate serial dilutions from the swab and dishcloth liquids in duplicate onto R2A medium (Difco, Sparks, MD, USA), utilizing the spread plate technique. Agar plates were incubated at 30°C for five days; then the bacteria were enumerated by counting colony-forming units (CFU). The number of HPC bacteria per square centimeter was then calculated for each sample.

Total coliforms and *E. coli* were enumerated using Colilert Quanti-Trays™ (IDEXX Laboratories, Inc. Westbrook, ME, USA) as per the manufacturer's instructions.

Species identification

For detection of *Listeria monocytogenes*, 1.0 ml of each dishcloth sample was used to inoculate UVM Modified Listeria Enrichment Broths (Difco Laboratories, Detroit, MI, USA) and incubated for 24 hours at 30°C in a dry heat block. From turbid UVM broth samples, 0.1 ml volumes were transferred to selective enrichment Fraser Broth (Difco Laboratories, Detroit, MI, USA) and incubated at 35°C for 24 to 48 hours. After incubation, 0.1 ml from the esculin-positive samples were placed on the selective chromogenic medium RAPID'L.mono (BIO-RAD, Hercules, CA, USA), using the spread plate technique, and incubated for an additional 24 to 48 hours at 35°C.

Three disparate colonies from each R2A agar plate were also subcultured on Tryptic Soy Agar (TSA; Difco, Sparks, MD, USA) plates, using the streak for isolation method. The pure cultures were then transferred to MacConkey Agar (Difco, Sparks, MD, USA) plates, Gram-stained and further characterized using the oxidase and catalase tests. Isolated colonies from the TSA plates were also resuspended in inoculating fluid (Biolog, Inc. Hayward, CA, USA) to a turbidity approximately equivalent to Biolog turbidity standards and then used to inoculate Biolog MicroPlates™ (Biolog, Inc., Hayward, CA, USA) as per the manufacturer's instructions. The plates were incubated for 24 hours at 35°C. The results were manually analyzed by use of the Biolog MicroLog 1 System (Program Version 4.20).

Statistical analysis

A Student's t-test was used to compare the bacterial counts recovered from dishcloths in restaurants and bars. Geometric means were used to report the results and were utilized in the statistical analyses. Geometric means were utilized for all bacterial counts because of the presence of outlying data values. Similar studies conducted in household kitchen environments have also employed geometric means *(3, 6, 12)*.

FIGURE 1. Bacterial levels found in dishcloths and on tabletops in restaurants and bars

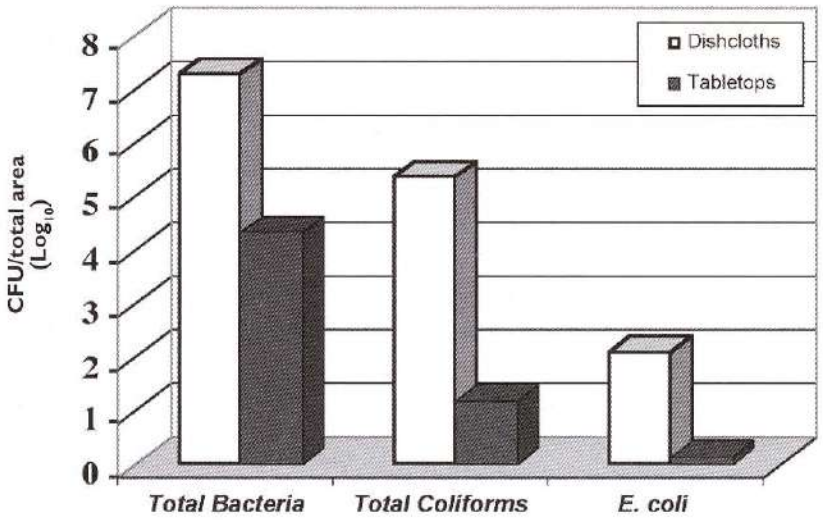


FIGURE 2. Comparison of bacterial levels in dishcloths from restaurants and bars

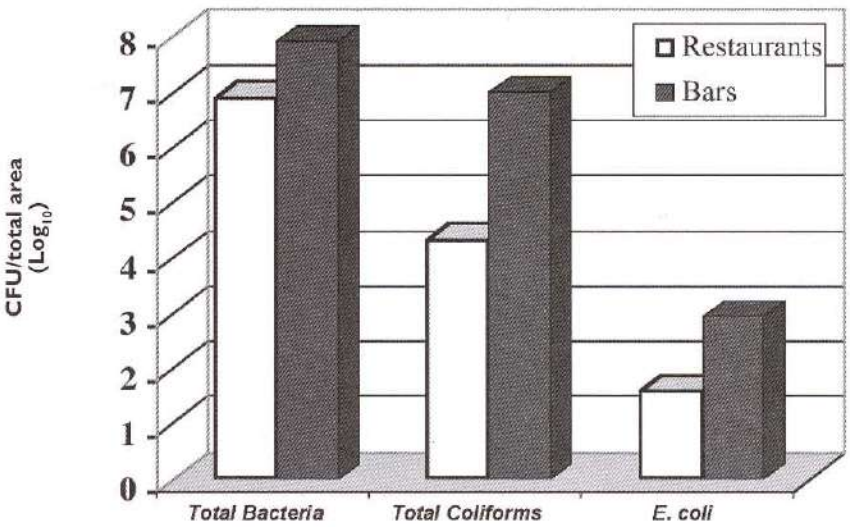
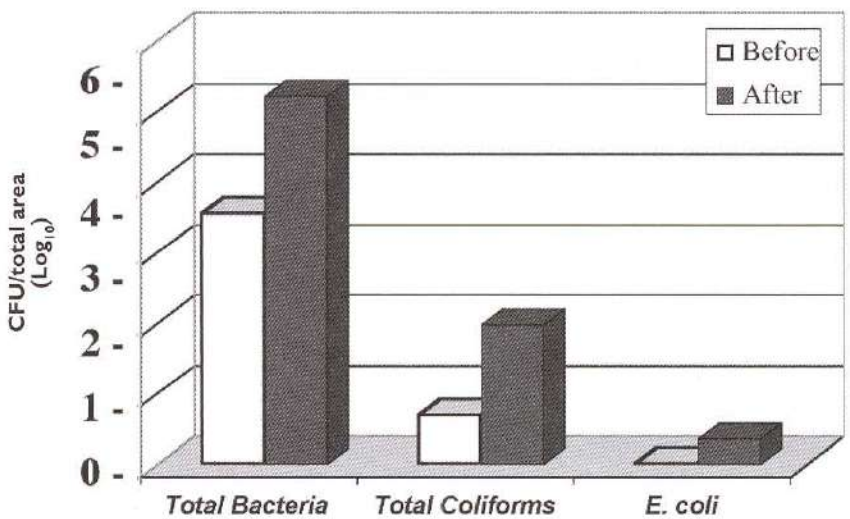


FIGURE 3. Bacteria found on tabletops before and after cleaning in restaurants



RESULTS

HPC, total coliforms and *E. coli* bacteria

Geometric means (GM) of approximately 1.9×10^7 CFU/cloth of heterotrophic plate count bacteria (range of 8.5×10^2 to 8.5×10^{10}), 2.2×10^5 CFU/cloth of total coliform bacteria (range of 70 to 1.0×10^{11}) and 1.2×10^2 CFU/cloth of *E. coli* (range of 2.3 to 1.1×10^6) were isolated from dishcloths in restaurants and bars (Fig. 1). Total coliforms were found in 89.2% of the dishcloths sampled (7.6×10^5 CFU/cloth) and *E. coli* in 54.1% of dishcloths (1.9×10^3 CFU/cloth).

A geometric mean of 2.2×10^4 CFU for heterotrophic plate count bacteria (range of 8.3×10^2 to 2.4×10^7), 15.0 CFU for total coliform bacteria (range of 1.0 to 1.2×10^7) and 1.4 CFU for *E. coli* (range of 1.0 to 27.0) were isolated from swabs of tabletops in restaurants (Fig. 1). These numbers represent the bacteria found on the entire surface swabbed (approximately 156 cm^2). Total coliforms were found on 70% of tabletops (49.8 CFU/156 cm^2) sampled, and *E. coli* was found on 20% of tabletops (5.2 CFU/156 cm^2).

The levels of bacteria found in dishcloths from bars were higher than those found in dishcloths from restaurants (Fig. 2). In dishcloths from restaurants, there were approximately 7.7×10^6 CFU/cloth of HPC bacteria, 2.1×10^4 CFU/cloth of total coliforms and 3.7×10^1 CFU/cloth of *E. coli*. Figures for dishcloths from bars were approximately 8.7×10^7, 1.0×10^7 and 8.7×10^2 CFU/cloth of total bacteria, total coliforms and *E. coli*, respectively. These differences were significant ($P \leq 0.05$) for HPC bacteria and total coliforms, but not for *E. coli*.

Greater numbers of bacteria were found on tabletops that had been cleaned with a dishcloth than before cleaning (Fig. 3). Approximately 3.56×10^3 CFU/156 cm^2 heterotrophic plate count bacteria were found before cleaning. This number increased to 1.6×10^5 CFU/156 cm^2 (45-fold increase) after the tables had been wiped down with a dishcloth. Likewise, the numbers increased for total coliforms (4.9 to 92.2 CFU/156 cm^2) and *E. coli* (< 1 to 2.3 CFU/156 cm^2) following cleaning.

Bacterial species identification

No isolates of *Listeria monocytogenes* were recovered from dishcloths (0/37) in restaurants and bars; however, *Listeria inocua* was found in 9/37 dishcloths (24.3%). A list of bacterial species recovered from dishcloths is shown in Table 1. The other most commonly isolated spe-

TABLE I. Bacterial species isolated from dishcloths in restaurants and bars

Species	# Positive	Frequency (%)
Listeria inocua	9/37	24.3
Raoultella (Klebsiella) terrigena	7/37	18.9
Pseudomonas macuicola	6/37	16.2
Pseudomonas putida	6/37	16.2
Pseudomonas fluorescens	3/37	8.1
Ralstonia (Pseudomonas) pickettii	3/37	8.1
Enterobacter cloacae	3/37	8.1
Enterobacter agglomerans	2/37	5.4
Ralstonia (Pseudomonas) solanacearum	2/37	5.4
Cellulomonas hominis	2/37	5.4
Stenotrophomonas maltophilia	2/37	5.4
Acinetobacter calcoaceticus	2/37	5.4
Pseudomonas syringae	1/37	2.7
Klebsiella oxytoca	1/37	2.7
Klebsiella pneumoniae	1/37	2.7
Klebsiella spp.	1/37	2.7
Enterobacter aerogenes	1/37	2.7
Enterobacter asburiae	1/37	2.7
Enterobacter sakazakii	1/37	2.7
Staphylococcus aureus	1/37	2.7
Staphylococcus piscifermentans	1/37	2.7
Staphylococcus sciuri	1/37	2.7
Staphylococcus wameri	1/37	2.7
Serratia marcescens	1/37	2.7
Serratia rubidaea	1/37	2.7
Kluyvera ascorbata	1/37	2.7
Kluyvera cryocrescens	1/37	2.7
Microbacterium arborescens	1/37	2.7
Microbacterium testaceum	1/37	2.7
Aeromonas veronii	1/37	2.7
Bacillus mycoides	1/37	2.7
Bacillus subtillis	1/37	2.7
Brevundimonas vesicularis	1/37	2.7
Buttauxella izardii	1/37	2.7
Chryseobacterium gleum	1/37	2.7
Comamonas terrigena	1/37	2.7
Corynebacterium thomssenii	1/37	2.7
Dermobacter hominis	1/37	2.7
Escherichia vulneris	1/37	2.7
Herbaspirillum seropedicae	1/37	2.7
Pantoea punctata	1/37	2.7
Paucimonas lemoignei	1/37	2.7
Rhanella aquatilis	1/37	2.7
Roseomonas genomospecies	1/37	2.7

TABLE 2. Frequency (%) of most commonly isolated bacterial species in dishcloths/cleaning utensils

Species	Restaurants and bars[a]	Household Kitchens	
		Study 1[b]	Study 2[c]
***Pseudomonas* spp.**	56.8	31.0 – 38.1	31.8
***Enterobacter* spp.**	21.6	14.3 – 20.7	4.8
***Klebsiella* spp.**	27.0	0	0
***Listeria* spp.**	24.3	ND[d]	ND[d]
***Salmonella* spp.**	0	13.8 – 15.4	9.8
Staphylococcus aureus	2.7	18.6 – 20.0	> 60.0
Aeromonas hydrophila	0	0	19.5

a – present study included only dishcloths

b – study included both dishcloths and sponges (Enriquez et al. 1997b)

c – study included both sponges and loofahs (Chaidez and Gerba 2000)

d – presence not determined

TABLE 3. FDA approved chemical dishcloth sanitizers for food service establishments

Sanitizer	Concentration (mg/L)	Time (sec.)	Temperature (°C)	pH	Water Hardness (mg/L)
Iodine	12.5 to 25	30	≥ 24	≤ 5[a]	N/A
Chlorine[b]	25	7	49	≤ 10	N/A
	50	7	24	≤ 8	N/A
	50	7	38	10	N/A
	100	10	13	≤ 10	N/A
Quaternary Ammonium Compounds	200	30	≥ 24	N/A	≤ 500

a – or a pH no higher than the level for which the manufacturer specifies the solution is effective

b – any of the four sets of conditions specified may be used

N/A – not applicable

cies were *Raoultella* (*Klebsiella*) *terrigena* (18.9% frequency), *Pseudomonas macuicola* (16.2%), *Pseudomonas putida* (16.2%), *Pseudomonas fluorescens* (8.1%), *Ralstonia* (*Pseudomonas*) *pickettii* (8.1%) and *Enterobacter cloacae* (8.1%).

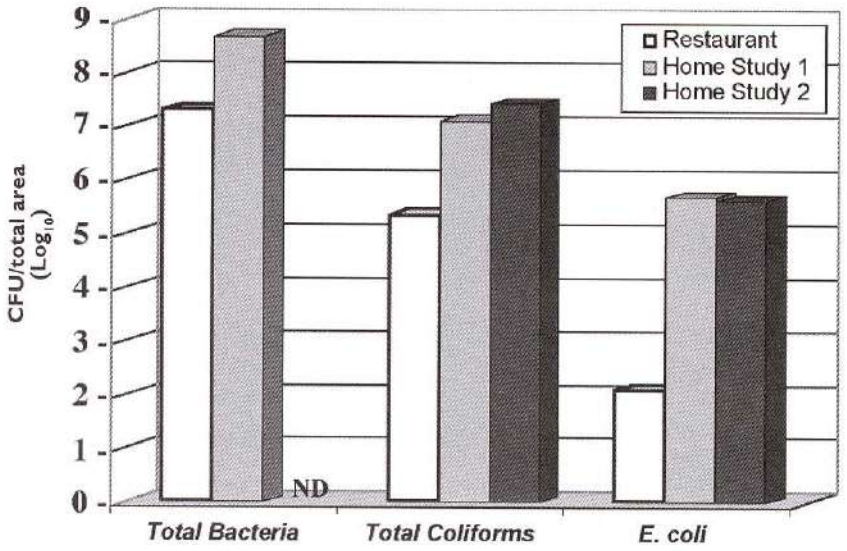
The most common genera isolated (Table 2) were *Pseudomonas* (6 species, 21 isolates, 56.8% frequency), *Klebsiella* (4 species, 10 isolates, 27.0% frequency), *Listeria* (1 species, 9 isolates, 24.3% frequency), *Enterobacter* (5 species, 8 isolates, 21.6% frequency) and *Staphylococcus* (4 species, 4 isolates, 10.8% frequency). *Staphylococcus aureus* was found in 1/37 dishcloths (2.7% frequency).

DISCUSSION

Self-disinfecting sponges, which are colonized by lower numbers of bacteria in comparison to regular sponges, reduce the transfer of total and fecal coliform bacteria to surfaces and to hands *(5)*. Self-disinfecting cloths are often improperly used, causing neutralization of the disinfectant *(14)*. The use of self-disinfecting cloths is therefore not likely to be a viable option for public food service establishments.

The FDA-approved chemical sanitizers for linens in restaurants and bars, and the specific conditions for their use,

FIGURE 4. Comparison of bacterial levels[a] in dishcloths from restaurants/bars and homes[b]



a – The number of *E. coli* found in restaurants/bars was compared to the number of fecal coliforms in homes

b – Study 1 (Rusin et al. 1998); Study 2 (Enriquez et al. 1997b)

ND – not determined

are listed in Table 3. Other sanitizers are also allowed so long as they are used in accordance with the manufacturer's use directions included in the labeling *(1)*. The purpose of these sanitizer solutions is to sanitize the cloths after they have been contaminated through use. Sanitization is the cumulative effect of treatments that results in at least a 5-$\log_{10}$ (99.999%) reduction in representative disease microorganisms of public health importance *(1)*. The FDA's federal food code recommends that linens used in restaurants and bars to wipe down food service areas be soaked in one of these approved sanitizers under the conditions specified in Table 3 *(1)*. As of September 2004, the federal food code had been adopted by 45 states and one territory and was in the process of being adopted by several others. The FDA's recommendations have therefore been mandated by regulatory agencies in most states *(1)*.

As soiled cloths are added to the sanitizing liquid, organic material in the cloths creates a demand on the sanitizer itself. It may also cause changes in pH and water hardness that will decrease the sanitizer's effectiveness or even neutralize the solution. The sanitizing solution should therefore be checked regularly and replenished/refreshed. The temperature of the sanitizing solution may also drop below the recommended minimum, thereby reducing its efficacy. Food service establishments often do not routinely monitor the quality of the sanitizer dip during use, and restaurants and bars therefore often fail to meet these sanitization criteria.

In the present study, bacterial levels found in dishcloths from bars were consistently higher than dishcloths used in restaurants. One possible explanation is that cloths from bars do not become visibly soiled as quickly as those from restaurants and therefore are not sanitized as frequently. Also, workers in bars are perhaps less aware or concerned about the need for proper sanitation of cloths than are restaurant workers. Cloths in bars are usually used to wipe up liquid spills rather than foods. If they are not sanitized as frequently because of lack of visible soiling and/or worker complacency, this provides a moist environment in which bacteria are able to survive for extended periods *(4, 8)*.

The levels of heterotrophic bacteria, total coliforms and *E. coli* found in dishcloths from restaurants and bars were compared to levels found in dishcloths in homes, as reported in previous studies (Fig. 4). The number of HPC bacteria was approximately 25-fold lower in dishcloths from restaurants and bars than in those from homes *(12)*. Likewise, the number of total coliforms was approximately 60- to 120-fold lower in dishcloths from restaurants/bars *(6, 12)*. The number of *E. coli* was also significantly (3,400- to 4,000-fold) lower (in comparison to the number of fecal coliforms) *(6, 12)*. The number of *E. coli* would be expected to be lower than the number of fecal coliforms present; however, the other differences between HPC and coliform bacterial counts could be due to the mandatory use of sanitizers and a greater frequency of cleaning in restaurants and bars. One should note that the Colilert assay used to determine the number of total coliforms in our study also varied from the mEndo plate counts utilized in the household studies *(6, 12)*. Thus, some portion of this discrepancy could be due to the use of different methods.

The total numbers of bacteria, coliforms and *E. coli* (vs. fecal coliforms) found on restaurant tabletops were also lower (2-, 9- and 12-fold, respectively) than those found on household kitchen countertops *(12)*. This was, again, possibly due to the required use of detergents/sanitizers in restaurants. Total bacteria found on tabletops after cleaning was 45-fold greater than before cleaning, perhaps implicating the dishcloths in tabletop contamination. This was most likely due to the inadequate sanitization of the linens used to wipe down tables.

Listeria monocytogenes was not found in any of the dishcloth samples; however, *Listeria inocua* was present in 24.3% of the dishcloths tested. The presence of another *Listeria* species could indicate that conditions may allow for contamination by and persistence of the pathogen *L. monocytogenes*.

Although many of the bacterial isolates identified were similar for both restaurants/bars and homes, *Pseudomonas* spp., and *Klebsiella* spp. were more prevalent in restaurants and bars whereas *Salmonella* spp., *Staphylococcus aureus* and *Aeromonas hydrophila* were more prevalent in homes (Table 2). *Salmonella* spp., which may be isolated from raw chicken and eggs, although commonly found in dishcloths used in household kitchens where raw foods are handled, are not likely to be found in dishcloths used to wipe down tabletops in restaurants and bars, where cooked foods are generally the only foods present. However, the other species differences noted suggest a possible species shift between the microbial populations, because presumably the original microbial populations should be similar in both environments. This is also possibly due to the mandatory and regular use of sanitizers in restaurants and bars.

Although this study was fairly small, it raises several interesting questions. For instance, although the bacterial numbers found in food service establishments were lower than the numbers found in homes,

considerable numbers of coliforms and *E. coli* were still present. This could represent a danger to the public, especially for populations at risk, including the very young, the elderly and the immunocompromised. Also, because the bacterial numbers found on tabletops after wiping with a cloth were higher than the numbers prior to cleaning, the use of such cloths in restaurants and bars could contribute to contamination of surfaces and to the spread of potentially harmful bacteria. Therefore, more careful monitoring of linen sanitization solutions used by food service establishments such as restaurants and bars may be called for.

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Research Paper

Allergen Removal and Transfer with Wiping and Cleaning Methods Used in Retail and Food Service Establishments

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ABSTRACT

Preventing the transfer of allergens from one food to another via food contact surfaces in retail food environments is an important aspect of retail food safety. Existing recommendations for wiping and cleaning food contact surfaces is mainly focused on preventing microorganisms, such as bacteria and viruses, from contaminating foods. The effectiveness of these wiping and cleaning recommendations for preventing the transfer of food allergens in retail and food service establishments remains unclear. This project investigated (i) allergen removal from surfaces by wiping with paper wipes, terry cloth, and alcohol quaternary ammonium chloride (quat) sanitizing wipes; (ii) cleaning of allergen-contaminated surfaces by using a wash–rinse–sanitize–air dry procedure; and (iii) allergen transfer from contaminated wipes to multiple surfaces. Food contact surfaces (stainless steel, textured plastic, and maple wood) were contaminated with peanut-, milk- and egg-containing foods and subjected to various wiping and cleaning procedures. For transfer experiments, dry paper wipes or wet cloths contaminated with allergenic foods were wiped on four surfaces of the same composition. Allergen-specific lateral flow devices were used to detect the presence of allergen residues on wiped or cleaned surfaces. Although dry wipes and cloths were not effective for removing allergenic foods, terry cloth presoaked in water or sanitizer solution, use of multiple quat wipes, and the wash–rinse–sanitize–air dry procedure were effective in allergen removal from surfaces. Allergens present on dry wipes were transferred to wiped surfaces. In contrast, minimal or no allergen transfer to surfaces was found when allergen-contaminated terry cloth was submerged in sanitizer solution prior to wiping surfaces. The full cleaning method (wash–rinse–sanitize–air dry) and soaking the terry cloth in sanitizer solution prior to wiping were effective at allergen removal and minimizing allergen transfer.

HIGHLIGHTS

- Wet cloths and wipes were more effective in allergen removal from surfaces than dry wipes.
- Prescraping food from surfaces prior to full cleaning aided allergen removal.
- Cloth storage in sanitizer solution minimized allergen transfer between surfaces.
- Allergens were difficult to remove from a textured plastic surface.

Key words: Allergen; Cross-contact; Food contact surface; Removal; Retail

The prevalence of food allergies among the U.S. population is estimated between 3 to 4%, with evidence of food allergies in children as high as 8% *(1, 5, 8, 17, 18)*. Allergic reactions to foods are the most common cause of anaphylaxis reported in the community *(5)*. With more than 54% of food expenditures in 2018 attributed to food purchases away from home, there is a need for evaluations of effective allergen control procedures in various food establishments to protect food-allergic consumers *(20)*.

Recommendations for ensuring the safety and protection of food prepared in retail and food service establishments are described in the U.S. Food and Drug Administration (FDA) Food Code *(23)*. Most state, local, tribal, and territorial regulatory agencies have adopted some edition of the FDA Food Code (hereafter "Food Code"), which is updated every 4 years by the FDA's Retail Food Protection Staff. Although many of the provisions in the Food Code were originally developed to reduce microbial risks associated with foods, the effectiveness of these practices for preventing allergen cross-contact remains unclear. The definition of major food allergens contained in the Food Allergen Labeling and Consumer Protection Act of 2004 *(22)* was added to the 2005 edition of the Food Code. The updated 2009 Food Code further specified that food allergy awareness must be part of the food safety training duties of the person in charge of the establishment. Additionally, the 2013 Food Code amended the cleaning

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and sanitizing frequency for food contact surfaces or utensils that are in contact with raw animal food that is a major food allergen, such as fish, followed by other types of raw animal foods. The 2015 supplement to the 2013 Food Code further specified that employees must be properly trained in food safety, including food allergy awareness, as it relates to assigned duties. Although recommendations are provided in Chapters 3 (Subpart 3-304) and 4 (Subparts 4-301, 4-501, 4-603, 4-703) of the 2017 edition of the Food Code *(23)* for manual warewashing or full cleaning and use limitations for wiping cloths, little information exists on whether they are effective at preventing allergen transfer, because these recommendations were originally developed to reduce microbial contamination risk *(19, 27)*.

Published information on the effectiveness of cleaning and wiping procedures used in retail and food service establishments for allergen control on food contact surfaces is scarce. Previous literature reports mostly focused on peanut distribution in different environments, such as the home, school, and hospitals or investigated peanut removal from hands or surfaces by using common cleaning agents or household or hospital wipes *(6, 14, 26)*. One of the few surveys on the occurrence of milk, egg, and gluten on food contact surfaces in school cafeterias was conducted by Ortiz et al. *(13)*. This research team determined the presence of milk, egg, and gluten on food contact surfaces and utensils used in school cafeterias in Spain and documented the percentage of positive results by allergen and general or exclusive use of surfaces and utensils.

Several publications on cleaning and other control strategies for preventing allergen cross-contact in a food manufacturing environment highlighted dry and wet cleaning methods along with indirect (visually clean) and direct (allergen-specific tests) validation and verification procedures when developing an effective allergen control program *(9, 15, 24)*. Additionally, the Food Code, which provides recommendations for ensuring the safety and protection of food prepared in retail and food service establishments *(23),* also provides some details about the cleaning of food contact surfaces, although these were originally focused to reduce microbial risks associated with foods. Although there are differences in the procedures used for allergen removal and cleaning in industrial food manufacturing operations compared with retail and food service operations, the factors influencing allergen removal are similar. Parameters that influence allergen removal include the nature of the allergenic food matrix (dry powder, wet, paste, or sticky, and high fat), allergen load applied to a surface, food contact material composition, surface characteristics (smooth, textured, or porous), and the type of wipe used in allergen removal *(16)*. The complex set of factors that influence allergen removal, combined with the reality that staff in a retail food setting often rely on speed and efficiency with regard to wiping and cleaning surfaces, can make allergen control in food establishments difficult.

The three primary objectives of this study were to investigate (i) the effectiveness of wiping on the removal of peanut, egg, and milk allergen from stainless steel (SS), textured polyethylene plastic, and maple hardwood surfaces; (ii) the impact of a manual wash–rinse–sanitize–air dry full cleaning method on allergen removal from allergen-contaminated surfaces; and (iii) the extent of allergen transfer to surfaces when using allergen-contaminated wipes or cloths. The materials and methods in this study were chosen with the main intent to mimic and study dry, wet, or sticky and paste food compositions of certain major food allergens that may be commonly found on food contact surfaces in various retail and food service establishments.

MATERIALS AND METHODS

Materials. Food-grade SS (304 alloy, 2B finish, Online Metal Supply, Houston, MO), textured polyethylene plastic cutting boards (15.24 by 25.4 cm; Food Service Warehouse, Greenwood, CO) and hard maple wood cutting boards (Carlisle-HLA800, 40.64 by 60.96 by 3.81 cm; Food Service Warehouse) were used for the study. The SS, plastic, and wood were cut to form coupons (~12 by 12 cm) prior to use. Coupons and surfaces were cleaned prior to each set of experiments by using the following procedure. All items were first rinsed individually under running warm tap water (~45°C), followed by applying a 2% solution of Micro-90 alkaline detergent (International Products Corporation, Burlington, NJ). Disposable paper towels (Scott C-Fold, Kimberly-Clark, Roswell, GA) were used to scrub the coupon surface, and warm tap water was used to remove the detergent solution. The cleaning procedure was repeated twice, and a final rinse step with deionized water was used before the coupons or items were placed on a dish rack to air dry.

Dry or powdered, wet, and sticky or paste forms of foods containing milk, egg, and peanut allergens were purchased at local grocery stores or online. The foods included Carnation nonfat dry milk powder (NFDMP; Nestlé, Solon, OH), Philadelphia cream cheese (Kraft, Northfield, IL), fluid whole milk (Dean Foods, Dallas, TX), whole egg crystals (Hoosier Hill Farm, Fort Wayne, IN), Hellmann's mayonnaise (Unilever, Englewood Cliffs, NJ), Jif Peanut Powder (The J.M. Smucker Company, Orrville, OH), and Skippy Creamy Peanut Butter (Hormel Foods Corporation, Austin, MN). The protein content (percentage) of each allergenic food was measured with the Kjeldahl test by a contract laboratory (Merieux NutriSciences, Crete, IL). Protein concentrations of nonfat dry milk, cream cheese, fluid whole milk, whole egg crystals, mayonnaise, peanut powder, and peanut butter were 35.3, 5.0, 3.2, 42.2, 1.0, 45.6, and 21.6% (on an as-is basis), respectively. The various protein concentrations are important to note because the different allergenic foods contained different amounts of protein, the analyte detected in the lateral flow device (LFD) assays.

WypAll X60 dry paper wipes (31 by 40 cm; Kimberly-Clark, Roswell, GA), dry terry dish cloths (86% cotton and 14% polyester blend; 30 by 30 cm; Central Restaurant Products, Indianapolis, IN), and sanitizing wipes saturated with 5.48% isopropyl alcohol and 175 ppm of quaternary ammonium chloride (quat; 20 by 26 cm; Table Turners Sani-Professional no-rinse hard, nonporous surface sanitizing wipes, PDI, Inc., Orangeburg, NY) were used in the wiping and transfer studies. Wet terry dish cloths soaked in warm tap water (~43°C) or in a 50 ppm of total chlorine bleach sanitizer solution (~43°C) for 5 min were also used in the experiments. Wet terry cloth was gently squeezed to remove excess water or sanitizer solution prior to use. Total chlorine levels in the tap water and sanitizer were measured by using the Hach thiosulfate drop test (product CN-21P; Hach, Loveland, CO) and test strips (product 2745050). The concentration of total chlorine used for sanitizing solution in this study (50 ppm total) is within

the concentration range (25 to 100 ppm of total chlorine) specified in the Food Code (Subpart 4-501.114) *(23)*.

Allergen detection. Coupon surfaces were swabbed after conducting the wiping, cleaning, and transfer experiments by using the instructions provided with Neogen allergen LFD kits. The presence of milk, egg, and peanut from swabbed surfaces was determined with allergen-specific Reveal 3-D (Neogen, Lansing, MI) LFD tests for total milk (product 8479), egg (product 902082Q), and peanut (product 901041L).

A set of experiments evaluated the effects of sanitizer residue (chlorine or quat) on LFD results. Tap water or chlorine sanitizer solutions (0 or 1 mL; 50 ppm or 100 ppm of total chlorine) were applied to clean, allergen-free surfaces. The surfaces were then swabbed and tested for responses with the LFD tests. Similarly, clean SS, plastic, and wood surfaces were also wiped with the quat sanitizing wipe for 5 s and then tested with a premoistened swab to determine if residual quat affected the LFD responses with the milk, egg, and peanut LFD test kits.

Another study also investigated the possibility of false-negative LFD responses when allergens were in the presence of sanitizers. This series of experiments used the liquid sampling procedure described in the allergen-specific test kits and did not involve swabs or coupons. The protocol used for milk allergen involved mixing 0.1 to 5 mL whole liquid milk with 5 mL of 100 ppm of total chlorine sanitizer solution for 30 s. One milliliter of the mixture was then added to the extraction buffer provided and then tested for the presence of milk with the procedure described in the milk LFD test kit. In a similar manner, 0.1 g of peanut butter was mixed for 30 s with 0.5 to 5 mL of 100 ppm of total chlorine sanitizer for the peanut allergen interference tests, but 0.25 mL of the mixtures were added to the extraction buffer, followed by testing for peanut by LFD. Egg allergen sanitizer interference studies examined the addition of 0.1 to 0.5 g of mayonnaise to 0.5 to 5 mL of 100 ppm of total chlorine sanitizer for 30 s, and 0.25 mL of the mixture was added to the extraction buffer. Similarly, whole egg crystals (0.05 g) added to 5 mL of sanitizer solution was also evaluated with a 30-s contact time with the egg LFD liquid sampling procedure. Overall, various ratios of the allergenic food (each containing different amounts of protein) to 100 ppm of total chlorine sanitizer solution were explored and ranged from a 1:1 to 1:100 ratio of allergen to chlorine sanitizer solution to simulate conditions near the maximum use limit for sanitizer solution. The 30-s mixing time was selected on the basis of the time frame used in the full cleaning study.

Wiping study. Each allergenic food was applied individually to the SS, plastic, and wood coupons to cover a surface area (10 by 10 cm) and spread as evenly as possible with a disposable spatula. The amounts of foods used to contaminate the coupons were as follows: peanut powder (0.05 g); peanut butter (0.1 g); NFDMP (0.05 g); cream cheese (0.1 to 4.0 g); fluid whole milk (1 mL); whole egg crystals (0.05 g); and mayonnaise (0.5 to 2.0 g).

Immediately after foods were applied to the coupons, each surface was then manually wiped for 5 s with a single dry paper wipe, dry terry cloth, or wet terry cloth (soaked in water or 50 ppm of total chlorine sanitizing solution prepared with bleach). Experiments in this study used sanitizing solutions near the mid-concentration level of 50 ppm of total chlorine instead of the upper limit of 100 ppm of total chlorine. After wiping, the presence of the residual allergen was determined by visually inspecting the coupon under room lighting by the same individual (typical of a food establishment) and by swabbing the surface with a premoistened swab by using the procedure described in each allergen-specific LFD test kit. For experiments evaluating sanitizing quat wipes, multiple wipes per surface were used if the surface tested positive for allergens after one wipe was used. Wiping experiments for each experimental condition (food contact surface, type of wipe, allergenic food type, and amount) were completed in triplicate.

A wiping time of 5 s was selected because experiments with 0.1 g of peanut butter or 0.05 g of whole egg crystals on the SS, plastic, and wood surfaces were visually clean on most surfaces after using the dry paper wipe. Wiping for 1 s did not yield a visually clean surface, but a 5- and 10-s wipe time removed most of the food soil from the coupons on the basis of visual inspection. The only exception was a very faint, light yellow stain noted after wiping peanut butter on the textured plastic surface in all triplicate trials.

Full manual cleaning by using the wash–rinse–sanitize–air dry method. Three contaminated coupons for each allergenic food and coupon type (SS, plastic, and wood) were prepared for the full cleaning study. The amounts of food applied to each coupon were peanut powder (0.5 g), peanut butter (1 g), whole egg crystals (1 g), mayonnaise (4 g), cream cheese (4 g), fluid whole milk (5 mL), and NFDMP (0.1 g). The manual ware-washing method with a three-bay sink as outlined in the Food Code was simulated in the laboratory by using three pails. The first pail was designated as a wash pail and contained 10 L of warm tap water (~43°C) mixed with 5 mL of detergent (Dawn Ultra, Procter and Gamble, Cincinnati, OH). The second pail acted as the rinse pail with 10 L of warm tap water (~43°C). The third pail contained 50 ppm of total chlorine sanitizer solution, prepared by mixing 6.6 mL of bleach with 10 L of warm tap water (~43°C). The Hach thiosulfate drop test was used to measure the total chlorine level, as described in the test kit. The full cleaning procedure involved submerging one SS coupon in the wash pail and manually wiping the surface under water in the wash pail with a clean terry cloth for 30 s. The coupon was then immersed in the rinse pail for 30 s, followed by submerging it in the sanitizer pail for 30 s. The final step was to air dry the coupons on a drying rack for a minimum of 30 min. The full cleaning procedure was repeated until all three SS, plastic, and wood coupons, having the same allergen load per surface, were washed consecutively by using the same wash, rinse, and sanitizer pails. After air-drying coupons for a minimum of 30 min, each surface was sampled with one premoistened swab and analyzed for allergen residue with the appropriate LFD test. All full cleaning experiments were conducted without scraping the surfaces with a plastic spatula (prescrape step) prior to washing the coupons. An exception was made for coupons contaminated with peanut butter, which were evaluated with and without a prescrape step. The full cleaning experiment was repeated three times.

Allergen transfer experiments. For the dry wipe transfer study, allergenic food was applied to the center of a dry paper wipe (WypAll X60). The amount of dry foods used to soil the dry wipe were as follows: whole egg crystals (0.01 to 0.05 g); peanut powder (0.01 to 0.05 g); and NFDMP (0.05 g). Sticky, paste, and wet foods were also evaluated in the study and included mayonnaise (0.5 to 2.0 g), peanut butter (0.1 g), fluid whole milk (1 mL), and cream cheese (0.5 g). The contaminated wipe was then used to wipe four consecutive coupon surfaces of the same composition for 5 s of contact time between the wipe and each surface. The wiped surfaces (1 to 4) were then sampled with a premoistened swab and analyzed for presence of allergen by using the appropriate LFD test.

A set of experiments evaluated the extent of transfer from terry cloth to wiped surfaces when the cloths were stored in sanitizer solution before use. The Food Code, Subparagraph 3-304.14 (B)(1), recommends that cloths in use for wiping counters and other equipment surfaces are held between uses in a chemical sanitizer solution. A sanitizer solution (50 ppm of total chlorine) was prepared by adding 2.5 mL of bleach to 3.78 L of warm tap water (~40 to 45°C), and residual chlorine level was measured. A clean terry cloth was soaked in sanitizer solution for 5 min and then gently squeezed to remove excess sanitizer solution. The center of the wet cloth was loaded with individual allergenic foods (0.05 g of whole egg crystals, 0.05 g of peanut powder, 0.05 g of NFDMP, 2.0 g of mayonnaise, 0.1 g of peanut butter, 1 mL of fluid whole milk, and 2.0 g of cream cheese), and the allergen-contaminated cloth was then wiped on the surface of one coupon type for 5 s. The same cloth was submerged in sanitizer solution for 15 s and then wiped on a second coupon of the same composition as the first. The same procedure was followed to wipe the remaining two other coupons. All four surfaces were sampled by using a premoistened swab (one swab per surface) and analyzed for the presence of peanut, milk, or egg residue with an LFD test. Transfer experiments were repeated in triplicate.

RESULTS AND DISCUSSION

Food service and retail food establishments often handle a wide variety of food allergens in various forms that routinely contact SS, as well as plastic or hardwood food contact surfaces, such as cutting boards, bowls, cookware, and utensils during food preparation. Allergenic food matrices selected for this study were chosen on the basis of an attempt to evaluate various forms of milk (NFDMP, whole liquid milk, and cream cheese), egg (whole egg crystals and mayonnaise), and peanut (peanut powder and peanut butter) allergens in a dry, wet, or sticky and paste composition, that may be commonly found in kitchens of food establishments in preparation of sandwiches or bakery items. Additionally, these foods were chosen because milk, eggs and peanuts are identified as "major food allergens" in the Food Allergen Labeling and Consumer Protection Act of 2004 and in the Food Code *(22, 23)*. The coupons or surfaces selected for use were chosen to reflect different finishes (smooth, textured, and porous) and materials of composition (SS, polyethylene plastic, and hard maple wood) of food contact surfaces used in food establishments. Similarly, the dry paper wipes, terry cloth, and disposable quat wipes chosen for the study reflect items described in Chapter 4 of the Food Code and are commonly used in food establishments for wiping surfaces with or without use of a bleach-based sanitizing solution *(23)*. The wiping and allergen transfer studies were designed to provide information on the effectiveness of some practices that may be used outside of the Food Code recommendations. The full cleaning method, as described in Chapter 4 of the Food Code, used the manual three-compartment warewashing method incorporating a detergent containing wash (compartment 1), clean water rinse (compartment 2), chlorine-based sanitizing step (compartment 3) and was followed by air drying the surfaces *(23)*. To simulate a practical use application of this cleaning method, three SS, three plastic, and three wood surfaces each having high allergen loads on the individual surfaces were manually cleaned and evaluated for allergen residue by using allergen-specific LFDs.

Use of LFDs to detect allergen residues. Allergen-specific LFD tests used in this study provided a rapid, qualitative assessment regarding the presence of allergen residue rather than quantitative results. Positive control experiments were conducted to ensure that the lowest amount of each allergenic food used in the experiments could be detected on the coupons prior to any wiping or cleaning. For all allergenic foods (0.01 g of peanut powder, 0.1 g of peanut butter, 0.05 g of NFDMP, 0.1 g of cream cheese, 1.0 mL of fluid whole milk, 0.05 g of whole egg crystals, and 0.1 g of mayonnaise), positive LFD responses (3 of 3) were recorded. The limit of detection (LOD) for the peanut, milk, and egg LFD tests were not determined for each of the allergenic foods evaluated in this study.

Negative control experiments were used to confirm that the presence of chlorine sanitizer did not result in positive LFD results or interfere with the immunochemical tests. For example, testing 100 ppm of total chlorine sanitizer directly, by mixing with the extraction buffer included in the milk, peanut, and egg LFD kits, tested negative and showed no interference with the LFD test response (Supplemental Table S1). "High-positive" LFD results reflect an overloaded sample having a high allergen concentration. Additional experiments were also conducted to determine if the ability to detect allergenic food was influenced by residual sanitizer solution. Varying ratios of whole liquid milk, peanut butter, mayonnaise, or whole egg crystals and 100 ppm of total chlorine sanitizer solution were mixed for 30 s and analyzed with the appropriate LFD, after dilution with extraction buffer included with each LFD kit. The results of the LFD tests are shown in Table S1. All triplicate responses were positive or high positive (as described in Table S1 and the test kit insert on reading LFD results) for the presence of the allergens that indicated that 100 ppm of total chlorine sanitizer solution did not interfere with the LFD tests under the tested conditions. Additionally, sanitizer residue (chlorine or quat) swabbed from clean surfaces tested negative with the peanut, milk, and egg LFD tests.

Wiping study. It is common practice within retail and food establishments to routinely wipe surfaces with disposable wipes or reusable cloths. The current (2017) edition of the Food Code *(23)* provides recommendations and use limitations of wiping cloths from a microbial control perspective. An important distinction for this study is to note that "wiping" for allergen removal is not equivalent to "cleaning" as described in the Food Code. Both Tebbutt *(19)* and Welker et al. *(27)* examined cleaning and wiping from a microbial control perspective and concluded that wiping surfaces having a food soil is different from cleaning a surface.

Information is currently lacking on the effectiveness of wiping methods on the removal of peanut, milk, and egg allergens from common food contact surfaces used in food establishments. This wiping study investigated removal of allergens in dry, wet, paste, and sticky forms and used five

TABLE 1. *Frequency of detecting peanut residue after wiping peanut powder from coupons, as determined with a peanut-specific lateral flow device (LFD)*[a]

	No. of positive LFD results/total LFD tests with each type of wipe					
Coupon type	Dry wipe	Dry terry cloth	Wet terry cloth (tap water)	Wet terry cloth (sanitizer solution)[b]	Alcohol quat wipe (one wipe)	Alcohol quat wipe (multiple wipes)
SS	3/3[c]	3/3	0/3	0/3	(f+)[d] 4/4	0/3 (2 wipes)
Plastic	3/3	2/3	0/3	0/3	(f+) 4/4	(f+) 2/3 (2 wipes) 0/3 (3 wipes)
Wood	3/3	3/3	0/3	0/3	(f+) 2/4	0/3 (2 wipes)

[a] Peanut powder (0.05 g) wiped from coupons. A positive control test with 0.01 g of peanut flour on SS, plastic, and wood coupons resulted in 3 of 3 positive LFD results. All wiped surfaces appeared visually clean. LOD of Neogen Reveal 3-D peanut LFD: 2 μg of peanut per 100 cm^2.
[b] Sanitizer solution refers to a 50 ppm of total chlorine sanitizing solution prepared with bleach.
[c] Ratio describes the number of positive LFD responses/total LFDs used.
[d] (f+), faint positive LFD response.

different types of wipes: a dry wipe (WypAll X60), a dry terry cloth, a wet terry cloth soaked in tap water, a wet terry cloth soaked in 50 ppm of total chlorine sanitizer solution, and a sanitizing disposable quat alcohol wipe. In general, the dry wipe and dry terry cloth were not effective in completely removing the different forms of peanut-, milk-, or egg-containing foods from most of the surfaces under the conditions tested as shown in Tables 1 to 7. Use of the dry wipe or cloth on the dry forms of the allergenic foods (i.e., peanut powder, nonfat dry milk, and egg crystals) was generally not adequate in removing allergens, because positive LFD results were detected on many of the surfaces in the triplicate trials, although the surfaces appeared visually clean (Tables 1, 3, and 6). For instance, as shown in Table 1, when the dry wipe was used to wipe peanut powder (0.5 g) from the SS, plastic, and wood, peanut residue was detected by LFD on all surfaces in triplicate trials. The dry terry cloth was used in the same manner, and peanut residue was detected on the SS, wood, and plastic surfaces in all three trials, except for one replicate trial for the plastic surface that showed complete removal of peanut powder. Similar to the results observed with the dry and powdered form of allergens, use of the dry wipe and dry terry cloth was not effective at removing allergenic food pastes (i.e., peanut butter, cream cheese, and mayonnaise) from the SS, plastic, and wood coupons (Tables 2, 4, and 7), although in some cases, the surfaces appeared visually clean.

The effectiveness of the wet terry cloth soaked in either tap water or 50 ppm of total chlorine sanitizer solution at allergen removal depended on the amount and form of the food allergen (dry, wet, paste, or sticky) and the composition of the coupon. For example, as shown in Tables 1, 4, and 7, the use of a wet terry cloth (soaked in tap water or sanitizer solution) to remove 0.05 g of peanut powder, 0.5 g of cream cheese, or 0.5 g of mayonnaise from coupon surfaces resulted in no detectable peanut, milk, or egg residues, respectively, on SS, plastic, and wood surfaces in triplicate trials. However, when higher amounts of cream cheese (Table 4) and mayonnaise (Table 7) were loaded on the wood or plastic surfaces, the wet terry cloth was not

TABLE 2. *Frequency of detecting peanut residue after wiping peanut butter from coupons, as determined with a peanut-specific lateral flow device (LFD)*[a]

	No. of positive LFD results/total LFD tests with each type of wipe					
Coupon type	Dry wipe	Dry terry cloth	Wet terry cloth (tap water)	Wet terry cloth (sanitizer solution)[b]	Alcohol quat wipe (one wipe)	Alcohol quat wipe (multiple wipes)
SS	2/3[c]	(f+) 3/3	2/3	2/3	3/3[d]	2/3 (2 wipes) 0/3 (3 wipes)
Plastic	3/3[e]	3/3	3/3	3/3	3/3	3/3 (2 wipes) (f+) 2/3 (3 wipes) 0/3 (4 wipes)
Wood	3/3	(f+) 3/3	3/3	2/3	3/3	(f+) 2/3 (2 wipes) 0/3 (3 wipes)

[a] Peanut butter (0.1 g) wiped from coupons. A positive control test with 0.1 g of peanut butter on SS, plastic, and wood coupons resulted in 3 of 3 positive LFD results. (f+), faint positive LFD response. LOD of Neogen Reveal 3-D peanut LFD: 2 μg of peanut per 100 cm^2.
[b] Sanitizing solution refers to a 50 ppm of total chlorine sanitizing solution prepared with bleach.
[c] Ratio describes the number of positive LFD responses/total LFDs used.
[d] SS surface showed slight sheen when wiped with one quat wipe. Plastic and wood surfaces appeared visibly clean.
[e] Very faint yellow residue on plastic observed.

TABLE 3. *Frequency of detecting milk after wiping nonfat dry milk powder (NFDMP) from coupons, as determined with a milk-specific lateral flow device (LFD)*[a]

	No. of positive LFD results/total LFD tests with each type of wipe					
Coupon type	Dry wipe	Dry terry cloth	Wet terry cloth (tap water)	Wet terry cloth (sanitizer solution)[b]	Alcohol quat wipe (one wipe)	Alcohol quat wipe (multiple wipes)
SS	(h+) 3/3[c]	3/3	(f+) 3/3	(f+) 3/3	3/3	0/3 (2 wipes)
Plastic	(h+) 3/3	3/3	(f+) 3/3	(f+) 2/3	3/3	0/3 (2 wipes)
Wood	(h+) 3/3	(f+) 3/3	(f+) 1/3	0/3	(f+) 2/3	0/3 (2 wipes)

[a] NFDMP (0.05 g) wiped from coupons. A positive control test with 0.05 g of NFDMP on SS, plastic, and wood surfaces resulted in high positive LFD response (h+) 3 of 3 positive LFD results. All wiped surfaces were visibly clean. (f+), faint positive LFD response. Neogen Reveal 3-D milk LOD: 20 μg milk per 100 cm^2.
[b] Sanitizing solution refers to a 50 ppm of total chlorine sanitizing solution prepared with bleach.
[c] Ratio describes the number of positive LFD responses/total LFDs used.

always effective at allergen removal. The coupons appeared to be visually clean, unless noted otherwise in the tables.

In general, disposable quat wipes were effective for allergen removal from the various surfaces, especially when multiple wipes were used (Tables 1 to 7). In most cases, two, three, or four wipes were needed to effectively remove allergens from surfaces and test negative (0 of 3) with the LFDs. The textured plastic surface was more difficult to wipe clean than the SS or wood surfaces when contaminated with sticky or paste forms of the allergenic foods, and additional wipes were often required to completely remove the allergen to levels below the LFD detection limit. As shown in Table 2, three wipes were required to remove 0.1 g of peanut butter from the SS and wood surfaces, but the textured plastic required four wipes to test negative for peanut by using the LFD tests. An early study by Tebbutt *(19)* and Welker et al. *(27)* also found that it was challenging to remove microbial contaminants from polypropylene plastic and wood surfaces. All quat-wiped surfaces were visually clean after using one wipe to remove 0.1 g of peanut butter, with the exception of a slightly oily sheen on the SS surface. Overall, these results are similar those reported by Watson et al. *(26)* who demonstrated the effectiveness of using one or more sanitizer wipes to remove peanut butter from a variety of different surfaces (a nonporous plastic table, a plastic toy, and plastic ball).

Although SS and plastic surfaces are commonly found in food establishments, the use of hardwood surfaces has been a subject of debate, mainly due to microbiological safety concerns. Research on the cleanability of different food contact surfaces showed that it is was more difficult to recover bacteria inoculated onto the surfaces of hardwood (maple, beech, oak, or walnut) coupons than from plastic (polyethylene or polyacrylic) surfaces *(2, 3, 7)*. The researchers attributed their findings to the porosity of hardwood coupons. Additionally, Gehrig et al. *(7)* found through scanning electron microscopy that surfaces of polyethylene cutting boards after heavy use, had rough "cavernous" surfaces that could retain and later release bacteria.

In contrast, a study by Lucke and Skowyrska *(11)* found no significant differences between the hardwood and polyethylene cutting boards, with respect to cleanability from a microbial control perspective. A recent review by Aviat and Gerhards *(4)* suggests that in addition to the porosity of hardwood surfaces, reduced recovery of bacteria inoculated onto hardwood food contact surfaces can be attributed to the presence of antimicrobial compounds in wood. On the basis of recent research, wood surfaces may

TABLE 4. *Frequency of detecting milk after wiping cream cheese from coupons, as determined with a milk-specific lateral flow device (LFD)*[a]

	No. of positive LFD results/total LFD test with each type of wipe											
	Dry wipe	Dry terry cloth		Wet terry cloth (tap water)			Wet terry cloth (sanitizer solution)[b]			Alcohol quat wipe (one wipe)		Alcohol quat wipe (multiple wipes)
Coupon type	0.1 g	0.1 g	0.5 g	0.5 g	2 g	4 g	0.5 g	2 g	4 g	0.1 g	0.5 g[c]	0.5 g
SS	3/3[d]	(f+) 3/3	3/3	0/3	0/3	2/3	0/3	0/3	0/3	0/3	3/4	0/3 (2 wipes)
Plastic	3/3	(f+) 2/3	2/3	0/3	3/3	3/3	0/3	2/3	(h+) 3/3	0/3	4/4	(f+) 1/3 (2 wipes)
Wood	3/3	(f+) 3/3	2/3	0/3	2/3	3/3	0/3	(f+) 1/3	(h+) 2/3	0/3	3/4	0/3 (2 wipes)

[a] Cream cheese (0.1 to 4 g) wiped from coupons. A positive control test with 0.1 g of cream cheese on SS, plastic, and wood surfaces resulted in 3 of 3 positive LFD results. (f+), faint positive LFD response. (h+), high positive LFD response. LOD of Neogen Reveal 3-D milk LFD: 20 μg milk per 100 cm^2.
[b] Sanitizer solution refers to a 50 ppm of total chlorine sanitizing solution prepared with bleach.
[c] SS surface showed slight sheen when wiped with one quat wipe. Plastic and wood surfaces appeared visibly clean.
[d] Ratio identifies the number of positive LFD responses/total LFDs used.

TABLE 5. *Frequency of detecting milk after wiping fluid whole milk from coupons, as determined with a milk-specific lateral flow device (LFD)*[a]

	No. of positive LFD results/total LFD tests with each type of wipe					
Coupon type	Dry wipe	Dry terry cloth	Wet terry cloth (tap water)	Wet terry cloth (sanitizer solution)[b]	Alcohol quat wipe (one wipe)[c]	Alcohol quat wipe (multiple wipes)
SS	3/3[d]	3/3	3/3	3/3	(h+) 4/4	0/3 (2 wipes)
Plastic	3/3	(h+) 3/3	3/3	3/3	(h+) 4/4	(vf+) 3/3 (2 wipes) 0/3 (3 wipes)
Wood	3/3	3/3	(vf+) 3/3	(vf+) 2/3	3/4	0/3 (2 wipes)

[a] Fluid whole milk (1.0 mL) wiped from coupons. A positive control test with 1.0 mL of fluid milk on SS, plastic, and wood surfaces resulted in high positive LFD response (h+) 3 of 3 positive LFD results. (vf+), very faint positive LFD response. LOD of Neogen Reveal 3-D milk LFD: 20 μg milk per 100 cm^2.
[b] Sanitizer solution refers to a 50 ppm of total chlorine sanitizing solution prepared with bleach.
[c] SS surface showed slight sheen when wiped with one quat wipe. Plastic and wood surfaces appeared visibly clean.
[d] Ratio describes the number of positive LFD responses/total LFDs used.

TABLE 6. *Frequency of egg on surfaces after wiping whole egg crystals from coupons, as determined with an egg-specific lateral flow device (LFD)*[a]

	No. of positive LFD results/total LFD tests with each type of wipe					
Coupon type	Dry wipe	Dry terry cloth	Wet terry cloth (tap water)	Wet terry cloth (sanitizer solution)[b]	Alcohol quat wipe (one wipe)	Alcohol quat wipe (multiple wipes)
SS	(h+) 3/3[c]	(h+) 3/3	2/3	1/3	3/3	3/3 (2 wipes) 0/3 (3 wipes)
Plastic	(h+) 3/3	(h+) 3/3	3/3	2/3	3/3	3/3 (2 wipes) (f+) 1/3 (3 wipes)
Wood	(h+) 3/3	3/3	0/3	0/3	2/3	(f+) 2/3 (2 wipes) 0/3 (3 wipes)

[a] Whole egg crystals (0.05 g) wiped from coupons. A positive control test with 0.05 of whole egg crystals on SS, plastic, and wood surfaces resulted in high positive LFD response (h+) 3 of 3 positive LFD results. All wiped surfaces were visibly clean. (f+), faint positive LFD response. LOD of Neogen Reveal 3-D egg LFD: 20 μg egg per 100 cm^2 (older kit version with type 3 extraction buffer). LOD of Neogen Reveal 3-D egg LFD: 10 μg egg per 100 cm^2 (new version of kit with type 8 extraction buffer and wetting solution).
[b] Sanitizer solution refers to a 50 ppm of total chlorine sanitizing solution prepared with bleach.
[c] Ratio describes the number of positive LFD responses/total LFDs used.

TABLE 7. *Frequency of detecting egg after wiping mayonnaise from coupons, as determined with an egg-specific lateral flow device (LFD)*[a]

	No. of positive LFD results/total LFD tests with each type of wipe								
	Dry wipe	Dry terry cloth	Wet terry cloth (tap water)		Wet terry cloth (sanitizer solution)[b]		Alcohol quat sanitizing wipe (one wipe)		Alcohol quat sanitizing wipe (multiple wipes)
Coupon type	0.5 g	0.5 g	0.5 g	2 g	0.5 g	2 g	0.5 g	2 g[c]	2 g
SS	(f+) 3/3[d]	(f+) 3/3	0/3	0/3	0/3	0/3	0/3	(f+) 4/4	0/3 (2 wipes)
Plastic	(f+) 3/3	(f+) 2/3	0/3	0/3	0/3	0/3	0/3	(f+) 4/4	0/3 (2 wipes)
Wood	(f+) 1/3	(f+) 1/3	0/3	0/3	0/3	(f+) 2/3	0/3	(f+) 3/4	0/3 (2 wipes)

[a] Mayonnaise (0.5 to 2 g) wiped from coupons. A positive control test with 0.1 g of mayonnaise on SS, plastic, and wood surfaces resulted in 3 of 3 positive LFD results. (f+), faint positive LFD response. LOD of Neogen Reveal 3-D egg LFD: 20 μg egg per 100 cm^2 (older kit version with type 3 extraction buffer). LOD of Neogen Reveal 3-D egg LFD: 10 μg egg per 100 cm^2 (new version of kit with type 8 extraction buffer and wetting solution).
[b] Sanitizer solution refers to a 50 ppm of total chlorine sanitizing solution prepared with bleach.
[c] SS surface showed slight sheen or smear with 2 g of mayonnaise when wiped with one quat wipe. Wiped plastic and wood surfaces appeared visibly clean.
[d] Ratio identifies the number of positive LFD responses/total LFDs used.

TABLE 8. *Effectiveness of a wash-rinse-sanitize cleaning method for removing allergic food from SS, plastic, and wood coupon surfaces*[a]

	Food soil on coupon:							
Coupon type	Peanut powder (0.5 g)	Peanut butter (1 g)	Peanut butter (1 g) with prescrape step	Whole egg crystals (1 g)	Mayonnaise (4 g)	Cream cheese (4 g)	Fluid whole milk (5 mL)	NFDMP (0.1 g)
SS (trials 1, 2, 3)	0/3, 0/3, 0/3[b]	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3
Plastic (trials 1, 2, 3)	0/3, 0/3, 0/3	3/3, 3/3, 3/3[c]	(f+) 2/3 (f+) 3/3 (f+) 3/3[c]	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3
Wood (trials 1, 2, 3)	0/3, 0/3, 0/3	(f+) 1/3 0/3 (f+) 1/3[d]	(f+) 1/3 (f+) 1/3 (f+) 1/3[d]	0/3, 0/3, 0/3	0/3, 0/3, 0/3[d]	0/3, 0/3, 0/3	0/3, 0/3, 0/3	0/3, 0/3, 0/3

[a] NFDMP, nonfat dry milk powder. All surfaces were visibly clean unless noted otherwise. (f+), faint positive LFD response. Neogen Reveal 3-D peanut LOD: 2 μg peanut per 100 cm^2. Reveal 3-D total milk LOD: 20 μg milk per 100 cm^2. Reveal 3-D egg LOD: 20 μg egg per 100 cm^2 (old version). Reveal 3-D Egg LOD: 10 μg egg per 100 cm^2 (new version).
[b] Ratio identifies the number of positive LFD responses/total LFDs used. Results are shown for three independent trials.
[c] Very faint yellow residue on plastic visually observed for five of nine plastic surfaces after full cleaning to remove peanut butter.
[d] One wood coupon had a visible oil stain after washing.

pose a lesser relative risk from a microbiological point of view, and it appears from this study that the same may also be true for allergen transfer.

The success of cleaning procedures on removal of allergenic foods from food contact surfaces depends on several factors, including the types of surfaces and cleaning methods available, especially because both factors are interrelated *(11, 16)*. The effectiveness of wipes for allergen removal may also be impacted by the absorbency of the wipe, the solvent used for wet wipes, the state of the allergen matrix (wet, sticky or paste, or dry), and the amount of food or allergen loaded on the surface. For parameters evaluated in this study, use of a wet wipe, cloth, or quat wipe to remove a dry allergen from a surface appeared to be more effective than use of a dry wipe. The food contact surface condition (smooth versus textured) appeared to play a role in determining the degree of effectiveness when wiping allergens from surfaces, similar to the results of studies that evaluated removal of microbial contaminants from food contact surfaces *(19, 27)*.

To more closely simulate what would be done in retail and food service operations, visual inspection of wiped surfaces was conducted by the same individual who performed the wiping experiments. Although surfaces that were visually clean did not always correspond to negative LFD test results, visual inspection provided a first step for evaluating the effectiveness of wiping treatments. For example, as shown in Table 5, wiping 1 mL of liquid milk with one quat wipe resulted in positive LFD responses on all surfaces, although no visible residue was apparent on the plastic or wood, and only a very slight sheen was apparent from an angled view on the SS surface. Use of two quat wipes resulted in all surfaces appearing visually clean, but the textured plastic surface contaminated with 1 mL of whole liquid milk still resulted in 3 of 3 very faint positive LFD results, and three quat wipes were required to correspond to negative LFD results. Similarly, 0.5 g of mayonnaise was easily wiped from each surface with one quat wipe, and all surfaces were visually clean and had negative LFD results (0 of 3; Table 7). Increasing the amount of mayonnaise to 2 g and use of a quat wipe resulted in faint positive LFD responses on all surfaces, which indicated that the amount of egg residue was near the LOD of the egg-specific LFD kit. Although all plastic and wood surfaces were visually clean, a slightly oily smear was initially visible only on the SS coupons, which then appeared visually clean after the mayonnaise residue dried. Two quat wipes were required to remove 2 g of mayonnaise from each surface to obtain a visually clean and negative LFD (0 of 3) response on all SS, plastic, and wood surfaces, as noted in Table 7.

Limitations that exist with visual assessment of cleaning effectiveness include the type and adequacy of the lighting, the color and textural differences between the food contact surface and the allergen residue, and the visual acuity of the examiner. In this study, the use of white plastic coupons hindered visualization of light-colored foods, such as milk, cream cheese, mayonnaise, and NFDMP. In these circumstances, visual inspection may not provide adequate assessment of the presence of food residues. Also, we found instances in which the surfaces appeared visually clean but still tested positive for allergen residue on the basis of the LFD test results. The significance of these results is not clear because the allergen-specific LFD tests used in this study provide qualitative rather than quantitative results. Thus, it is difficult to determine the amount of hazardous allergenic residue. It was observed that most allergen LFD results on some visually clean surfaces were faintly positive, suggesting that the amount of allergen present was close to the LOD of the LFD test and thus likely to be quite low. However, more research is needed to understand the significance of these positive residue results.

Full cleaning study. A full cleaning method, also referred to as the "wash–rinse–sanitize–air dry" procedure simulated the process of using a three-bay sink and air-drying surfaces on a dish rack after cleaning. The entire wash–rinse–sanitize–air dry procedure was repeated for a

total of three independent trials. In this experiment, the amounts of food allergen added to each coupon was substantially greater than those used in the wiping study. As shown in Table 8, results demonstrated that the full cleaning method was consistently effective in allergen removal in triplicate trials (0 of 3, 0 of 3, 0 of 3 positive LFD test results for each type of surface and all surfaces were visually clean) for all types of coupons and for all allergenic foods, with the exception of peanut butter. The textured plastic coupons retained peanut residue as detected by the peanut-specific LFD in all three trials (3 of 3, 3 of 3, and 3 of 3), but two faint positive residues and negative responses were found for wood surfaces in the triplicate trials (f+ 1 of 3, 0 of 3, f+ 1 of 3). Note that during washing, peanut butter from the contaminated coupons (1 g of peanut butter per coupon) was transferred into the wash water (10 L). Because nine coupons were consecutively washed, the wash water contained up to 900 ppm of peanut butter at the conclusion of each trial. Also, because wood coupons were washed last in this study, the faint positive LFD results in two of the independent trials may be attributed to peanut butter present in the wash water that may have redeposited on the wood surfaces. The wood surfaces appeared visually clean except for a slightly oily and wet stain, yet the wood surfaces tested negative or registered faint positive LFD results for peanut residue.

All the SS surfaces appeared visually clean and tested negative for peanut in the LFD tests, which is most likely attributed to the smooth SS surface finish and because the SS surfaces were washed first in all trials. The white, polyethylene plastic coupons on the other hand, tended to retain peanut butter within the grooves of the textured surface and displayed a faint yellow color stain in five of the nine plastic coupons. Thus, approximately 44% of the textured plastic surfaces appeared visually clean, but all of the LFDs were positive for peanut residue. Implementing a prescrape step to remove the bulk of the peanut butter residue prior to washing improved the effectiveness of the cleaning procedure for the textured plastic coupons, with faint positive (f+ 2 of 3, f+ 3 of 3, f+ 3 of 3) LFD responses recorded in the three trials.

Relatively few studies report the effectiveness of a full manual cleaning procedure on allergen removal. The presence of milk, egg, and gluten on utensils, cookware, and other food contact surfaces present in school cafeterias and kitchens in Spain was examined by Ortiz et al. *(13)*. In that study, where the food contact surfaces were either washed with an automatic dishwasher or manually washed, milk residue was not found on the surfaces with LFD tests, but 15% of egg and 45% of gluten LFD results were positive. Cleaning conditions (i.e., time and temperature of the cleaning procedures, detergent concentrations, and use of three basins for manual washing) were not described. In addition, it was also unclear whether the positive results were due to recontamination of the surfaces by use of allergens in daily operation and management of the cafeteria. Miller et al. *(12)* found food contact surfaces and food prepared in a commercial kitchen could become contaminated with gluten if controls were not in place to prevent dispersal of gluten-containing ingredients.

In general, manual warewashing appeared to be effective for allergen removal when practiced according to the procedures outlined in the Food Code. Using a prescrape step (Subpart 4-603.12 Precleaning) to remove the bulk of allergenic food residues and decreasing food load in the wash water improved overall effectiveness of the full cleaning procedure *(23)*. Although not studied here, changing the wash water frequently to maintain clean solutions is another factor that can improve cleaning effectiveness. Other factors that may impact cleaning effectiveness include the amount and type of allergenic food on the surface, time and temperature of the wash solution, type and concentration of detergent in the wash sink, composition and finish of food contact surface material, and the mechanical and manual force used during the washing step. Other strategies to clean and minimize cross-contact include washing the prescraped allergen surface more than once, increasing the submersion time in wash water, or simply maintaining dedicated cutting boards or surfaces when possible, especially if using textured plastic materials with peanut butter. The U.S. Department of Agriculture cutting boards and food safety fact sheet *(21)* also suggests using a dedicated cutting board for raw meat, poultry, and seafood and maintaining a separate food contact surface for fresh produce to prevent microbial cross-contamination, despite the ability to effectively clean cutting boards from a microbial control perspective. This concept can also be extended to sticky allergenic foods, such as peanut butter and other similar foods, which can be problematic for effective manual warewashing on select materials.

A limitation of the full cleaning study design involved the use of a single order to wash the coupons (SS, plastic, and wood). Future experiments should randomize the order of cleaning the different surfaces to allow for exposure to wash water having varying levels of food soils. Another limitation of this washing study was the absence of food soils that were dried, cooked, or heated on the surfaces. Cooked food soils tend to require more manual force and cleaning effort in removing denatured proteins, such as heated milk, which can adhere to equipment and surfaces *(16, 25)*.

Allergen transfer study. The focus of this series of experiments was to determine the extent of allergen transfer to surfaces from a contaminated wipe or cloth. Unlike previous studies in which coupon surfaces were directly contaminated with allergenic foods, the allergenic foods were placed on dry wipes or sanitizer-soaked terry cloth for transfer experiments. In the experiments that used dry wipes, one allergen-contaminated dry wipe was used to wipe four consecutive coupon surfaces of the same material composition, followed by testing all four surfaces for the presence of allergens with allergen-specific LFD tests.

Most dry or powdered allergens transferred from the dry wipe to all four wiped surfaces as shown in Table 9. Whole egg crystals (0.01 g) on the dry wipe showed a

TABLE 9. *Transfer of dry or powdered allergenic foods to food contact surfaces with contaminated dry paper wipes*[a]

Allergen	Food contact surface	Surface 1	Surface 2	Surface 3	Surface 4
0.01 g of whole egg crystals[b]	SS	3/3[c,d]	3/3	3/3	3/3
	Plastic	3/3[d]	3/3	2/3	2/3
	Wood	3/3	3/3	3/3	1/3
0.05 g of whole egg crystals	SS	(h+) 3/3[d]	3/3	3/3	3/3
	Plastic	(h+) 3/3[d]	3/3	3/3	3/3
	Wood	(h+) 3/3	3/3	3/3	3/3
0.01 g of peanut powder	SS	(f+) 3/3	2/3	0/3[e]	0/3
	Plastic	3/3[d]	3/3	(f+) 3/3	3/3
	Wood	(f+) 3/3	0/3[e]	0/3	0/3
0.05 g of peanut powder	SS	3/3[d]	3/3	3/3	2/3[d]
	Plastic	3/3	3/3	3/3	3/3
	Wood	3/3	3/3	2/3	(f+) 2/3
0.05 g of NFDMP	SS	3/3[d]	3/3[d]	3/3	3/3
	Plastic	(h+) 3/3	3/3	3/3	3/3
	Wood	(h+) 3/3	3/3	3/3	3/3

[a] Surfaces 1 to 4 are visibly clean unless noted otherwise. (h+), high positive LFD response. (f+), faint positive LFD response. NFDMP, nonfat dry milk powder. Neogen Reveal 3-D Peanut LOD: 2 μg peanut per 100 cm^2. Reveal 3-D total milk LOD: 20 μg milk per 100 cm^2. Reveal 3-D egg LOD: 20 μg egg per 100 cm^2 (old version).
[b] Reveal 3-D egg LOD: 10 μg egg per 100 cm^2 (new enhanced version used in third replicate test with 0.01 g of whole egg crystals).
[c] Ratio identifies the number of positive LFD responses/total LFDs used.
[d] Very light powder observed.
[e] Denotes the first surface with no allergen residue transfer, as shown with a 0 of 3 LFD response.

mixed degree of egg transfer to surface 4, while a higher allergen load of 0.05 g of whole egg crystals on the dry wipe, consistently transferred egg to all surfaces with (3 of 3) positive LFD results. Peanut powder (0.01 g) resulted in no detectable transfer (0 of 3) on wood coupon 2 and SS coupon 3, respectively. However, peanut residue was present on all textured plastic surfaces in all three trials. The NFDMP (0.05 g) also transferred from the dry wipe to all SS, plastic, and wood coupon 4, with positive LFD responses in all three trials.

Wet, paste, and sticky forms of allergens also transferred from the dry wipe to many of the subsequently wiped surfaces, as shown in Table 10. Only mayonnaise (0.5 g) resulted in minimal egg allergen transfer to subsequent surfaces, with no egg detected on all SS, plastic, and wood surface 3 (0 of 3). Increasing the food load to 2 g of mayonnaise on the dry wipe led to extended allergen transfer to some surface 4 plastic and wood coupons, but egg LFD responses were only faintly positive. In general, allergen absorption by the dry wipe and the porous wood

TABLE 10. *Transfer of sticky, paste, and wet allergenic foods to food contact surfaces with contaminated dry paper wipes*[a]

Allergen	Food contact surface	Surface 1	Surface 2	Surface 3	Surface 4
0.5 g of mayonnaise	SS	3/3[b]	0/3[c]	0/3	0/3
	Plastic	3/3	(f+) 1/3	0/3[c]	0/3
	Wood	3/3	0/3[c]	0/3	0/3
2.0 g of mayonnaise	SS	3/3[d]	3/3	(f+) 3/3	0/3[c]
	Plastic	3/3	3/3	(f+) 3/3	(f+) 3/3
	Wood	3/3	3/3	(f+) 3/3	(f+) 1/3
0.1 g of peanut butter	SS	3/3	2/3	0/3[c]	1/3
	Plastic	3/3[d]	3/3	3/3	3/3
	Wood	3/3	(f+) 3/3	(f+) 3/3	(f+) 3/3
1 mL of whole milk	SS	3/3[d]	3/3[d]	3/3[d]	3/3[d]
	Plastic	3/3	3/3	3/3	3/3
	Wood	(f+) 3/3	(f+) 3/3	(f+) 3/3	(f+) 3/3
0.5 g of cream cheese	SS	(f+) 3/3[d]	(f+) 3/3[d]	(f+) 3/3[d]	(f+) 3/3[d]
	Plastic	(f+) 3/3	(f+) 3/3	(f+) 3/3	(f+) 3/3
	Wood	(vf+) 3/3	(vf+) 3/3	(vf+) 3/3	(vf+) 2/3

[a] Surfaces 1 to 4 are visibly clean, unless noted otherwise. (f+), faint positive LFD response. (vf+), very faint positive LFD response. Neogen Reveal 3-D peanut LOD: 2 μg peanut per 100 cm^2. Reveal 3-D total milk LOD: 20 μg milk per 100 cm^2. Reveal 3-D egg LOD: 20 μg egg per 100 cm^2 (old version).
[b] Ratio identifies the number of positive LFD responses/total LFDs used.
[c] The first surface with no allergen residue transfer as shown with a 0 of 3 LFD response.
[d] Slight sheen or stain observed.

TABLE 11. *Transfer of dry allergenic foods to food contact surfaces from a contaminated terry cloth submerged in sanitizer solution (50 ppm of total chlorine) prior to wiping each surface*[a]

Allergen	Food contact surface	Surface 1	Surface 2	Surface 3	Surface 4
0.05 g of whole egg crystals	SS	3/3[b]	3/3	0/3[c]	0/3
	Plastic	3/3	3/3	0/3[c]	0/3
	Wood	3/3	0/3[c]	0/3	0/3
0.05 g of peanut powder	SS	3/3[d]	(vf+) 1/3	0/3[c]	0/3
	Plastic	3/3	(vf+) 3/3	0/3[c]	0/3
	Wood	1/3	0/3[c]	0/3	0/3
0.05 g of NFDMP	SS	3/3	0/3[c]	0/3	0/3
	Plastic	3/3	0/3[c]	0/3	0/3
	Wood	(vf+) 1/3	0/3[c]	0/3	0/3

[a] Surfaces 1 to 4 are visibly clean unless noted otherwise. (vf+), very faint positive LFD response. NFDMP, nonfat dry milk powder. Neogen Reveal 3-D peanut LOD: 2 μg peanut per 100 cm^2. Reveal 3-D total milk LOD: 20 μg milk per 100 cm^2. Reveal 3-D egg LOD: 10 μg egg per 100 cm^2 (new enhanced egg kit).
[b] Ratio identifies the number of positive LFD responses/total LFDs used.
[c] The first surface with no allergen residue transfer, as shown with a 0 of 3 LFD response.
[d] Very slight residue observed.

surface may provide one explanation for the many faint positive LFD results detected on wood, compared with the positive LFD results registered on the smooth SS or textured plastic surfaces. Additionally, the lower protein content in the mayonnaise compared with the egg powder may have been responsible for the mixed and faint positive results for allergen transfer on surface 4. One disparity of note in Table 10 is with the 0.1 g of peanut butter transfer experiment between SS surface 3 in which 0 of 3 LFD results were observed and SS surface 4, with 1 of 3 positive LFD responses. A possible explanation is that peanut butter present on the wipe did not make contact with SS coupon 3 but was able to transfer to SS surface 4 during the wiping step. Experiments with whole fluid milk and cream cheese showed milk transfer to all SS, and plastic surface 4 from the dry wipe, with only faint positives noted on the wood surface.

Prior studies have shown that reusable wiping cloths harbored bacteria when they were not stored in sanitizing solutions *(10, 19)*. The Food Code guidelines on use limitations for wipe cloths, as discussed in Subparagraph 3-304.14 (B)(1), were followed to determine the extent of allergen transfer from a wet terry wipe cloth that is contaminated with allergen *(23)*. The objective was to simulate current recommendations for use and storage of a cloth, by submerging the allergen-contaminated wipe cloth in sanitizer solution before wiping each surface. Storage of the cloth in sanitizer solution prior to wiping each surface resulted in no dry allergen transfer to some surface 2 and no transfer to surface 3 (Table 11) for the dry forms of peanut and egg allergens investigated in this study. The NFDMP, on the other hand, showed no transfer to surface 2 when the cloth was stored in sanitizer solution prior to wiping surfaces. The detection of allergen residue on surface 1 was expected because the allergen was added directly to the wet sanitizer-soaked cloth and transferred immediately to surface 1, with the intentional objective to show allergen transfer from wet allergen contaminated terry cloth to the initial surface. Note that the peanut powder and NFDMP both had minimal transfer of allergen from the cloth to wood surface 1, which may be attributed to the porous nature of the wood surface.

A wet terry cloth contaminated with wet, paste, or sticky allergens (Table 12) that was submerged in sanitizer solution before wiping surfaces transferred allergens to a lesser extent than the dry paper wipes (Table 10). Minimal fluid milk transfer was noted on SS and plastic surface 1, and no detectable milk transfer on surface 2 was observed for all surfaces (Table 12). Interestingly, fluid milk (1 mL) was not detected by LFD on wood surface 1 in all three trials, which may be due to absorption of the milk by the wood surface and/or the wet terry cloth. Cream cheese (2 g) was not detectable on SS or wood surface 3 but was detected in 1 of 3 trials on textured plastic surface 3. The wipe cloths contaminated with 2 g of mayonnaise showed no detectable transfer of egg allergen to surface 3 for SS, plastic, and wood when the cloth was submerged in the sanitizer pail between wiping surfaces. Peanut butter (0.1 g) resulted in the greatest extent of allergen transfer from the wipe cloth to surface 3 SS, plastic, and wood in triplicate tests. However, surface 4 (plastic and wood) resulted in no peanut transfer (0 of 3), while the SS surface 4 had one very faint positive (1 of 3) peanut LFD response.

Overall, the results of the allergen transfer study indicate that the current Food Code *(23)* recommendations for use limitations requiring wipe cloth storage in sanitizer pails between use minimizes allergen transfer from the wipe cloths to surfaces. When soiled wipe cloths are stored in the sanitizer pail, the food present on cloths is likely transferred to the sanitizer solution and increases the food load to the solution. This results in a depletion of active sanitizer (chlorine) in the sanitizer solution and a need to replace the solution when concentrations are below the specific temperature or sanitizer guidelines as stated in the Food Code *(23)*. The practice of preparing fresh sanitizer solution helps prevent the buildup of food soils and allergens in the sanitizer solution, which potentially could contaminate food contact surfaces and also ensures that sanitizer levels are at

TABLE 12. *Transfer of wet, paste, or sticky allergenic foods to food contact surfaces from a contaminated terry cloth submerged in sanitizer solution (50 ppm of total chlorine) prior to wiping each surface*[a]

Allergen	Food contact surface	Surface 1	Surface 2	Surface 3	Surface 4
2.0 g of mayonnaise	SS	3/3[b,c]	0/3[d]	0/3	0/3
	Plastic	3/3	2/3	0/3[d]	0/3
	Wood	3/3	(f+) 1/3	0/3[d]	0/3
0.1 g of peanut butter	SS	3/3[c]	3/3	2/3	(vf+) 1/3
	Plastic	3/3	3/3	(f+) 3/3	0/3[d]
	Wood	3/3	(vf+) 3/3	(vf+) 1/3	0/3[d]
1 mL of whole milk	SS	(vf+) 1/3	0/3[d]	0/3	0/3
	Plastic	(vf+) 1/3	0/3[d]	0/3	0/3
	Wood	0/3[d]	0/3	0/3	0/3
2 g of cream cheese	SS	(vf+) 3/3	(vf+) 2/3	0/3[d]	0/3
	Plastic	3/3	(f.+) 3/3	1/3	0/3[d]
	Wood	(vf+) 3/3	(vf+) 1/3	0/3[d]	0/3

[a] Surfaces 1 to 4 are visibly clean unless noted otherwise. (f+), faint positive LFD response. (vf+), very faint positive LFD response. Neogen Reveal 3-D peanut LOD: 2 μg peanut per100 cm^2. Reveal 3-D total milk LOD: 20 μg milk per 100 cm^2. Neogen Reveal 3-D egg LOD: 10 μg egg per 100 cm^2 (new enhanced egg kit).
[b] Ratio identifies the number of positive LFD responses/total LFDs used.
[c] Very light sheen observed.
[d] First surface with no allergen residue transfer, as shown with a 0 of 3 LFD responses.

appropriate levels to address microbial concerns. Although most of the coupons were visually clean when examined after wiping, allergens were detected with LFD tests on some of the surfaces. The inability to visually detect food residue on surfaces during the transfer study may be due the very low amounts of allergenic foods on the surfaces and the color and texture of the coupons that prevented visual detection of residue.

Some limitations of this study include the absence of blinded tests for determination of visually clean surfaces, a lack of uniformity of how the allergenic foods were applied to the surfaces, an inability to quantify allergens remaining on the surface, and focusing on a single allergen matrix instead of food allergen mixtures, among others. In addition, the wiping, cleaning, and allergen transfer study was performed on freshly applied food soils. The results would likely have been different if foods were dried onto surfaces prior to wiping because dried food soils can be difficult to remove *(16)*. The manual cleaning process is also subjective and typically conducted to a specific end point, which is often the visually clean standard. Although efforts to conduct the experiments in the same manner were made, subtle differences in the amount of pressure used in wiping and cleaning, absorbency of the wipe, and varying saturation levels of the cloth may impact the effectiveness of allergen removal and transfer. Additionally, the surfaces used in this study were similar in color (white polyethylene plastic and natural maple hardwood) to some of the allergens (NFDMP, whole liquid milk, cream cheese, mayonnaise, peanut butter, and peanut powder) used, which occasionally made visual inspection for allergen residue challenging at times. Future experiments may explore different combinations of allergen food soils, other allergen-specific LFD tests, quantitative tests, various colored surfaces and topologies, as well as a range of different detergent concentrations, including varying time and temperature parameters for cleaning and wiping.

Overall, the nature and amount of allergen on a surface, as well as the type and state of wipe cloth, food contact surface texture and material composition, influenced the effectiveness of wiping and washing treatments on allergen removal and the extent of allergen transfer on surfaces. In summary, the wiping study suggested that wet terry cloth (soaked in tap water or sanitizer solution) and alcohol quat wipes were generally more effective in allergen removal than dry wipes. Additionally, allergenic foods in this study appeared to be more difficult to remove from the textured plastic surface than the SS or wood surfaces. In general, the full cleaning method (wash–rinse-sanitize–air dry) for manual warewashing with detergent and sanitizer was effective at removing most allergenic food residues and tended to be more effective at removing higher allergen loads from surfaces than using wipes or cloths alone. A prescrape step prior to washing improved the removal of peanut butter on surfaces. Due to the nature of peanut butter and its adherence to textured plastic, multiple washings or use of dedicated cutting surfaces are recommended. Contaminated dry paper wipes tended to transfer allergens to subsequently wiped surfaces under the conditions of this study. However, storage of cloths in sanitizer solution between wiping surfaces, as prescribed in the Food Code *(23),* minimized allergen transfer. Many of the surfaces tested in this study had only faint positive responses for the allergen, suggesting that the amount of allergen residue may be near the LOD of the LFD. Although more research is needed to understand the potential health hazard of residues detected by LFDs in this study, using a visibly clean end point in combination with other food safety measures appears to be prudent approaches for allergen removal.

Further research is needed to quantify the amount of allergen present on surfaces when faint positive results are registered. Additional research is also needed to evaluate the amount of transfer from surfaces with low amounts of allergenic residue to other food items.

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SUPPLEMENTAL MATERIAL

Supplemental material associated with this article can be found online at: https://doi.org/10.4315/JFP-20-025.s1

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PEER-REVIEWED ARTICLE

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Characterizing Microbial Cross-Contamination on Large Surfaces Using a Traditional "Cloth and Bucket" Disinfection Method

ABSTRACT

Use of buckets containing soiled disinfectant solutions for disinfection is regularly practiced in food service and other settings. This study characterized microbial transfer of vegetative bacteria (*Listeria innocua* and *Escherichia coli*), spores (*Bacillus cereus*), and a virus (MS2 bacteriophage), to large surfaces, using a "cloth and bucket" method with a commonly used quaternary-ammonium compound (QAC) disinfectant (with or without 5% soil) and a phosphate-buffered-saline (PBS) control. We also characterized concentrations of organisms in the bucket solutions after wiping. With disinfectant (with or without soil), there was little transfer of vegetative bacteria. Transfer occurred readily with the PBS control (4.8 ± 1.0 and 3.3 ± 0.9 log CFU/surface for *Listeria innocua* and *Escherichia coli*, respectively). Spores were transferred efficiently, regardless of whether PBS or QAC was used or whether test was with or without soil (range, 6.5 to 7.8 log CFU/surface). MS2 bacteriophage appeared to be eliminated relatively quickly. When the QAC did not inactivate the organism (regardless of soil load), high microbial loads (≥ 87.9% of initial inoculum) were detected in the bucket solution after wiping experiments. This study suggests that reusable cloth can potentially promote contamination of surfaces, sometimes in the presence of disinfectant. This is concerning for food service and other settings in which disinfection practices rely on the cloth and bucket system.

INTRODUCTION

Continuous use of buckets containing soiled water or disinfectant solutions for disinfection of surfaces is a regular practice in food service establishments, schools, and many other settings. It is not uncommon to use a single sponge or cloth multiple times over a day or a shift to clean environmental surfaces. However, little is known about the safety of this practice, except that, microbiologically speaking, it would be expected to be hazardous because of concerns about consistent risk for cross-contamination.

There have been many studies to characterize the transfer of microbes among surfaces, hands, and foods but very few attempting to quantify this phenomenon as a function of

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cloth use or wiping and even fewer looking at viral pathogens. Smith et al. *(16)* observed that, when using clean, wetted wipes applied to surfaces previously inoculated with 10^5 CFU of common nosocomial bacteria (specifically methicillin-resistant *Staphylococcus aureus*, spores of *Clostridium difficile*, and *Escherichia coli*), between 2 and 3 log CFU of the initial inoculum was removed, showing some mechanical removal of organisms by the action of wiping. Bergen et al. *(4)* observed cross-contamination to microfiber cloths from surfaces inoculated with 10^4 CFU *Enterococcus faecalis* and spores of *Bacillus cereus*. However, Rossi et al. *(12)* observed cross-contamination of 0.01 to 1% of initial bacterial load to clean surfaces upon wiping with naturally contaminated industrial sponges. Gibson et al. *(8)* demonstrated that the efficiency of transfer of several viruses (specifically murine norovirus, feline calicivirus, GI.1 human norovirus [HNV], and bacteriophages PRD1 and MS2) to acrylic and stainless steel surfaces was dependent upon both the virus and the cloth type.

A recurring difficulty with trying to quantify the degree of cross-contamination associated with wiping events is standardization of experimental protocols because key parameters (e.g., pressure, distribution of force, and the mechanics of the wiping motion) can have a significant effect on results. A machine called the Wiperator (Filtaflex, Almonte, Canada) simulates the orbital action of wiping and allows presetting of pressure, duration, and the number of wiping strokes. Although there is a standardized method for the Wiperator *(2)*, only two published articles have documented its use, one focused on a multilaboratory validation of instrument performance using sanitizing wipes *(13)*, and the other investigated the efficacy of various detergent wipes to remove and transfer common nosocomial bacterial pathogens from stainless steel surfaces *(11)*; in both, only wiping on very small surfaces was characterized. To our knowledge, there have been no systematic studies describing the degree to which cross-contamination occurs when using soiled cloths to disinfect surfaces in a real-world, scaled-up setting.

The aim of this study was to characterize the degree of cross-contamination of representative gram positive and negative bacteria (specifically, *Listeria innocua* and *E. coli*), spores (*Bacillus cereus*), and viruses (MS2 bacteriophage as a human enteric virus surrogate), to large surfaces, with a traditional "cloth and bucket" method and a commercial quaternary ammonium compound (QAC) disinfectant commonly used in restaurant settings (with and without additional soil) and a phosphate-buffered saline (PBS) (no disinfectant) control. In addition, we characterized the concentrations of these organisms transferred to, and remaining in, the bucket disinfectant solutions after wiping with the cloth and bucket method.

MATERIALS AND METHODS

Bacterial cultures and enumeration

Listeria innocua (ATCC 33091) and *Escherichia coli* (ATTC 25922) were selected for this study as surrogates for *Listeria monocytogenes* and pathogenic *E. coli*, respectively. Overnight cultures of *L. innocua* and *E. coli* were prepared in 10 mL of tryptic soy broth, with shaking at 140 rpm at 37°C for 21 to 27 h. Cultures were then centrifuged (model 5810R, Eppendorf, Hamburg, Germany) at room temperature at 2,200 relative centrifugal field (RCF) for 15 min. Pellets were recovered and resuspended in 10 mL of PBS and centrifuged again at room temperature at 2,200 RCF for 15 min. Pellets were then recovered and resuspended in a final volume of 600 µL of PBS, for a final concentration of 10^8 to 10^9 CFU/mL. Immediately before inoculating surface 1–dirty (S1d), the cultures were combined for a final volume of approximately 1.2 mL. Enumeration of bacteria after swabbing was done by plating serial dilutions in PBS on modified oxford agar or MacConkey Agar at 37°C overnight (18 to 20 h) for *L. innocua* and *E. coli*, respectively.

Bacteriophage culture and enumeration

MS2 coliphage (ATCC 15597-B1) stocks at a concentration of 10^9 to 10^{10} PFU/mL were used as initial inoculum. Stock solutions were prepared per the protocol described in U.S. National Science Foundation standard 55 *(3)*. Enumeration of MS2 was performed on serial dilutions by the double agar layer method in accordance with the method of Su and D'Souza *(17)* with *E. coli* F+ C3000 cells as host (ATCC B-15597).

Spore culture and enumeration

Bacillus cereus spores (ATCC 49063) at a concentration of approximately 10^8 to 10^9 CFU/mL were produced according to Johnson et al. *(9)*. Spores were harvested in sterile distilled water, held at 4°C for 72 h to ensure lysis of vegetative cells, and stored in glycerol at 4°C until use. Absence of vegetative cells in the stock solution was confirmed by phase-contrast microscopy. Enumeration of spores was done by plating serial dilutions on tryptic soy agar and followed by incubation at 37°C overnight.

Surface inoculation and wiping experiments

Laminate countertops were purchased from Home Depot (catalog 1000018831, Atlanta, GA) and sectioned into multiple 2-ft (0.6 m) by 3-ft (0.9 m) (6 ft^2 [0.56 m^2] surfaces. A diagram of the entire workspace is shown in *Fig. 1a* and *Fig. 1b*. One hour before inoculation, all surfaces were disinfected by spraying with 10% bleach (5-min contact time) and wiping with a clean, disposable paper cloth. This was followed by spraying with 70% ethanol and wiping with a clean, disposable paper cloth. The surfaces were then allowed to naturally air dry for 1 h. A cleaning validation or negative control sample was taken by swabbing a 12-in (30.5 cm) by 12-in (1 ft^2 [0.09 m^2]) area of S1d *(Fig. 1b)* with a sampling template (catalog 900206, Environmental Monitoring Systems, North Charleston, SC) with an environmental sampling swab in 10 mL D/E neutralizing broth (catalog

FIGURE A

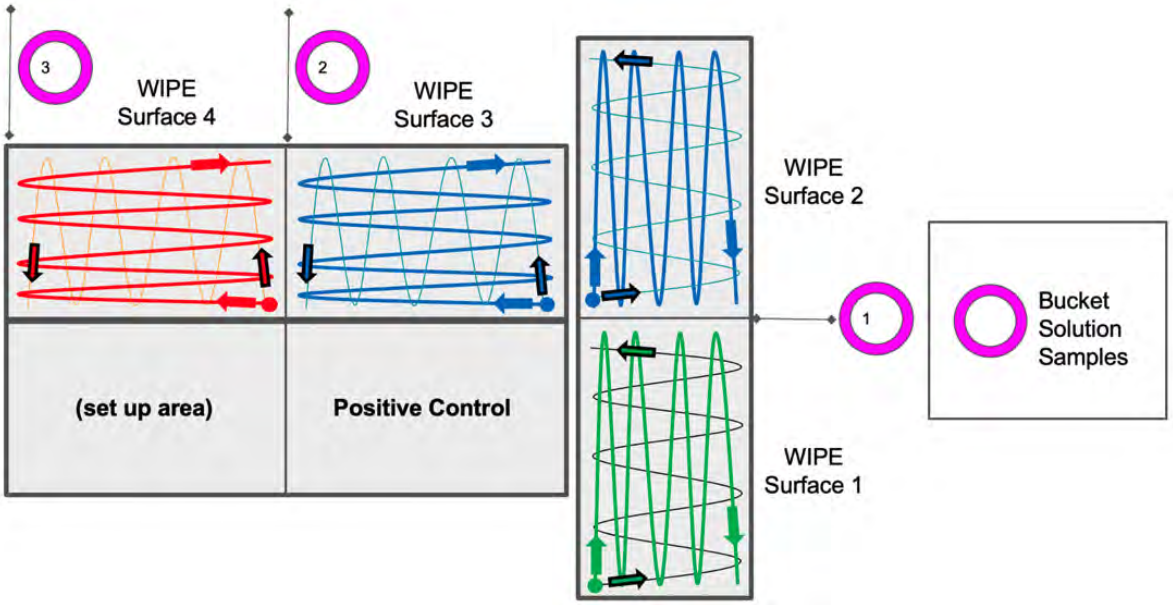

FIGURE B

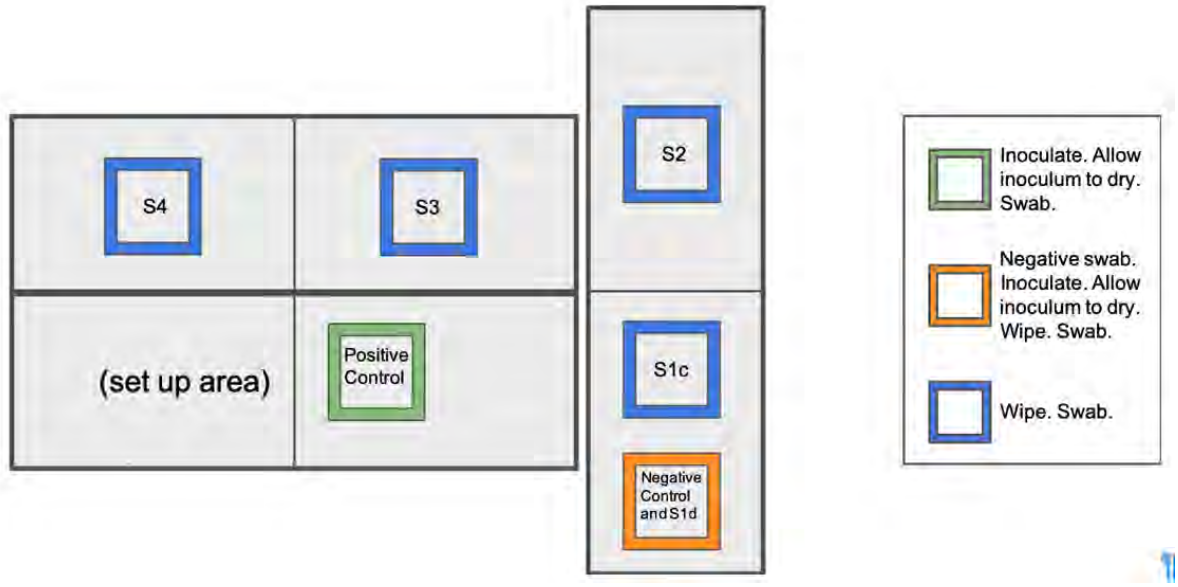

FIGURE 1. Overall experimental design. (a) A diagram of the wiping protocol, including the timing for collection of water samples drawn from the wiping bucket solution. (b) Diagram of the swabbing locations for each of the individual laminate surfaces.

EZ-10HC-PUR, EZ Reach Sponge, World Bioproducts, Libertyville, IL, with a 1.5- by 3-in. [3.8- by 7.6-cm] sponge) before inoculating the surface. The swabbing procedure was as follows, with swabbing locations shown in *Fig. 1b*. First, as much of the broth as possible was squeezed out of the swab. Starting at the top left, swabs were swiped within the template area from left to right, right to left, ending at the bottom right (as many swipes as needed). The swab was flipped over and the surface was reswabbed in the same manner starting at the bottom right, from bottom to top, top to bottom, ending in the top left (as many swipes as needed). This was repeated two more times in both diagonal directions. The handle of the swab was twisted off, and the swab was returned to the bag containing the neutralizing broth.

After the negative-control surface was swabbed (*Fig. 1b*; Neg S1d), the positive-control surface and S1d *(Fig. 1b)* were inoculated with one of the microbial suspensions (prepared as described above). For both the positive control surface and the S1d *(Fig. 1b)*, a 12- by 12-in (1 ft^2) inoculation area was designated, and 25 spots of 20 µL each of the inoculum (500 µL total inoculum volume) was placed over each 1-ft^2 area. The inoculum was allowed to dry before wiping experiments took place. Drying of the inoculum ranged from 45 min to 2 h, was dependent on the surrogate, and was confirmed by visual inspection. The entire 1-ft^2 inoculated area of the positive control surface was swabbed as described above.

The surface wiping procedure is diagrammed in *Fig. 1a*. A standard terry cloth bar rag (catalog B00KKRCS2Q, All In Safety, Bloomfield, NJ), 16 in. (40.6 cm) by 19 in. (48.3 cm), was folded in half and then into thirds, resulting in a 50-in2 (322.6-cm^2) wiping area. The folded towel was placed into a bucket containing one of three solutions: (i) PBS (2 L), used as a no disinfectant control; (ii) Oasis 146 (Ecolab, Saint Paul, MN), prepared per manufacturer's instructions (QAC; 2 L hard water + 7.8 mL concentrated disinfectant; final target disinfectant concentration of 400 ppm), used as a representative "clean" disinfection solution; or (iii) QAC prepared per manufacturer's instructions (described in *(2)*), with an additional 5% soil load prepared according to an ASTM standard *(1)*, used as a representative "dirty" disinfection solution. The cloth was submerged in the bucket solution and used to manually mix the bucket's contents with a gloved hand by swirling the contents in a circular motion. After thorough wetting, the cloth was squeezed out by hand and was then used to wipe in a back-and-forth motion from S1d to surface 1–clean (S1c). Wiping started at the top left corner of S1d (where the dried inoculum was located), and the cloth was used to wipe top left to top right, right to left, left to right, ending in the bottom right corner of S1c with a total of eight swipes. Wiping was then repeated starting back in the top left to bottom left, bottom to top, top to bottom, ending in the top right with a total of eight swipes.

The folded cloth was then placed back into the bucket of solution, squeezed out, and used to wipe surface 2 (S2) in the same back and forth motion described above *(Fig. 1a)*, making sure to use the same area of the cloth surface for wiping. The cloth was then immediately used to wipe surface 3 (S3; *Fig. 1a*), before being placed back into the bucket with solution and squeezed out before wiping surface 4 (S4; *Fig. 1a*) in the same back and forth motion described above.

A 1-ft^2 swab sample was taken from all surfaces *(Fig. 1b)* using the swabbing procedure described above for the negative control surface. Microorganisms were eluted from the swabs by squeezing the swab in the neutralizing buffer 120 times between two fingers before enumeration by plating serial dilutions of the neutralizing broth in PBS on selective medium with incubation as described above in enumeration methods for each microorganism. Microorganism counts from the 1-ft2 sampling areas were adjusted to reflect number of microorganisms present on the entire 6-ft^2 surface.

Bucket solution sampling

Bucket solution was sampled immediately after wiping S1, S3, and S4 by drawing 1mL from the bucket using a pipette *(Fig. 1a)*. The sample was transferred to a 15-mL conical tube containing 9 mL of D/E neutralizing broth. Samples were processed for enumeration of microorganisms as described above. In all cases, no difference was seen in the counts from the three 1-mL solution samples (data not shown). Results were calculated to reflect the total number of organisms remaining in the entire 2-L volume of the bucket solution by averaging the counts from the three 1-mL solution samples and multiplying by 2,000.

Statistical analysis

All experiments were independently replicated in triplicate on separate days. Results are presented as mean total CFU or PFU per 6 ft^2 surface ± standard deviation and as a percentage of the total CFU or PFU transferred to, and remaining in, the bucket solution for liquids (Excel, Microsoft Corporation, Redmond, WA).

RESULTS AND DISCUSSION

In food service establishments, schools, and many other settings, the use of the cloth and bucket method for cleaning environmental surfaces is common. Because little is known about the potential for these practices to spread pathogenic bacteria, viruses, and spores, the aim of this study was to characterize the spread of representative gram-positive and gram-negative vegetative bacteria, a spore, and a surrogate virus from laminate surface to laminate surface using a scaled-up "real life" experimental design. In addition, we sought to characterize the concentrations of those organisms transferred to, and remaining in, the bucket solutions after wiping events had been carried out because residual organisms could be the source of potential ongoing recontamination in real-world settings.

To replicate the initial contamination source, S1d was inoculated with the test microorganism; after which, a

TABLE 1. Cross-contamination efficiency ratios of microorganisms from an inoculated laminate surface to a clean laminate surface with a single wiping step using the cloth and bucket method

Organism	Treatment	CFU/PFU on surface 1–dirty (mean ± standard deviation)	CFU/PFU on surface 1–clean (mean ± standard deviation)	Cross-contamination efficiency (mean ± standard deviation)[a]
L. innocua	PBS	7.24 ± 0.99	6.79 ± 0.88	1.08 ± 0.06
	QAC	3.77 ± 0.27	LOE[b]	N/A[b]
	QAC + 5% soil	4.18 ± 0.29	3.51 ± 0.38	1.20 ± 0.05
E. coli	PBS	5.26 ± 1.26	5.08 ± 1.29	1.05 ± 0.05
	QAC	3.19 ± 0.42	LOE[b]	N/A[b]
	QAC + 5% soil	3.72 ± 0.30	3.01 ± 0.40	1.28 ± 0.17
B. cereus	PBS	8.85 ± 0.06	8.75 ± 0.08	1.01 ± 0.01
	QAC	9.04 ± 0.34	8.90 ± 0.22	1.01 ± 0.02
	QAC + 5% soil	9.13 ± 0.16	9.20 ± 0.07	0.99 ± 0.02
MS2	PBS	6.34 ± 0.96	5.80 ± 0.86	1.09 ± 0.03
	QAC	5.51 ± 0.94	4.41 ± 0.78	1.26 ± 0.17
	QAC + 5% soil	5.50 ± 0.88	4.76 ± 0.22	1.15 ± 0.18

[a]Cross-contamination efficiency was calculated as a ratio of the total number of organisms on the inoculated side of S1d to the total number of organisms on S1c after the first wiping event (S1d/S1c).

[b]Not applicable (N/A), when the organism was completely inactivated by the disinfectant (limit of enumeration [LOE] reached) and ratios could not be determined.

terry-cloth bar cloth was dunked in a solution and used to wipe the contaminated area in a back and forth motion to the clean side of the surface (S1c). By determining the number of microorganisms remaining on S1d, and the number that were moved to S1c by the cloth during wiping, we were able to determine the efficiency of cross-contamination from the initial contamination source to a clean surface, also known as the initial cross-contamination event *(Table 1)*. The efficiency of cross-contamination was calculated as a ratio of the number of organisms enumerated from S1d to the number of organisms enumerated from S1c. A result close to 1.0 indicated that close to an equal number of the test organisms were found on both the inoculated and the cross-contaminated sides of S1 after wiping and that the organism was easily moved from one side of the surface to the other. Cross-contamination efficiency ranged from 0.99 to 1.28, showing the test organisms were moved efficiently from the inoculated side of S1 (S1d) to the clean side of S1 (S1c). In some cases, this occurred even when the disinfectant was used, with or without soil. This shows that the initial wiping of a contaminated surface using the traditional cloth and bucket method easily spreads organisms to clean areas of the same surface.

The efficacy of disinfection was dependent upon microorganism, bucket solution type, and sequence of wiping actions. These data are provided in *Figs. 2* through *Figs. 5* as log PFU or CFU transferred to a surface for each of the sequential wiping actions. For *E. coli* and *L. innocua*, when the bucket contained PBS alone (control), cross-contamination occurred with each sequential wiping step, although its efficiency reduced with subsequent wiping events *(Figs. 2 and 3)*. By the fourth wiping event, about 5-log less CFU were deposited on the clean recipient surface. Further, cross-contamination appeared less efficient if first preceded by rinsing the cloth in the bucket solution (as was the case for S1 vs. S2 and S3 vs. S4) as compared to two sequential wipes without a cloth rinse (S2 versus S3).

When the bucket contained the QAC solution, with or without added soil, the disinfectant quickly inactivated both *L. innocua* and *E. coli* and effectively prevented cross-contamination, which was negligible after the first wipe (S1c) and below assay enumeration limits (< 2.78 log CFU/surface) for S2, S3, and S4.

Overall, these results were expected because it is readily accepted that quaternary ammonium compounds are effective in inactivating vegetative gram-positive and gram-negative bacteria *(6)*. These data are consistent with the study of Scott and Bloomfield *(15)*, in which two different types of cloths were evaluated for cleaning in a food-preparation

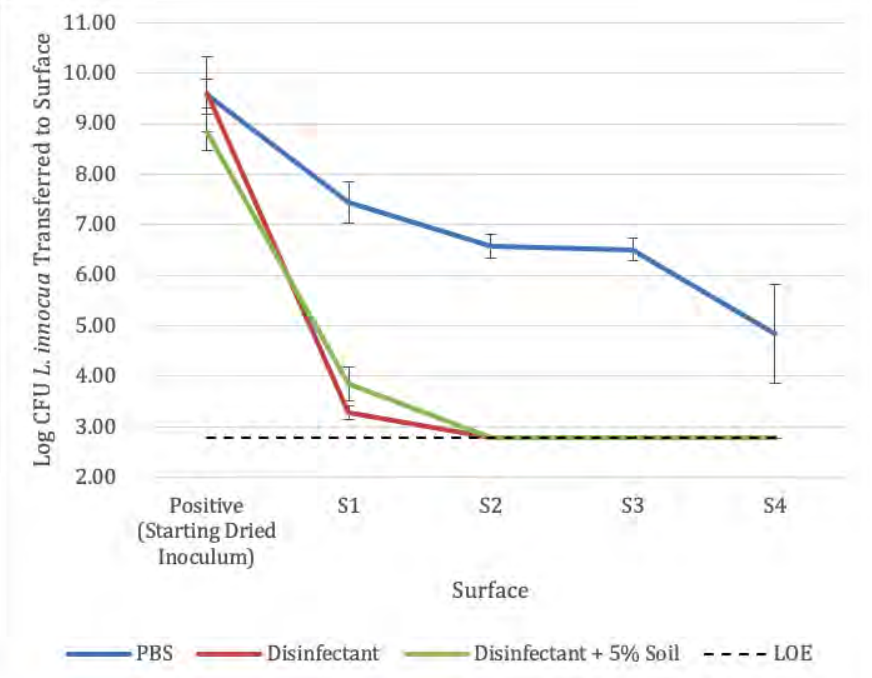

FIGURE 2. Log CFU of *Listeria innocua* transferred to, and remaining on, laminate surfaces during wiping experiments. Surface 1 was inoculated at the same level as the positive surface (starting dried inoculum) before wiping experiments. Cloth was used to wipe surfaces sequentially from surface 1 through surface 4 and was submerged in the bucket solution (PBS, disinfectant, or disinfectant + 5% soil) after wiping surfaces 1, 3, and 4, but not surface 2.

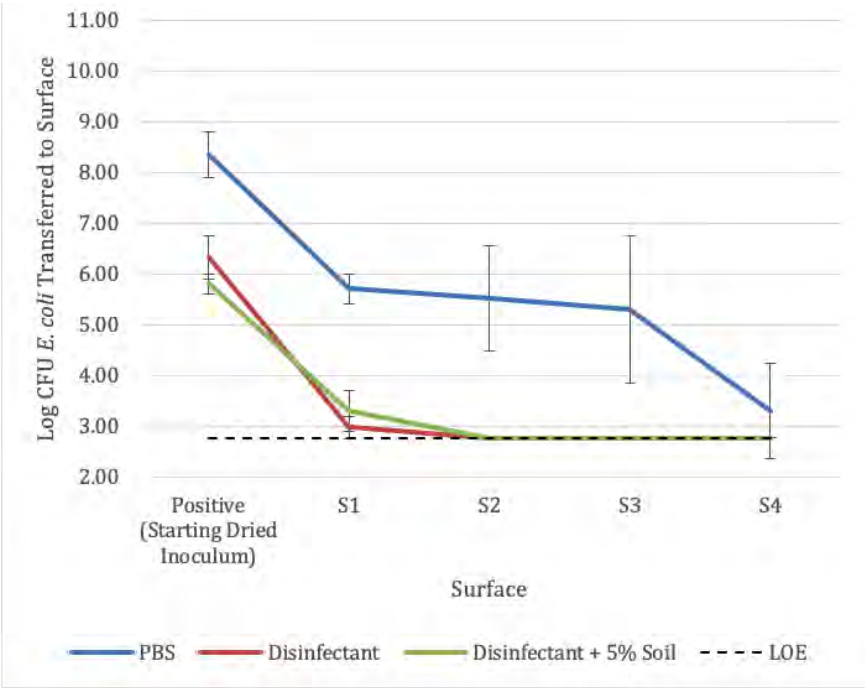

FIGURE 3. Log CFU of *Escherichia coli* transferred to, and remaining on, laminate surfaces during wiping experiments. Surface 1 was inoculated at the same level as the positive surface (starting dried inoculum) before wiping experiments. Cloth was used to wipe surfaces sequentially from surface 1 through surface 4 and was submerged in the bucket solution (PBS, disinfectant, or disinfectant + 5% soil) after wiping surfaces 1, 3, and 4, but not surface 2.

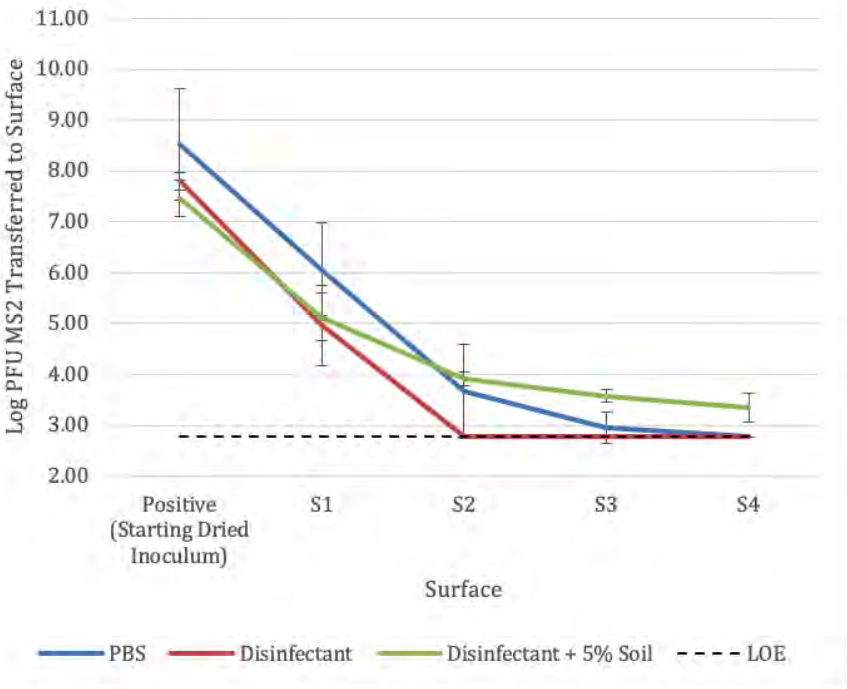

FIGURE 4. Log PFU of MS2 bacteriophage transferred to, and remaining on, laminate surfaces during wiping experiments. Surface 1 was inoculated at the same level as the positive surface (starting dried inoculum) before wiping experiments. Cloth was used to wipe surfaces sequentially from surface 1 through surface 4 and was submerged in the bucket solution (PBS, disinfectant, or disinfectant + 5% soil) after wiping surfaces 1, 3, and 4, but not surface 2.

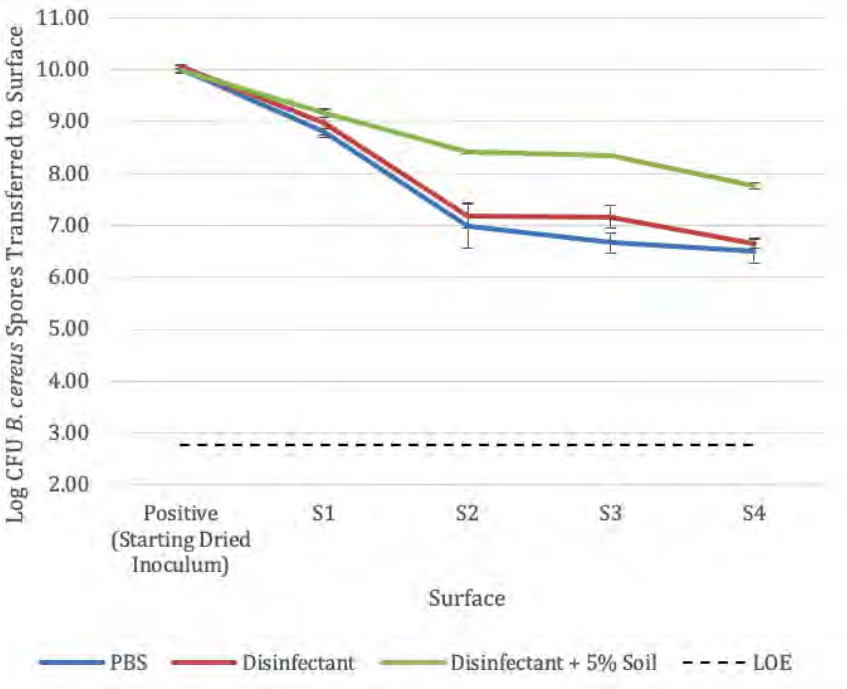

FIGURE 5. Log CFU of *Bacillus cereus* spores transferred to, and remaining on, laminate surfaces during wiping experiments. Surface 1 was inoculated at the same level as the positive surface (starting dried inoculum) before wiping experiments. Cloth was used to wipe surfaces sequentially from surface 1 through surface 4 and was submerged in the bucket solution (PBS, disinfectant, or disinfectant + 5% soil) after wiping surfaces 1, 3, and 4, but not surface 2.

area. They observed high aerobic plate counts for both cleaning cloths and on the associated surfaces after cleaning in the absence of a disinfectant. What was interesting in the current study was that the efficacy of the disinfectant was maintained even in the presence of a relatively high soil load, despite suggestions that a higher concentration of QAC is needed to be efficacious in the presence of high soil *(5)*. Medrano-Félix et al. *(10)* demonstrated that households in which a QAC disinfectant intervention was introduced had reduced numbers of *E. coli* on kitchen countertops over time, compared with households that did not receive the QAC intervention, which showed no change or increased numbers of *E. coli* on countertops. Our work also demonstrates the efficacy of QAC disinfectants against representative gram-negative and gram-positive bacteria, even in the presence of a significant organic load.

The results for bacteriophage MS2 are shown in *Fig. 4*. The results for the positive control (PBS as bucket solution, no disinfectant) showed that quantifiable cross-contamination occurred through wiping of S3. With the first wipe, approximately 2.5 log PFU/surface was removed and/or inactivated, giving a concentration of 6.1 ± 0.9 log PFU on S1. After submerging the cloth in PBS and using that cloth to wipe down S2, 3.7 ± 0.9 log PFU was transferred, with 3.0 ± 0.3 log PFU/surface then transferred to S3, representing subsequent cross-contamination. After submerging the cloth in PBS for a second time, the MS2 was not detected on S4 after the last wiping event, at least within the enumeration limit of the assay (which was < 2.78 log PFU/surface).

The data for QAC, with and without added soil, were similar but not identical to that for PBS. In the absence of added soil, MS2 became undetectable on S2, showing some benefit of the QAC in preventing long-term cross-contamination. For QAC with 5% soil experiments, cross-contamination was never completely ameliorated since quantifiable virus was present even on S4, albeit the concentrations of MS2 for S3 and S4 were low, at 3.6 ± 0.1 log PFU/surface and 3.4 ± 0.3 $\log_{10}$ PFU/surface, respectively. For all three treatments, rapid inactivation and/or removal of virus occurred between the positive control and S2; thereafter, inactivation or cross-contamination was either marginal or nonexistent (because the assay limit of enumeration had been reached).

MS2 was chosen for use as a surrogate for human enteric viruses, specifically HNV. It has been shown that HNV has long-term persistence (weeks) on surfaces, and in general, QACs have poor efficacy against HNV *(19)*. The results of this study were somewhat surprising if taken in the context of MS2 being used to model HNV behavior. The fact that so much of the virus was lost between the positive control and S2, whether or not the disinfectant was present, suggests that MS2 was effectively removed by the act of wiping. There is little information on the efficacy of rubbing to remove HNV, with one study showing approximately 1 log removal of HNV depending on the type of cloth used *(8)*. In the same study, the impact of cloth type on the transferability of HNV surrogates (MS2 and PRD1 bacteriophages and feline calicivirus) to stainless steel surfaces was evaluated and found to be cloth dependent, ranging from very little transferred to around 3 log PFU. Hence, we should be cautious in assuming that HNV would be removed by cloth wiping because there are many variables in our study that were not evaluated. Unfortunately, because removal appeared to be so effective, there was only a small window (about 1 log PFU) in which to evaluate efficacy of the QAC, not enough to make any compelling conclusions about sanitizer efficacy. In short, further studies are required to truly understand the behavior of HNV with respect to cross-contamination and inactivation in reusable cloth-and-bucket scenarios.

Results for wiping experiments with *B. cereus* differed quite considerably from those for the vegetative bacteria and MS2. In the absence of a disinfectant (PBS control), 8.8 ± 0.1 log CFU/surface remained on S1 after the first wiping step, suggesting that approximately 1.2 log CFU/surface was removed by the act of wiping when compared with the positive control. After submerging the cloth in PBS and then using that cloth to wipe down S2, a total of 7.0 ± 0.4 log CFU/surface was transferred. This degree of cross-contamination remained relatively consistent for subsequent wiping steps (S3 and S4). When QAC without added soil was used as the bucket solution, very similar results were observed, strongly suggesting that the QAC had no sporicidal effect on *B. cereus*. This was not unexpected because the efficacy of QACs on spores has been shown to be formulation dependent *(6)*. The addition of 5% soil to the disinfectant solution had something of a protective effect in wiping experiments, with only 0.8 log CFU/surface removed in the first wiping action and relatively consistent cross-contamination (8.4 ± 0.1 log CFU/surface, 8.3 ± 0.1 log CFU/surface, and 7.8 ± 0.1 log CFU/surface for S2, S3, and S4, respectively) occurring thereafter.

Collectively, *B. cereus* spores were readily transferred from surface to surface, regardless of the solution used for wiping experiments. The spores were resistant to inactivation by the QAC and may have been protected by the addition of soil. As was the case for the vegetative bacteria, cross-contamination appeared less efficient if first preceded by rinsing the cloth in the bucket water (as was the case for S1 versus S2 and S3 versus S4) as compared with two sequential wipes without a cloth rinse (S2 versus S3). These data clearly demonstrate the environmental resilience of spores and their ease of spread from surface to surface using reusable cloths, regardless of whether or not a QAC disinfectant is present. This was perhaps expected because some studies of disinfection of *C. difficile* spores have found that QAC-based disinfectants did not have sporicidal properties *(7)*. The results of this study support those of previous ones *(18)* showing that *C. difficile* spores are easily transferred by reusable cloths to surfaces across multiple wiping events.

TABLE 2. Numbers of microorganisms detected in bucket solution after wiping experiments

Organism	Treatment	Positive input control (mean CFU/PFU ± standard deviation)	Bucket solution (mean CFU/PFU ± standard deviation)	% transferred to and remaining in bucket solution[a]
L. innocua	PBS	9.58 ± 0.74	9.49 ± 0.99	99.1
	QAC	9.60 ± 0.28	N/A-LOE[b]	N/A-LOE[b]
	QAC + soil	8.83 ± 0.37	N/A-LOE[b]	N/A-LOE[b]
E. coli	PBS	8.13 ± 0.18	8.54 ± 0.78	105.0
	QAC	6.33 ± 0.43	N/A-LOE[b]	N/A-LOE[b]
	QAC + soil	5.81 ± 0.20	N/A-LOE[b]	N/A-LOE[b]
B. cereus	PBS	10.01 ± 0.07	10.54 ± 0.22	105.3
	QAC	10.06 ± 0.03	9.48 ± 0.19	94.2
	QAC + soil	9.98 ± 0.03	9.96 ± 0.03	99.8
MS2	PBS	8.52 ± 1.09	8.39 ± 0.99	98.5
	QAC	7.80 ± 0.18	N/A-LOE[b]	N/A-LOE[b]
	QAC + soil	7.46 ± 0.35	6.56 ± 0.38	87.9

[a]Transferred to, and remaining in, the bucket solution was calculated by dividing the number of organisms detected in the bucket solution by the number of organisms detected in the positive input control and multiplying by 100 [(bucket solution mean/positive input control mean) × 100].

[b]Not applicable (N/A), when the organism was completely inactivated by the disinfectant (limit of enumeration [LOE] reached) and ratios could not be determined.

It is important to note that the results shown in this study are limited to the organisms included, the use of selective media (which may prevent recovery of injured cells), presence of laminated surfaces, the QAC product chosen, and the use of terry-cloth bar towels. Because we did not account for injured cells, our results could have underestimated surviving populations on the surfaces and in the bucket water, meaning that the number of organisms transferred from one surface to another, and into the bucket solution, could have been higher. Future studies using nonselective medium or increasing the incubation time on selective medium would be an appropriate next step. In addition, it was not possible to standardize wiping pressure because of the large surface area of the surfaces studied. We also did not measure the concentration of the QAC after it was prepared (although we did follow manufacturer's instructions) because we were attempting to simulate a real-life scenario as much as possible. Front-of-house retail food service employees are not likely to measure QAC concentration in prepared solutions, and if they did, there is no record of the accuracy of those measurements. Although measuring the active ingredient concentration in studies such as these is not always common, measuring the QAC concentration, especially after the addition of soil, would have been interesting, but was outside the scope of this study. It has also been shown that the efficacy of QACs can be reduced by cloth towels *(5)*, and that effect was not characterized in the current study. Some common practices also include a cleaning step before disinfection, and a cleaning step was not characterized here. Hence, this study only evaluated disinfection, although it should be noted that the surfaces were very clean, with the exception of a very small amount of inoculum, at the onset of the experiments. Further method-development studies to optimize and standardize wiping actions, such as pressure on larger surfaces, are warranted, as discussed in Sattar and Maillard *(14)*, as well as those that investigated the effect of cleaning a surface before disinfection, and how QACs are affected by cloth towels in this scaled-up model.

The data for the microbial concentrations in bucket solutions after wiping are provided in *(Table 2)*. Note that, when organisms were present and not inactivated by the QAC, their concentrations were very high and represented >85% of the initial inoculum enumerated from the positive control surface. In all cases, high concentrations of the microbes were detected in the control (PBS) bucket solutions after wiping. This suggests that the absence of disinfectant use in cloth and bucket cleaning protocols could result in survival of vegetative bacteria, viruses, and spores, some of which

could be pathogenic and may be cross-contaminated during subsequent wiping steps. When the bucket was filled with a QAC-based disinfectant at manufacturer-recommended concentration, even in the presence of added soil, the vegetative bacterial cell load in the solution was effectively controlled to below assay enumeration limits, meaning that the QAC effectively prevented microbial survival and cross-contamination in subsequent wiping steps. On the other hand, bucket solutions containing QAC, both with and without added soil, had little efficacy against the spores in this study because a very high concentration of spores remained in those solutions and could serve as a source of cross-contamination in sequential wiping. As stated above, the MS2 data were mixed and may not be indicative of the behavior of HNV.

CONCLUSIONS

The aim of this study was to characterize the degree of cross-contamination of representative gram-positive and -negative bacteria, spores, and viruses, to large surfaces, using a traditional cloth and bucket method. We used a commercial QAC disinfectant commonly used in restaurant settings (with and without additional soil) and a PBS (no disinfectant) control. The intention was to perform the study on large surfaces that are more representative of real-world retail food-sector environments than most previous studies, which used very small surface areas.

Although the effective inactivation of vegetative bacteria by QAC disinfectants is well recognized *(6, 12)*, the current study shows that both *L. innocua* and *E. coli* were readily transferred to laminate surfaces in the absence of a disinfectant. We also demonstrated how easily *B. cereus* spores were transferred across surfaces with the cloth and bucket method, even in the presence of the QAC disinfectant with and without soil. Although the bacteriophage results were inconclusive and there are other potentially important factors not explored in our study (such as wiping pressure or the possible decreased activity of QACs when using cloth towels, which may aid the spread of organisms to surfaces *(4)*), our study does suggest that use of reusable cloths in cloth and bucket systems could potentially promote cross-contamination and recontamination of laminate surfaces. This has significance to food service establishments, schools, and many other settings. Characterizing the efficacy of other disinfectants and/or disposable wipe disinfection systems in preventing the transfer of microorganisms between surfaces, compared with the QAC cloth and bucket system evaluated in this study, would be useful in developing best practices in disinfection of large surfaces.

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Removal and Transfer of Viruses on Food Contact Surfaces by Cleaning Cloths

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Contamination of food contact surfaces with pathogens is considered an important vehicle for the indirect transmission of food-borne diseases. Five different cleaning cloths were assessed for the ability to remove viruses from food contact surfaces (stainless steel surface and nonporous solid surface) and to transfer viruses back to these surfaces. Cleaning cloths evaluated include two different cellulose/cotton cloths, one microfiber cloth, one nonwoven cloth, and one cotton terry bar towel. Four viral surrogates (murine norovirus [MNV], feline calicivirus [FCV], bacteriophages PRD1 and MS2) were included. Removal of FCV from stainless steel was significantly greater ($P \leq 0.05$) than that from nonporous solid surface, and overall removal of MNV from both surfaces was significantly less ($P \leq 0.05$) than that of FCV and PRD1. Additionally, the terry towel removed significantly fewer total viruses ($P \leq 0.05$) than the microfiber and one of the cotton/cellulose cloths. The cleaning cloth experiments were repeated with human norovirus. For transfer of viruses from cloth to surface, both cellulose/cotton cloths and microfiber transferred an average of 3.4 and 8.5 total PFU, respectively, to both surfaces, and the amounts transferred were significantly different ($P \leq 0.05$) from those for the nonwoven cloth and terry towel (309 and 331 total PFU, respectively). There was no statistically significant difference ($P > 0.05$) in the amount of virus transfer between surfaces. These data indicate that while the cleaning cloths assessed here can remove viruses from surfaces, some cloths may also transfer a significant amount of viruses back to food contact surfaces.

Each year in the United States and worldwide, human noroviruses (HuNoVs) are the leading cause of nonbacterial gastroenteritis, being associated with 80 to 90% of reported outbreaks (17). Moreover, HuNoVs are the primary cause of food-borne disease outbreaks reported in the United States, causing 5.5 million (58%) illnesses each year (37). Economically, HuNoVs cost approximately $625 per case—equivalent to $3.7 billion each year with respect to food-borne illnesses attributable to HuNoVs (39). Noroviruses may be transferred to people via a direct route (i.e., person to person) or indirectly (i.e., fecal-oral route) by contact with fomite (inanimate) surfaces (6) and ingestion of contaminated food and water (33).

Contaminated fomite surfaces have been well-documented to be a route of HuNoV transmission, especially with respect to outbreaks in enclosed environments such as long-term care facilities, hospitals, cruise ships, camping trips, and military settings (18, 19, 25, 34, 54). One of the critical factors of HuNoV transmission is its ability to persist long term in the environment. Lamhoujeb et al. (2009) reported that HuNoVs can persist on stainless steel and polyvinylchloride (PVC) surfaces for from 1 to more than 7 weeks, depending on the surface, temperature, and relative humidity (24). In addition, once a surface becomes contaminated, virus particles can easily be transferred between inanimate and animate objects (e.g., from contaminated surfaces to hands and vice versa) (3, 20). It is still unclear how many food-borne disease outbreaks are a direct result of transmission of HuNoVs to foodstuffs via contaminated food contact surfaces. However, because of the extremely low infectious dose (as few as 18 infectious virus particles) (49), high number of viruses shed during infection (10^{11} and 10^{6} genomic copies per gram of stool or vomit, respectively), and ability to persist, fomite surfaces are considered to be a major route in the spread of HuNoV gastroenteritis (27, 36).

Cleaning with chemical disinfectants and sanitizers is considered an important step in preventing the transmission of HuNoVs from contaminated surfaces. The efficacy of various cleaning compounds (alcohols, quaternary ammonium compounds, sodium hypochlorite) against both HuNoVs and HuNoV surrogates (murine norovirus [MNV], feline calicivirus [FCV], MS2 bacteriophage) on different surface materials, primarily stainless steel, melamine, and PVC, has been assessed (3, 16, 31). It is important to note that most studies are based on inactivation of cultivable HuNoV surrogates since there is no cell culture assay to measure the infectivity of HuNoVs. Overall, the studies investigating disinfectants on surfaces agree that the most effective compound against HuNoVs is sodium hypochlorite (NaClO). However, the concentration (5,000 ppm, or 15.6 ml bleach in 1 liter of water) of NaClO determined to be most effective for inactivation of HuNoVs far exceeds what is mandated (i.e., 200 ppm) for sanitizing food contact surfaces in the *Food Code* published by the U.S. Food and Drug Administration (FDA) (50). In order to use this high concentration of NaClO on food contact surfaces, the area that is disinfected must then be rinsed with clean water and receive a final wipe down with a 200-ppm bleach solution (50). Furthermore, prior to sanitization, the area should also be cleaned with detergent and water in order to remove food residues and maintain the expected efficacy of the sanitizing compound (46). Moreover, the concentration and contact time required for initial inactivation of HuNoV may damage (i.e., oxidize) stainless steel surfaces, the surfaces predominantly used and recommended for food preparation. Because of this, quaternary ammonium and

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ethyl alcohol compounds are most often used during regular cleaning and sanitizing of food contact surfaces, even though these sanitizers are not very effective against nonenveloped viruses such as HuNoVs and other enteric viruses (e.g., rotavirus, hepatitis A virus, and adenovirus) (16, 45).

Another component involved in the cleaning and sanitizing of food contact surfaces is the cloth used to wipe these surfaces during regular and intermittent cleaning of food preparation areas and tabletops. Because cleaning cloths come in contact with potentially contaminated surfaces, their ability to remove pathogens from surfaces as well as their potential to transfer pathogens to clean surfaces must be evaluated. Tebbutt (1988) (48) evaluated disposable and reusable disinfectant cloths for cleaning Formica surfaces inoculated with fecal bacteria and concluded that while reusable cloths are more convenient and less expensive, these cloths are often not disinfected properly, and thus, use of disposable cloths may reduce the risk of cross contamination. More recent studies have also reported on the effectiveness of select cleaning cloths (e.g., nonwoven fiber, microfiber, and generic kitchen cloths) for removal of bacteria (22, 23); however, none have evaluated cloths for their effectiveness against viral pathogens, and few have evaluated the cloth as a source for potential cross contamination within food service industry environments (48).

Therefore, the goal of the present study was to evaluate five different cleaning cloths for their ability to remove HuNoVs, MNV, FCV, and bacteriophages MS2 and PRD1 from a stainless steel surface and a nonporous acrylic-based, solid surface. The potential for each cleaning cloth type to transfer viruses back to the surfaces was also evaluated. To our knowledge, this is the first study to evaluate cleaning cloth efficacy for removal of viruses from food contact surfaces and transfer of viruses from cloth to surface.

MATERIALS AND METHODS

Preparation of virus stocks. MS2 and PRD1 bacteriophages were prepared as described previously, with modifications for MS2 (1, 15). Briefly, MS2 (ATCC 16696-B1) and PRD1 bacteriophages were generated using the double-agar-layer (DAL) method and *Escherichia coli* C3000 (ATCC 15597) and *Salmonella enterica* subspecies *enterica* serovar Typhimurium LT2 (ATCC 19585) bacterial hosts, respectively. The bacteriophages were then extracted from cell lysates with an equal volume of chloroform (Sigma, St. Louis, MO), sterile filtered, centrifuged at 4,000 × *g* for 30 min at 4°C, aliquoted, and stored at −80°C. Stock titers were determined by the DAL method. Both MS2 and PRD1 were selected because of their prior use as surrogates for enteric viruses, such as NoV and human adenoviruses, respectively (8, 12). MNV (type 1) and FCV (strain F9) stocks were propagated in monolayers of RAW 264.7 (ATCC TIB-71) and Crandall Reese feline kidney (CrFK) cells, as described previously (14). MNV and FCV stock titers were determined by plaque assay as described by Gibson and Schwab (2011) (14). Both MNV and FCV were chosen because of their prior use as surrogates for the study of HuNoVs (4, 8, 16, 26).

Human norovirus was prepared from a diarrheal stool sample as described previously, with modifications (1). Briefly, a stool sample positive for Norwalk virus GI.1 (denoted substrain 8fIIb and kindly provided by Kellogg Schwab, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD) was diluted in 1× phosphate-buffered saline (PBS) to make a 10% (wt/vol) stool suspension. The stool suspension was vortexed for 5 min, followed by centrifugation at 3,000 × *g* for 10 min at 4°C to pellet the suspended solids and clarify the sample. The supernatant was removed, placed in a new tube, and stored at 4°C. While the exact concentration of HuNoV particles in the stool sample was unknown, positive amplicons could be detected up to a dilution of 1:10,000 of the prepared stool sample by heat release and real-time reverse transcription-PCR (RT-PCR) (refer to Table 1 for primer/probe information; for PCR conditions, see below).

Real-time RT-PCR assay for NoV. For detection of HuNoVs, real-time RT-PCR was completed using a Mastercycler ep *realplex*^{4} system (Eppendorf, Hamburg, Germany). Prior to amplification, HuNoV RNA was extracted by heat release at 95°C for 5 min as described previously (41). For the HuNoV-positive control during real-time RT-PCR, HuNoV RNA was extracted from the prepared stool sample using a QIAamp DNA blood minikit and buffer AVL with carrier RNA (Qiagen, Valencia, CA), following the manufacturer's protocols. The positive-control HuNoV RNA was aliquoted and stored at −80°C.

Amplification of HuNoV RNA was performed in 25-μl reaction mixtures containing 12.5 μl of 2× master mix (QuantiTect Probe RT-PCR kit; Qiagen, Valencia, CA), 5 U RNase inhibitor (Promega, Madison, WI), custom primers (Integrated DNA Technologies, Coralville, IA) and dual-labeled TaqMan probes (Biosearch Technologies, Novato, CA) at the final concentrations reported in Table 1, 5 μl of prepared sample, and diethyl pyrocarbonate (DEPC)-treated water for the remaining volume. Real-time RT-PCR amplification was performed under the following conditions: reverse transcription for 30 min at 50°C and denaturation for 15 min at 95°C, followed by 40 cycles of denaturation at 95°C for 15 s and annealing/extension at 60°C for 60 s.

Real-time RT-PCR assay for inhibition. Real-time RT-PCR inhibition analysis using a hepatitis G virus (HGV) armored RNA standard (Asuragen, Austin, TX) was completed for all samples as described previously (15) using the primers and probes listed in Table 1. Briefly, each 25-μl reaction mixture contained 12.5 μl of 2× master mix (QuantiTect Probe RT-PCR kit; Qiagen), 5 U RNase inhibitor (Applied Biosystems), 400 nM primers (Invitrogen) and 200 nM dual-labeled TaqMan probe (Biosearch Technologies, Novato, CA), 5 μl of prepared sample, 2 μl of a known amount of HGV RNA, and DEPC-treated water for the remaining volume. Real-time RT-PCR amplification was performed under the following conditions: reverse transcription for 30 min at 50°C and denaturation for 15 min at 95°C, followed by 40 cycles of denaturation at 95°C for 15 s and annealing/extension at 60°C for 60 s. The quantity of HGV measured in the unknown sample was compared to the quantity measured in corresponding HGV-positive controls. Each batch of samples assayed for inhibition included a negative control of HGV master mix containing DEPC-treated water substituted for HGV RNA and at least 3 positive-control reaction mixtures containing only HGV RNA and no sample. A sample was deemed uninhibited if the cycle threshold (C_T) of the seeded HGV was less than 1 cycle higher than the mean of the expected C_T obtained from the HGV-positive controls. Conversely, a sample was determined to be inhibited if the C_T of the seeded HGV was more than 1 cycle higher than the mean of the expected C_T obtained from the HGV-positive controls. Complete absence of a C_T value for seeded HGV was indicative of total inhibition of the real-time RT-PCR.

Assessment of virus removal from surfaces. Five cleaning cloths were assessed for removal of viral surrogates and HuNoVs from stainless steel and solid surfaces. Two different blended cellulose/cotton cloths (cellulose, 70%; cotton, 30%), microfiber, nonwoven wipes (viscose, 50%; polyester, 50%), and generic cotton terry bar towels (100% cotton) were assessed. Cloths were selected on the basis of current (e.g., cotton terry bar towels) and/or potential (e.g., microfiber) use by the food service industry and commercial availability. The cloths were cut into 5-cm^2 pieces, placed in sterilization pouches (VWR, Radnor, PA), and autoclaved at 121°C and 15 lb/in^2 for 15 min. Stainless steel sheets (type 304/14 gauge and type 430/15 gauge; Advance Tabco, Edgewood, NY) and 3- by 3-in. (7.6-cm^2) 100% acrylic-based, nonporous solid surface samples (13-mm-thick Wilsonart laminate; Wilsonart International, Inc., Temple, TX) were used for all experiments. Surfaces were sterilized before the beginning of the described study and after each experiment. For stainless steel, the surfaces were initially cleaned with soap and water, wrapped in aluminum foil, and autoclaved at 121°C and 15 lb/in^2 for 15 min. After each experiment, the stainless steel surfaces were exposed to UV light for 30 min in a biosafety

level 2 (BSL-2) hood, followed by application of a 10% solution of household bleach for 10 min. The stainless steel surfaces were then autoclaved, cleaned again, wrapped in aluminum foil, and autoclaved again. For the acrylic-based solid surface, the same protocol was followed, except the solid surface could not be autoclaved.

One hundred microliters of a prepared virus cocktail containing on average of 5.4×10^5, 1.1×10^6, 1×10^5, and 7.4×10^5 PFU of each viral surrogate (MS2, PRD1, FCV, and MNV, respectively) was inoculated by random spotting onto either a 7.6-cm^2 area of solid surface or stainless steel. One hundred microliters of 1× PBS was also inoculated onto one 7.6-cm^2 surface as a negative control. For HuNoVs, 100 μl (corresponding to 10,000 RT-PCR units [RT-PCRU]) of prepared, undiluted HuNoV-containing stool was used for inoculation. Inoculated surfaces were allowed to dry completely for 30 to 45 min in a BSL-2 hood.

With sterile forceps, a 5-cm^2 piece of sterile cloth was dampened with high-quality, Milli-Q lab water (Millipore, Billerica, MA) and placed on the 7.6-cm^2 surface. The surface was wiped by hand 3 times vertically and 3 times horizontally. Gloves were worn throughout the process and sprayed with 70% ethanol between cloths. We attempted to minimize variability between experimental replicates due to differences in the pressure applied to the cloth while wiping by having the same person conduct all of the removal and transfer experiments.

The surfaces and cleaning cloths were then eluted as described below in "Recovery of viruses from cloths and surfaces." The cleaning cloths were eluted for recovery only of viral surrogates and not of HuNoV. For every cloth type-surface type paired experiment, each cloth was assessed in triplicate with two positive surface controls (i.e., the surface was inoculated but not wiped), one negative surface control (i.e., a surface inoculated with 1× PBS was wiped), and one negative cloth control (i.e., no wiping was done). All eluates and inocula were assayed for MS2, PRD1, MNV, and FCV as described for the stock preparations. Each assay included both positive (known amount of viral surrogate) and negative (1× PBS) controls. Dilutions for viral surrogates were prepared in 1× PBS. Preliminary experiments in which each virus stock was seeded on the other virus host cell line did not generate any cross-reactive plaque formation, nor did the seeding affect the formation of the expected number of PFU for the host virus (data not shown). Real-time RT-PCR was used for analysis of HuNoV. For real-time RT-PCR, eluates were prepared by making 2-fold serial dilutions in DEPC-treated water, and RNA was extracted by heat release for 5 min at 95°C.

Assessment of virus-to-surface transfer. Initially, 5-cm^2 pieces of cleaning cloths were dampened with high-quality, Milli-Q lab water (Millipore). The damp cloths were subsequently seeded in duplicate with 100 μl of prepared virus cocktail containing approximately 10^5 to 10^6 PFU of each viral surrogate (MS2, PRD1, MNV, FCV). The virus cocktail was allowed to equilibrate to the cloth for 1 min. Each 7.6-cm^2 surface was wiped with one inoculated cloth 3 times vertically and 3 times horizontally. For each cloth type-surface type paired experiment, one positive-control cloth was also inoculated with the viral surrogate cocktail but not used for wiping. The surfaces and cleaning cloths were then eluted as described below in "Recovery of viruses from cloths and surfaces." All eluates and inocula were assayed for MS2, PRD1, MNV, and FCV as described for stock preparation and titer determination. Transfer experiments were completed using only viral surrogates and did not include assessment of HuNoVs due to the low stock concentrations and real-time RT-PCR limit of detection.

Recovery of viruses from cloths and surfaces. Prior to assessment of cleaning cloths, a method for elution of the viruses from the surfaces as well as from the cleaning cloths was optimized. For elution of viruses from the surfaces, a method described previously by Taku et al. (2002) was used with modifications (47). Briefly, 600 μl of elution buffer (0.05 M glycine [pH 6.5], 0.1% Tween 80, and 0.3 M NaCl) was added to the 7.6-cm^2 areas of inoculated surfaces. The elution buffer was allowed to contact the surface for 10 min. Using a sterile cell scraper (Fisher Scientific, Pittsburgh, PA), the surface was scraped to spread the elution buffer and detach ad-

TABLE 1 Primers and probes for detection of human norovirus and hepatitis G virus[a]

Microorganism	GenBank accession no.	Primer or probe name	Primer/probe[b] final concn (nM)	Sequence[c]	Product size (bp)	Product region	Reference
Human norovirus (GI)	M87661	Cog1-F	1,000	5′-CGYTGGATGCGNTTYCATGA-3′	85	ORF1-ORF2 junction	21
		Cog1-R	1,000	5′-CTTAGACGCCATCATCATTYAC-3′			
		Ring1A-TP probe	100	5′-FAM-AGATYGCGATCYCCTGTCCA-BHQ-3′			
		Ring1B-TP probe	100	5′-FAM-AGATCGCGGTCTCCTGTCCA-BHQ-3′			
Hepatitis G virus (internal standard)	U44402	HepG-F	400	5′-CGGCCAAAAGGTGGTGATG-3′	185	5′ UTR[d]	40
		HepG-R	400	5′-CGACGAGCCTGACGTCGGG-3′			
		HepG probe	200	5′ AGGTCCCCTCTGGCGCTTGTGGCGAG-3′			

[a] Hepatitis G virus was the RNA internal standard for analysis of inhibition.
[b] The 6-carboxyfluorescein (FAM) quencher is black hole quencher 1 (BHQ-1).
[c] Mixed bases in degenerate primers and probes are as follows: Y = C and T; R = A and G; B = C and T; G; N = A, C, T, and G.
[d] UTR, untranslated region.

hered viruses. The elution buffer was then collected from the surface using a micropipette. The total volume of buffer containing viruses was recorded in order to calculate recovery efficiency.

For elution of viruses from cleaning cloths, the cloths (5-cm^2 pieces) were placed in 50-ml polypropylene tubes containing 20 ml of elution buffer. The tubes containing cloths were processed at room temperature for 30 min with shaking at 150 rpm. After shaking, the elution buffer containing viruses from the cloths was removed from the tube and placed in a new 50-ml polypropylene tube. The total volume of buffer containing viruses was recorded in order to calculate recovery efficiency.

Statistical analyses. For all experiments, statistical analyses were performed using JMP software (version 9.0; SAS, Cary, NC). Virus PFU values were transformed to logarithmic values to achieve a normal distribution. One-way analysis of variance (ANOVA) and Tukey-Kramer honestly significant difference (HSD) were used when performing two or more mean comparisons within a data set. In all cases, statistical significance was set at an α value of ≤ 0.05.

RESULTS

Recovery efficiency of elution method. To assess the efficiency of the elution method, virus recoveries were calculated for both the surfaces and the cleaning cloths for virus removal and transfer experiments, respectively. Values for recovery efficiency were based on the number of PFU reported for the positive controls (surface or cloth) divided by the number of PFU in the inoculum. The optimized elution method described in the Materials and Methods section achieved average overall efficiencies of recovery from the surfaces of >100, 37, 41, and 57% of MS2 ($n = 14$), PRD1 ($n = 14$), MNV ($n = 9$), and FCV ($n = 8$), respectively. Elution efficiencies from cleaning cloths during transfer experiments for MS2 ($n = 38$), PRD1 ($n = 40$), and FCV ($n = 10$) were >100, >100, and 36%, respectively. Elution efficiency of MNV from cleaning cloth transfer experiments could not be calculated because the values for the positive controls for the assay (i.e., MNV of a known concentration analyzed simultaneously with the samples to ensure the validity of the plaque assay) were significantly lower than expected; thus, the PFU counts obtained from elution of the cleaning cloths were not considered valid and these data were excluded.

Removal of viruses from solid surface and stainless steel. On average, the five cleaning cloths removed 2.85 $\log_{10}$ and 3.15 $\log_{10}$ units of the viral surrogates on solid surface (Fig. 1A) and stainless steel (Fig. 1B), respectively. Statistically significant differences ($P = 0.0031$) between surfaces were seen for removal of FCV, with stainless steel surfaces yielding greater removal. In addition, removal of MNV from both surfaces combined was significantly less than removal of FCV and PRD1 ($P = 0.0016$ and 0.0004, respectively) (Fig. 1). Comparing total virus removal by cleaning cloth type, the terry bar towel removed significantly fewer viruses than the cellulose/cotton blend 1 ($P = 0.0064$) and the microfiber ($P = 0.0016$) cloths. Initially, the microfiber was used as a dry cloth, but upon further consideration, a dampened microfiber cloth was used for remaining removal experiments. The dry microfiber removed an average of ≤ 10 PFU ($P \leq 0.05$) (data not shown), while the dampened microfiber cloth performed similarly to the other cloths. Therefore, data for microfiber removal of viruses presented in Fig. 1 include only the $\log_{10}$ amount removed by damp microfiber.

Data collected on removal of HuNoVs by cleaning cloths are presented in Table 2. These data are results from elution of the surface after wiping with the contaminated cloths. Results for cellulose/cotton cloth 2 are shown for only one experiment (performed in triplicate) on each surface, as this cloth became unavailable for use in the remaining replications. During preliminary analyses, total inhibition (i.e., no detection of the HGV RNA standard within the sample matrix, as indicated by lack of a C_T value) was detected in samples undiluted and diluted to 2^{-1} (data not shown); therefore, all samples were analyzed at a 2^{-2} dilution. Even still, samples diluted to 2^{-2} exhibited partial (i.e., a shift or increase in the expected C_T value for the HGV RNA standard) and/or total inhibition. The impact of inhibitors on the real-time RT-PCR assays makes quantitative interpretation of these data nearly impossible.

Transfer of viruses to solid surface and stainless steel. Results of the transfer of total combined virus surrogates (MS2, PRD1, FCV) from the cleaning cloths to stainless steel are provided in Fig. 2. Data for MNV have not been included due to issues occurring with the described plaque assay and a lack of sufficient sample volume remaining to repeat assays. The cellulose/cotton cloths and microfiber transferred an average of 3.4 and 8.5 total virus PFU, respectively, to the solid surface. These three cloths were significantly different ($P < 0.0001$) from the nonwoven and terry towel cloths for transfer of viruses to solid surface (Fig. 2). For all three viral surrogates (FCV, MS2, PRD1), the nonwoven and terry towel cloths transferred an average of 3.3×10^2 and 8.3×10^2 PFU to the solid surface, respectively. For stainless steel, cellulose/cotton cloth 1 transferred 2.6 PFU, which was significantly different from the amounts for nonwoven and terry towel cloths ($P < 0.0001$ and $P = 0.0009$, respectively). In addition, the microfiber cloth transferred to stainless steel significantly less virus ($P = 0.0110$) than the nonwoven cloth (Fig. 2).

DISCUSSION

Application of appropriate cleaning tools for the removal of viruses from food contact surfaces—or any surface—is a critical step in preventing the indirect transfer of viruses to persons at food service establishments (6). Therefore, the effectiveness of various cleaning cloths for their removal and subsequent transfer of HuNoVs and HuNoV surrogates on food contact surfaces was studied.

Initially, a method for elution of viruses from surfaces and cleaning cloths was optimized. The method published by Taku et al. (2002) (47) was modified here through the addition of 0.3 M NaCl and 0.1% Tween 80 to the 0.05 M glycine buffer (pH 6.5) that was originally described. The inclusion of NaCl and Tween 80 has been previously described and demonstrated to enhance elution efficiencies from various food and environmental matrices (2, 11, 32, 51). The recovery efficiencies of 37 to >100% for elution of viruses from the surfaces reported here are similar to the recoveries of 32 to 71% for FCV from stainless steel reported by Taku et al. (2002) (47). Our modification of this method was also shown to be effective for recovery of MNV, MS2, PRD1, and HuNoVs from both stainless steel and acrylic, solid surface.

Studies evaluating various cleaning cloths for removal of pathogens within food service environments remain limited, while research in hospital settings (e.g., studies of stainless steel, furniture laminate, and ceramic tile surfaces) has been frequently reported. With respect to hospital settings, microfiber and ultramicrofiber cloths have received the bulk of attention for their potential to improve cleaning efficacy without the need for added detergents (29). Most recently, Smith et al. (2011) (44) evaluated

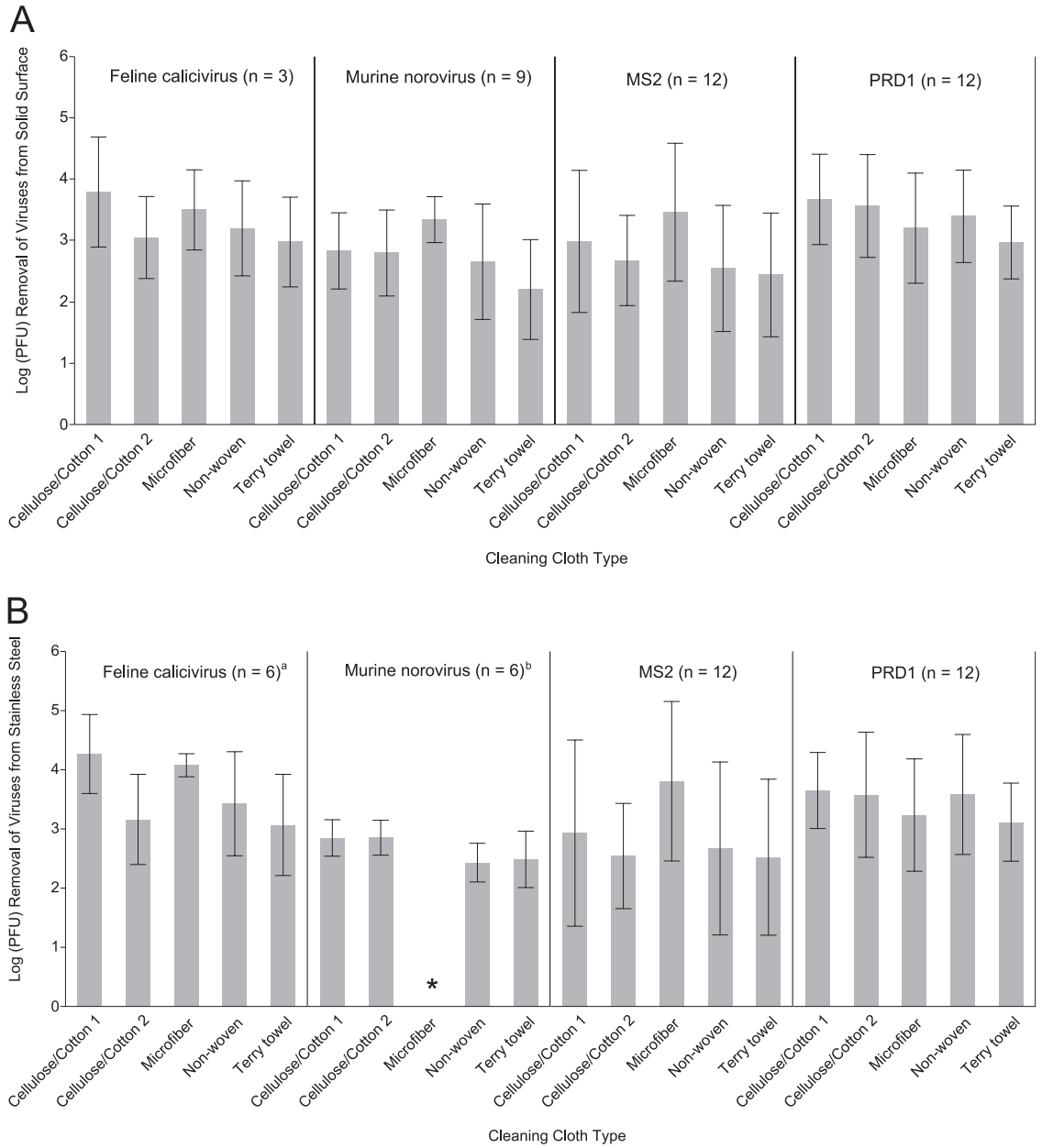

FIG 1 Virus removal from solid surface (A) and stainless steel (B) by cleaning cloth and virus type. Error bars indicate standard deviations. *, only dry microfiber was included in these data for MNV removal, and thus, the data were excluded from statistical analyses, as dry microfiber was determined to be significantly different from dampened cleaning cloths; a, statistically significant difference ($P = 0.0031$) in removal of FCV from solid surface and stainless steel; b, statistically significant difference in removal of MNV from both surfaces compared to FCV and PRD1 removal ($P = 0.0016$ and 0.0004, respectively).

10 different damp microfiber cloths for removal of pathogens known to cause health care facility-associated infections: *Clostridium difficile* spores, *E. coli*, and methicillin-resistant *Staphylococcus aureus*. The authors reported a mean $\log_{10}$ reduction of 2.21 when single-use damp microfiber cloths were used, while lower reduction levels were reported during repeat use of the cloths to clean a succession of contaminated surfaces. Other studies reported similar or better bacterial reduction values for damp microfiber cloths, depending on the surface and organism (7, 28). Although not directly comparable, the microfiber cloth evaluated in our study had a mean $\log_{10}$ reduction of 3.36 for viruses when used as a damp cloth on both surface types. Therefore, microfiber cloths seem to be effective in the removal of both viruses and bacteria from nonporous surfaces. With respect to food service environments, very few evaluations of cleaning cloths for removal of microbial contamination have been reported, and of those, only insufficiently characterized kitchen fiber cloths, generic cloths, disposable paper wipes, or nonwoven fabric sheets were used (22, 42, 48). Regardless, all of these studies evaluate efficacy against bacterial pathogens and not viruses, and thus, comparison and discussion of virus removal from food contact surfaces by cleaning cloths are not possible.

TABLE 2 Human norovirus removal from solid surface and stainless steel using cleaning cloths

Cleaning cloth type	Average C_T value (SD)[a]					
	Solid surface			Stainless steel		
	Rep 1	Rep 2	Rep 3[b]	Rep 1	Rep 2	Rep 3[b]
Cellulose/cotton 1	35.31	Not detected	Not detected	Not detected	38.55	Not detected
Cellulose/cotton 2	37.55	ND	ND	Not detected	ND	ND
Microfiber	33.90 (1.03)	32.89 (0.13)	37.33 (1.95)	33.06 (0.44)	33.36 (0.09)	38.26
Nonwoven	34.51 (1.88)	33.67 (0.53)	39.00	33.00 (0.41)	33.15 (1.24)	38.28
Cotton terry towel	33.12 (0.28)	32.90 (1.16)	36.13 (1.60)	37.12 (2.16)	33.64 (1.27)	37.84
Positive control	32.83	31.61	37.19	34.27	32.04	35.86

[a] Values are average C_T values from triplicate samples (for each replicate) based on analyses of a 5-μl portion of a 2^{-2} dilution of eluate recovered from surfaces after wiping with cleaning cloths. The positive control is from a nonwiped, inoculated surface. All samples were partially inhibited (i.e., if the C_T of the seeded HGV was more than 1 cycle higher than the mean of the expected C_T obtained from the HGV-positive controls) unless otherwise indicated. Rep, replicate; not detected, no virus RNA was detected in the sample; therefore, no C_T values are reported; ND, not done. The standard deviation is not reported for those samples with less than 3 C_T values; a lack of a C_T value indicates that no RNA was amplified and does not indicate that less than 3 samples were assayed.

[b] None of the samples, including the positive controls, were inhibited.

Our study also demonstrates differences in virus removal between surfaces. In the current study, there was significantly greater removal of FCV from the stainless steel surface than from the solid surface (mean $\log_{10}$ reductions, 3.5 and 2.8, respectively), but this difference was not seen for MNV, MS2, and PRD1. The reasons for the difference in removal of FCV are not known but may be due to the variable affinities of FCV adsorption to solid surface and stainless steel. Electrostatic interactions, van der Waals forces, and hydrophobic effects are assumed to play a role in the interactions between virus particles and surfaces (13). Additional factors affecting adsorption include the different intrinsic characteristics, such as the isoelectric point, of the virus. In this experiment, the viral surrogates studied (FCV, MS2, MNV, and PRD1) may have slightly different net surface charges, as demonstrated by the different isoelectric points (4.9, 3.9, unknown [but thought to be similar to that of NoV at 5.0], and 4.2, respectively) (38, 52). Even with these differences, the elution buffer with a pH of 6.5 containing 0.3 M NaCl and 0.1% Tween 80 described here was formulated to inhibit electrostatic and hydrophobic interactions, thus disrupting adsorption to the surface. More likely, the difference in FCV removal is related to the variable efficiency of the plaque assay (i.e., random differences in virus adsorption and/or infectivity of the cells in the plaque assay). Significant differences between cleaning cloths were also reported for removal of both FCV and MNV from stainless steel but not from solid surface. A potential reason for these differences could be attributed to application of inconsistent pressure to the surface when wiping with the cleaning cloths; however, if this were the case, then one would expect all

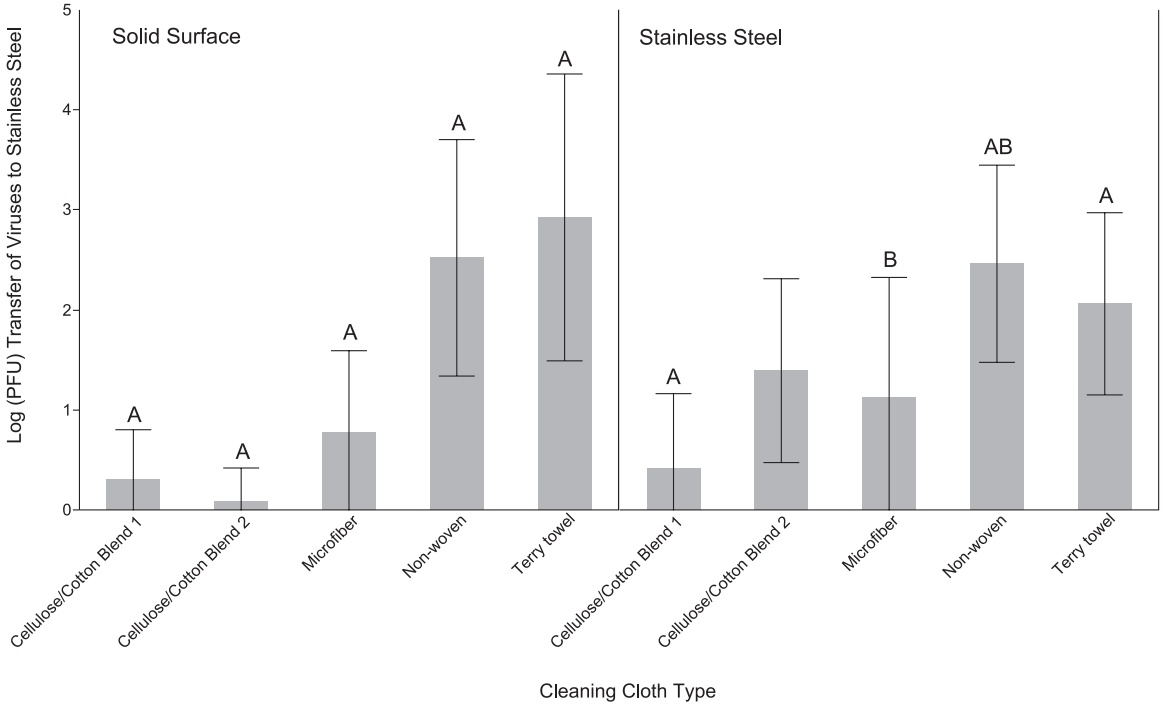

FIG 2 Total virus (FCV, MS2, PRD1) transfer to solid surface and stainless steel by cleaning cloths. Error bars indicate standard deviations. Letters above the bars represent statistically significant differences ($P \leq 0.05$) between cloth types for virus transfer within each surface type.

virus types to be affected, since a cocktail of all viruses was used for the inoculum.

Aside from evaluating the removal of HuNoV surrogates by cleaning cloths, we also evaluated HuNoV removal using real-time RT-PCR. These data, however, did not provide a clear picture of the cloths' effectiveness for removal of HuNoVs due to issues with inhibition of the assays. Here we used a clarified stool sample containing HuNoV GI.1 for the inoculum in order to minimize processing of the sample. Unfortunately, stool samples—even if clarified—contain numerous inhibitors (e.g., phenolic compounds, glycogen, fats, cellulose, bacterial debris, and heavy metals) that can impact the results of RT-PCR assays (30). Steps beyond simple clarification that may have helped to alleviate inhibitors in the stool sample include further processing with organic solvents such as Freon or Vertrel XF and purification using cesium chloride or sucrose gradients (10, 43). Initially, we did compare simple clarification by centrifugation with extraction of HuNoVs from the stool sample by Vertrel XF, and there was a slight loss of virus signal with minimal alleviation of inhibition (data not shown). Another possibility to address inhibition would have been to extract RNA from the eluates collected from the surfaces during evaluation of the cloths. Even though inhibition would have been less of an issue, the extraction efficiency for each sample would need to be assessed in order to provide the amount of certainty necessary to accurately quantify these data. In the end, we did not feel that this was warranted for the scope of the present study, though future research should be done to further evaluate HuNoV removal using cleaning cloths through the utilization of cesium chloride-purified HuNoVs and/or HuNoV-like particles (53).

The most obvious and potentially most critical difference in the cloths was demonstrated in the transfer experiments, where the cotton/cellulose and microfiber cloths transferred significantly less—approximately 2 orders of magnitude less—virus than the nonwoven cloths and cotton terry bar towels. Within the food service industry, cotton terry bar towels are most often used for cleaning, as they can be laundered and reused. The data presented in our study indicate that damp cotton terry bar towels transfer an average of 832 and 115 PFU of HuNoV surrogates (FCV, MS2, PRD1) back to solid surface and stainless steel, respectively. Similar levels of transfer were also demonstrated in our study when using a damp nonwoven cloth. Given the low infectious dose of HuNoVs and resistance to environmental degradation, this level of transfer for HuNoV surrogates should be considered when selecting the appropriate cloth for cleaning and for disinfection before reuse. The difference in the cloth transfer levels may be due to differences in fiber density, though this was not investigated in our study. For instance, the cellulose/cotton cloths have a more sponge-like construction, whereas the cotton terry bar towels have a more open construction with loose fabric loops to which the viruses may not adsorb as readily. The majority of data existing on the transfer of viruses to and from porous (e.g., food and hands) and nonporous (e.g., stainless steel and glass) surfaces primarily focus on transfer from hand to surface (3, 5, 20), surface to hand (35), hand to food (5), and surface to food (9); thus, this study represents the first report of the transfer of viruses from contaminated cloths to nonporous surfaces.

There are a few limitations in the design of our study. First, we used a 5- to 6-$\log_{10}$-unit virus inoculum for the removal and transfer experiments. This amount of virus is likely much greater than would be found on contaminated surfaces, not including surfaces contaminated by an episode of vomiting or other symptoms of acute gastrointestinal illness; even so, Julian et al. (2010) (20) concluded that inoculum size did not significantly influence the amount of virus transferred. Second, we elected to wipe inoculated surfaces 3 times vertically and 3 times horizontally without conducting an experimental evaluation of whether different wiping methods would be more appropriate for assessing the efficacy of cleaning cloths or the ability for the cleaning cloths to transfer viruses to surfaces. Previous studies have reported a variety of wiping methods, ranging from simple to complex, for assessing removal of bacteria (22, 23, 28, 48). If future studies for evaluation of cleaning cloths are developed, we feel a standard method would be beneficial for comparison of data across studies. Last, we did not evaluate the cloths in combination with a sanitizing agent. According to the FDA *Food Code* (§4-501.114), cleaning and wiping cloths should be stored in an approved sanitizing solution for reuse during an undefined period of time. However, we know that the most common sanitizing compounds (i.e., quaternary ammonium) are ineffective against HuNoVs and other viral pathogens; therefore, significantly increased efficacy is not likely. Furthermore, as this is the first study of its kind, we felt it to be important to first establish removal/transfer due to the cloth alone without compounding variables.

Overall, the findings of this study indicate that cleaning cloths composed of certain materials may be a valuable interim cleaning tool in the food preparation environment when time does not permit the use of a sanitizing agent. This study also demonstrated that some cleaning cloths may more readily transfer viruses back to the food contact surface if used after cleaning a contaminated area and present a potential risk to public health. Although effective at virus removal by themselves, future research should involve evaluation of cloths identified to be the most effective all around (i.e., cellulose/cotton blend cloths and microfiber) in combination with sanitizers and other cleaning regimens.

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Standing Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME Food Protection Manager Certification Committee (FPMCC)

DATE OF FINAL REPORT: *12/5/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☒ ***Executive Board***

REPORT SUBMITTED BY: **Susan Quam and Justin Daniel**

COMMITTEE CHARGE(S):

Issue # 2020-II-001

1. To carry out charges assigned via the Conference Issue process and from the Conference Executive Board relating to food protection manager certification and to adopt sound, uniform accreditation standards and procedures that are accepted by the Conference while ensuring that the conference Standards for Accreditation for Food Protection Manager Certification programs and the accreditation process are administered in a fair and responsible manner

Issue # 2020-II-004

1. Review the impact and feasibility of changing the frequency of required certification examination to a time period not to exceed four years from date of issuance, aligning knowledge demonstration by examination with the routine four-year update and publication of the FDA Retail Food Code.

COMMITTEE WORK PLAN AND TIMELINE: The committee met virtually every other month to complete its charges.

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

1. ***Overview of committee activities:***

   All meetings were scheduled from 2:00-4:00 p.m. Eastern time..

   December 1, 2021
   February 2, 2022
   April 6, 2022
   June 1, 2022
   August 3, 2022
   October 5, 2022

   Final reports and issues were reviewed via email

2. ***Charges COMPLETED and the rationale for each specific recommendation:***
   a. **2020-II-001**
      As part of the committee's normal review process, a Standards workgroup reviewed changes to the Standard and the proposed changes are submitted as a separate issue. The recommended changes are to either clarify a standard for the purpose of accreditation review or to fix grammar, punctuation, and formatting issues.

      The Bylaws workgroup reviewed the committee's bylaws (which are separate from the Conference's bylaws) and the proposed changes are submitted as a separate issue. The major update to the bylaws clarifies the maximum number of voting Certification providers on the committee to 5 total voting members, with those 5 members having one whole vote. Under the committee's current bylaws, if there is more than 5 accredited certification providers, the votes would be fractioned and the 5 votes would be spread out to the 6 or more providers. Fractionizing the votes is not practical. Under the change, all providers would be able to participate in the committee, but only the 5 appointed as voting members will have a vote.

   b. **2020-II-004**
      The committee discussed each of the II-004 impacts/feasibility issues at its April 6 and June 1 meetings. After vetting all of the issues identified, the committee unanimously voted to keep the maximum time frame for Certified Food Protection Manager certifications to five years. The committee felt the proposed change to four years would not improve food safety and would impact both regulatory and industry stakeholders in a negative way. Documents used in deliberation can be found in the 2021-22 FPMCC Minutes attachment.

3. ***Charges INCOMPLETE and to be continued to next biennium: none***

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

1.
2.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. ***Issue #1: Report – Committee Name: Food Protection Manager Certification Committee (FPMCC)***
List of content documents submitted with this Issue:
Committee Member Roster:
☒ ***See attached revised roster PDF*** ☐ ***No changes to previously approved roster***
"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) ***Other content documents:***

i. ***2023 CFP FPMCC Bylaws with Proposed Changes***

ii. ***2023 CFP Standard for Accreditation of FPM Certification Programs with Proposed Changes***

b. **List of supporting attachments:** ☐ ***Not applicable***

(1) 2021-22 FPMCC Minutes

1. ***Committee Issue #2***: Proposed Changes to the FPMCC Committee Bylaws
2. ***Committee Issue #3***: Proposed Changes to the Conference for Food Protection Standard for Accreditation of Food Protection Manager Certification Programs
3. ***Committee Issue #4:*** FPMCC Response to 2020-II-004

Committee Name: FOOD PROTECTION MANAGER CERTIFICATION revised 12.31.2022

Last Name	First Name	Position	Vote / Non-vote	Constituency	Employer	City	State	Telephone	Email	Notes
Quam	Susan	Chair	Non Voting	Industry - Support At Large	Wisconsin Restaurant Association	Madison	WI	608-216-2875	squam@wirestaurant.org	
Daniel	Justin	Vice Chair	Voting	Regulator - Local	Lincoln-Lancaster County Health Department	Lincoln	NE	402-441-8033	jdaniel@lincoln.ne.gov	
Sweet	Bridget	Member	Voting	Academia	Johnson & Wales University	Providence	RI	774-434-5146	bridget.sweet@jwu.edu	
Reich	Allen	Member	Voting	Academia	Northern Arizona University	Flagstaff	AZ	928-853-6340	allen.reich@nau.edu	
Wilson	David	Member	Voting	Consumer	After School Matters	LaGrange	IL	708-582-0022	d.wilson180@my.chicago.chefs.edu	
Dolhanyk	Anne	Member	Voting	Consumer	STOP Foodborne Illness	West Linn	OR	360-601-4264	adolhanyk@gmail.com	
Luebkemann	Geoffrey	Member	Voting	Industry - Food Service	Florida Restaurant & Lodging Association	Tallahassee	FL	850-224-2250	gluebkemann@frla.org	
Halbrook	Courtney	Member	Voting	Industry - Food Service	Topgolf	Dallas	TX	704-236-0890	courtney.halbrook@topgolf.com	
Wynne	Rebecca	Member	Voting	Industry - Food Service	Darden	Denver	CO	303-895-4042	rwynne@darden.com	
Dwyer	Tara	Member	Voting	Industry - Retail Food	Dave's Marketplace	East Greenwich	RI	401-4748905	tarad@davesmarketplace.com	
Allen	Consuelo	Member	Voting	Industry - Retail Food	Whole Foods Market	Austin	TX	512-426-8709	consuelo.allen@wholefoods.com	
vacant				Industry - Retail Food						Jeff Hawley retired from Harris Teeter December 1. Approved as CFP rep to ACAC by EB. See non-voting list
Koester	Laura	Member	Voting	Industry - Retail Food At Large	Harmons	Salt Lake City	UT	801-957-8472	laurakoester@harmonsgrocery.com	
Ciarimboli	Ellen	Member	Voting	Industry - Retail Food At Large	Hy-Vee, Inc.	West Des Moines	IA	515-453-2789	eciarimboli@hy-vee.com	
Corchado Torres	Liz	Member	Voting	Industry - Support Certification Org	National Registry of Food Safety Professionals	Orlando	FL	407.999.8126	lcorchado@nrfsp.com	
Piche	Kate	Member	Voting	Industry - Support Certification Org	National Restaurant Association / ServSafe	Chicago	IL	312-261-5348	kpiche@restaurant.org	
Smith	Melissa	Member	Voting	Industry - Support Certification Org	StateFoodSafety	Orem	UT	503-729-5667	melissa.smith@statefoodsafety.com	
Eastwood	Nick	Member	Voting	Industry - Support Certification Org	Always Food Safe	St. Paul	MN	612.203.4872	nick.eastwood@alwaysfoodsafe.com	
Anderson	Tom	Member	Voting	Industry - Support Certification Org	360 Training	Austin	TX	512-212-7343	tom.anderson@360training.com	

Derr	Samuel	Member	Voting	Industry - Support Training	Elite Food Safety Training	Naperville	IL	630-776-3430	sderr@elitefoodsafety.com	
Paster Cammarata	Tara	Member	Voting	Industry - Support Training	Paster Training, Inc.	Gilbertsville	PA	610-970-1776	tara.paster@pastertraining.com	
Roughan	George	Member	Voting	Industry - Support Training	TAP Series	Westlake Village	CA	818-889-8799 x 101	gr@tapseries.com	
Straughn	Ki	Member	Voting	Regulator - Local	Public Health Seattle & King County	Bellevue	WA	206-263-8088	kstraughn@kingcounty.gov	
Wiedmeyer	Lindy	Member	Voting	Regulator - Local At Large	City of Racine Public Health Department	Racine	WI	262-636-9567	lindy.wiedmeyer@cityofracine.org	
Woods	Yolanda	Member	Voting	Regulator - Local At Large	Shelby County Government	Memphis	TN	901-222-9190	yolanda.woods@shelbycountytn.gov	
Burns Savage	Nikki	Member	Voting	Regulator - Local At Large	Southern Nevada Health Districtg	Las Vegas	NV	702-686-7691	ntburns@cox.net	
Jackson	Jeff	Member	Voting	Regulator - State	Arkansas Department of Health	Little Rock	AR	870-847-7619	jeff.jackson@arkansas.gov	
Huffman	Troy	Member	Voting	Regulator - State (Federal replacement)	Colorado Department of Public Health & Environment	Denver	CO	303-692-3664	troy.huffman@state.co.us	
Smith	Colleen	Member	Voting	Regulator - State (Federal replacement)	NH DHHS	Concord	NH	603-271-4858	colleen.smith@dhhs.nh.gov	
Unkart	Sharon	Alternate	Non-Voting	Regulator - State	NEHA	Denver	CO	720-802-2142	sdunkart@neha.org	Moved to voting position from the alternate list. Replacing Sean Dunleavy
Non-voting										
Morris	Sheri	Member	Non-Voting	ACAC Representative	Pennsylvania Department of Agriculture	Harrisburg	PA	717-787-5289	shmorris@pa.gov	
Hawley	Jeff	Member	Non-Voting	ACAC Representative	Retired - Retail Industry	Matthews	NC	704-844-3098	jehawley718@gmail.com	
Krishna	Vijay	Consultant	Non-Voting	ANAB Representative	ANAB	Washington	DC	202-331-3614	vkrishna@ansi.org	
Wittry	Beth	Consultant	Non-Voting	Federal Govt	CDC	Atlanta	GA	770-488-7333	Xks5@cdc.gov	
Williams	Laurie	Consultant	Non-Voting	Federal Govt	FDA	College Park	MD	240-402-2938	laurie.williams@fda.hhs.gov	
Duggins	Quwanza	Consultant - alternate	Non-Voting	Federal Govt	FDA	Oklahoma City	OK	240-535-5969	quwanza.duggins@fda.hhs.gov	
Baker	Michael	Alternate	Non-Voting	Industry - Support Certification Org	National Registry of Food Safety Professionals	Chicago	IL	312-651-5783	mbaker@restaurant.org	
Conley	Mark	Alternate	Non-Voting	Industry - Support Certification Org	National Restaurant Association / ServSafe	Chicago	IL	312.583.9853	MConley@restaurant.org	

Johnson	Lars	Alternate	Non-Voting	Industry - Support Training	LAJ Consulting/ FoodSafetyGuy	San Jose	CA	507-990-5129	fsg@foodsafetyguy.com	
Morrison	Laura	Alternate	Non-Voting	Industry - Support	Ohio Restaurant Association	Columbus	OH	614-246-0205	lmorrison@ohiorestaurant.org	
Gillam	Tim	Alternate	Non-Voting	Industry - Food Service	Subway Restaurants	Milford	CT	570-688-3310	gillam_t@subway.com	
Rivas	April	Alternate	Non-Voting	Industry - Support Training	ATC Food Safety	Pfafftown	NC	707-363-6032	april.rivas@atrainingcompany.com	
Pollock	Evelin	Alternate	Non-Voting	Regulator - Local	Harris County Public Health	Houston	TX	713-248-5691	evelin.pollock@phs.hctx.net	

Food Protection Manager Certification Committee Bylaws

Preamble

The Food Protection Manager Certification Committee, hereinafter referred to as the Committee, of the Conference for Food Protection, hereinafter referred to as the Conference, exists to carry out charges assigned via the Conference Issue process and from the Conference Executive Board, hereinafter referred to as the Board, relating to food protection manager certification and operates within the objectives stated in the Constitution and Bylaws of the Conference.

Article I. Name.

The Name of the Committee is Food Protection Manager Certification Committee.

Article II. Objectives.

Section 1. Systematically identify and address issues concerning Food Protection Manager Certification Programs.

Section 2. Adopt sound, uniform accreditation standards and procedures that are accepted by the Conference.

Section 3. Promote uniformity among all jurisdictions that subscribe to the principles of the Conference by obtaining their recognition and adoption of the Conference Standards for Accreditation of Food Protection Manager Certification Programs.

Section 4. Promote strategies to enhance equivalence among food protection manager certificates issued by certifying organizations.

Section 5. Establish and refine policies and standards to which certifying organizations shall conform.

Article III. Organization and Operation.

Section 1. The Committee is a standing committee within the Conference.

Section 2. The Committee shall consider all Issues charged to the Committee and shall work to develop consensus. The Board may submit charges to the Committee at any time. The Committee is to deliberate the charges expeditiously, or within the time frame determined by the Board or the Committee Chair.

Section 3. The Committee shall use the protocol established in these Bylaws to address its charges.

Section 4. All Committee recommendations shall be submitted as Issues to the Conference for deliberation. The Committee shall follow the protocol for Issue submission as established by the Conference.

Section 5. All Issues, intellectual properties, and/or inventions created by the Committee and approved by the Assembly of Delegates become the property of the Conference.

Article IV. Quorum

A quorum to conduct Committee meetings and conference calls shall be the presence or participation of one more than half of the filled Committee positions**.** A Committee quorum shall be considered a sufficient number for voting on issues under deliberation. The decisions resulting from a quorum vote shall be deemed representative of the Committee.

Article V. Composition of Organizational Components and Eligibility Requirements for Serving in Official Capacities.

Section 1. The Committee shall be chaired by a Chair and Vice-Chair. Prior to each biennial Conference meeting, the incoming Chair and Vice-Chair shall be selected by the outgoing committee. The Chair, Vice-Chair and committee members shall be approved by the Board.

The Chair and Vice-Chair shall not be selected from the same constituency affiliation.

Section 2. The Committee Chair and Vice-Chair shall serve until the conclusion of the next biennial Conference meeting.

Section 3. The Committee Chair and Vice-Chair may serve consecutive terms with approval of the Board.

Article VI. Committee Structure and Representation.

Section 1. To be eligible to serve on the Committee as a voting member or non-voting alternate, individuals must commit in writing to active participation and be approved by the Conference Chair and the Board.

Section 2. The Committee Chair and Vice-Chair will select committee members and alternates from the list of volunteers from the most recent biennial meeting or recruit volunteers as appropriate to balance the committee as delineated in these Bylaws. In the event of a Committee vacancy with no designated alternate in that constituency, the Chair will first recruit from the remaining list of volunteers provided during the initial Committee selection process.

Section 3. The composition of voting members of the Committee is a balanced representation of industry, regulatory, academia, certification organizations, training providers, and consumers. The Committee membership representation shall consist of a maximum of thirty (30) full votes from the following constituencies:

Subsection 1. Nine (9) representatives from regulatory agencies with food safety responsibilities:

a. Two (2) Three (3) from State regulatory agencies;

b. Two (2) Three (3)from local regulatory agencies;

c. Two (2) from federal government agencies; and

d. Three (3) "At Large" appointments; (At large selections may include federal government agencies, state regulatory agencies and local regulatory agencies with food safety responsibilities.)

Subsection 2. Nine (9) industry representatives:

a. Three (3) from the foodservice (restaurant) industry;

b. Three (3) from the retail food store industry; and

c. Three (3) "At Large" appointments. (*At large selections may include professional or trade organizations that directly represent the restaurant, retail food, institutional foodservice, and food vending segments of the industry, and whose mission incorporates a public health protection component.)

Subsection 3. Five (5) total votes for certification organizations that are accredited by the Conference's accreditation process. Although there is no limit to the number of accredited certification organizations, this constituency shall have a maximum of five (5) votes.

Subsection 4. Three (3) Food Protection Manager training providers;

Subsection 5. Two (2) representatives from academia; and

Subsection 6. Two (2) consumer/independent representatives/public members.

Section 4. Committee members will serve a two (2) year term, concurrent with the cycle of the biennial Conference meeting. Committee members are eligible to serve for consecutive terms contingent upon an assessment by the Committee Chair and Vice-Chair to ensure a balance between members who have previously served on the Committee and new members.

Section 5. Up to two (2) non-voting alternates will be included on the Committee roster each for industry, regulatory, academia, training providers, and consumers to best represent the category of each constituency. Each certification organization participating on the Committee may designate one (1) alternate from their own organization. In the event a Committee member resigns or is no longer able to serve the remainder of their term, the Chair shall select an alternate from the affected constituency to fill the open seat.

Section 6. The incoming Chair of the Committee shall make every effort to retain at least 50% of the Committee membership for a continuing term. This retention is recommended due to the complexity of issues, the need to retain continuity of Committee functions, and the short time frame between biennial Conference meetings.

Section 7. In the event a Committee member changes constituency during their term, the Chair may consider them for any open seat on the Committee which needs representation from their constituency or consider any open alternate position. If the Chair determines that there are no appropriate openings available, the Committee member will be asked to resign from the committee.

Article VII. Committee Organization, Operation, and Meetings

Section 1. The Committee shall receive its direction from the Board. The Board shall assign the Committee its charges as approved during the biennial Conference meeting. The Board may assign additional charges to the Committee to ensure that the Conference Standards for Accreditation of Food Protection Manager Certification Programs and accreditation process are administered in a fair and responsible manner.

Section 2. The Committee shall meet in-person at least annually and at the biennial Conference meeting. All Committee meetings are open to anyone to attend. In addition to meetings, the Committee shall schedule conference calls, as deemed appropriate, for addressing issues under deliberation. In the event that sensitive, financial or proprietary information is under consideration by the Committee, the Chair shall have the option to conduct an executive session until the confidential portion of the proceedings has been concluded.

Section 3. In addition to the charges received from the Board, Committee members may submit Issues and alternative recommendations to the Committee for discussion. Issues and recommendations introduced by Committee members shall be submitted using the Conference format.

Section 4. Presentations for in-person Committee meetings shall be submitted to the Committee Chair and Vice-Chair for review at least 2-weeks prior to meeting dates.

Section 5. Voting.

Subsection 1. A consensus building decision process will be used. When Committee members are asked to vote, each member will be able to express one of three positions.

- A thumb up indicates agreement with the issue on the floor
- A thumb sideways means the position on the floor is not the member's optimal solution, but they can accept the position
- A thumb down indicates that a member does not agree with the issue on the floor and would like an alternative recommendation considered.

The Committee Chair shall provide an opportunity for the dissenting member(s) to express the alternative position(s). After discussion of these alternative positions, the Chair will call for a final vote from the Committee.

Subsection 2. Except for certification organizations, all voting Committee members and alternates designated for that meeting shall have one (1) vote.

Subsection 3. All certification organizations accredited by the Conference's accreditation process participating on the Committee shall not to exceed a total of five (5) votes.

- If more than five (5) certification organizations volunteer to participate on the Committee, the five (5) votes allocated to certification organizations shall be fractionalized (evenly divided).
- The voting fraction shall be determined when the final committee membership is approved by the Board and shall remain in effect until the next biennial Conference meeting.
- Each certification organization shall be allowed no more than one (1) vote or one (1) voting fraction at any meeting.

Subsection 4 3. The Vice-Chair may voice positions on issues and may vote on all matters before the Committee.

Subsection 5 4. The Chair is a non-voting member of the Committee; however, in the event of a tie, the Chair may vote as the tie-breaker.

Section 6. Committee funding. The Board may allocate funds to the Committee for its charges. These funds may be used to contract the services of outside experts to assist the Committee, attend meetings with potential accreditation entities, and other miscellaneous expenses that the Committee must incur, e.g., use of meeting rooms. Funding shall not be allocated to cover an individual Committee member's travel or per diem expenses to attend meetings. Committee funding may be used only as directed by the Board.

Article VIII. Duties of the Committee Chair

Section 1. The Chair and Vice Chair, with the approval of the Board shall select Committee members in accordance with these Bylaws.

Section 2. The Chair, with concurrence of two-thirds (2/3) of the voting members of the Committee may appoint non-voting Ex-Officio consultants and advisors to the Committee in accordance with these Bylaws.

Section 3. The Chair shall preside at all meetings of the Committee, except as provided in these Bylaws.

Section 4. The Chair shall coordinate the arrangement of meetings and conference calls and ensure that meeting dates and locations are posted in advance on the Conference web site.

Section 5. The Chair shall be responsible for distributing to Committee members and other meeting participants an agenda for the meeting or conference call. This agenda may be distributed by email, fax, mail, or other suitable means.

Section 6. The Chair may assign a Committee member, using a rotation basis or other appropriate means among all Committee members, to take minutes during designated meetings and conference calls.

Section 7. The Chair shall be responsible for distributing minutes of all Committee meetings or conference calls in a timely manner, usually within three weeks of the event.

Section 8. The Chair may designate ad hoc workgroups to conduct research, study proposals, and develop procedures or recommendations related to complex issues and/or charges to address the charges of the Board and complete the duties of the Committee.

Article IX. Duties of the Committee Vice-Chair

Section 1. In the event the Chair is unable to perform the duties of the Chair, the Vice-Chair shall act as Chair.

Section 2. When acting as Chair, the Vice-Chair shall perform all the necessary duties for the Committee as outlined in these Bylaws.

Section 3. The Vice-Chair shall perform all duties assigned by the Chair.

Article X. Duties of Committee Members/Alternates

Section 1. Committee members shall have the responsibility to notify the Committee Chair of their inability to attend a meeting or participate on a conference call at least

fifteen (15) days prior to the scheduled meeting or conference call. For any committee member that is unable to attend a scheduled meeting or conference call, an alternate will be assigned. Selection of the designated alternate will be agreed upon by the Committee Chair and the absent member and chosen to best represent the constituency of the absent member. This designated alternate may vote on issues before the committee only during the specified meeting or conference call.

Section 2. Committee members and alternates shall have the responsibility to review for comment standards, reports, recommendations, issues or other Committee documents distributed within the time frames designated by the Committee.

Section 3. Committee members and alternates shall have the responsibility to complete work assignments within time frames designated by the Committee.

Section 4. Committee members and alternates shall have the responsibility to notify the Committee Chair or the Chair's designee of their inability to complete a work assignment.

Section 5. Committee members that do not participate for three (3) consecutive meetings and/or conference calls shall have their continued participation as Committee member assessed by the Committee Chair and evaluated by the Committee. The Committee member may be subject to being removed from their membership position. Removal of a Committee member for failure to perform duties as specified in these Bylaws, shall require the concurrence of two-thirds (2/3) of the voting members of the Committee.

Article XI. Committee Advisors, Subject Matter Experts, Paid Consultants and Conference Appointments

Section 1. Federal participants (FDA/USDA/CDC) may appoint an advisor and an alternate to serve as non-voting ex-officio members of the Committee. The alternate may act in the advisor's place if the advisor is unable to attend.

Section 2. The Conference Chair, at the request of the Committee Chair, with approval of the Executive Board, may appoint a psychometrician advisor to serve as a non-voting ex officio member of the Committee.

Section 3. The Chair and Vice-Chair may invite, with approval from the Committee, subject matter experts, external to the Committee, to participate in meetings and conference calls, or to work with an ad hoc workgroup, if it is determined that such individuals would provide additional information, insight, clarification, guidance or other assistance to the Committee, for a specified purpose. These subject matter experts will be non-voting guests in meetings and conference calls.

Section 4. The Committee may contract the services of a paid consultant for issues beyond the scope of the Committee's expertise, if deemed necessary or if charged by the Board. Contractual obligations for paid consultant services shall have the concurrence of two-thirds (2/3) of the voting members of the Committee and be approved by the Board.

Section 5. Conference appointments to the ANSI-CFP Accreditation Committee (ACAC) shall serve as non-voting ex-officio members of the Committee.

Article XII. Workgroups

Section 1. Workgroups shall report to the Committee Chair and Vice-Chair as determined by the Committee Chair.

Section 2. Each workgroup shall select a group leader who is responsible to report group activities to the Committee Chair and Vice-Chair.

Section 3. Workgroups shall provide written reports and recommendations to the full Committee for deliberation.

Article XIII. Committee Reports

Section 1. The Committee Chair shall be responsible for preparing written or oral reports to the Board detailing the activities and expenditures of the Committee. Written reports of the Committee's activities shall be submitted as required by the Conference procedures.

Section 2. The Committee Chair shall coordinate the development of a final report of the Committee activities to Council II with recommended actions. The final report shall be done as part of an Issue submission and shall comply with all Conference procedures.

Section 3. The Committee Chair, Vice-Chair, or designee as specified in writing to the Council II Chair, shall be in attendance when Council II meets during the Conference meeting to present and discuss the Committee's report and any Issues submitted by the Committee.

Article XIV. Amendments

The Food Protection Manager Certification Committee Bylaws may be altered, amended, or repealed by two-thirds (2/3) vote of the Committee and final concurrence from the Board, and then submitted as an Issue during the next biennial meeting.

Conference for Food Protection

Standards for Accreditation of Food Protection Manager Certification Programs

Preamble

The Conference for Food Protection, hereinafter referred to as the CFP, is an independent voluntary organization that has identified the essential components of a nationally recognized Food Protection Manager *Certification* Program and established a mechanism to determine if *certification organizations* meet this Standard. The CFP Standard for *Accreditation* of Food Protection Manager *Certification* Programs is intended for all *legal entities* that provide *certification* for this profession. The Standard has been developed after years of CFP's research into, and discussion about, Food Protection Manager *Certification* Programs.

All *certification organizations* attesting to the *competency* of Food Protection Managers, including *regulatory authorities* that administer and/or deliver *certification* programs, have a responsibility to the individuals desiring *certification*, to the employers of those individuals, and to the public. *Certification organizations* have as a primary purpose the evaluation of those individuals who wish to secure or maintain Food Protection Manager *Certification* in accordance with the criteria and Standard established through the CFP. *Certification organizations* issue *certificates* to individuals who meet the required level of *competency*.

The professionals involved in the credentialing process for *Certified Food Protection Managers* shall recognize that the justification for regulating entrance to the occupation of *Certified Food Protection Manager* is to:

- protect and promote food safety for the welfare of the public;
- ensure that the responsibility and liability for overseeing the protection of safety and welfare of the public lies with those governmental jurisdictions at the Federal, state and local levels having the power to set forth laws regulating entrance to and performance in this occupation;
- ensure that the rights of the public at large and of those members of the public who wish to enter this occupation shall be balanced in terms of fairness and due process in the form of a credentialing process for admitting qualified persons to perform in that occupation; and
  ~~Delete space~~
  ensure the highest possible degree of validity in the Certified Food Protection Manager credentialing process by carefully determining the competencies necessary to prevent foodborne illness, implementing standardized testing processes, and

promoting the appropriate interpretation and use of test results ~~ensure that the *validity* of the credentialling process for *Certified Food Protection Manager* is dependent on unbiased application of all aspects of that process, requiring careful determination of the competencies necessary to prevent foodborne illness, unbiased education and training for acquisition of those competencies, and fair assessment practices to ensure that individuals have achieved master of the competencie~~

Therefore, professionals involved in the credentialing process for *Certified Food Protection Manager* accept responsibilities based on these considerations.

The CFP Standard is based on nationally recognized principles used by a variety of organizations providing *certification* programs for diverse professions and occupations.*Accreditation*, through the process recognized by CFP, indicates that the *certification organization* has been evaluated by a third-party *accrediting organization* and found to meet or exceed all of the CFP's established Standard.

To earn *accreditation*, the *certification organization* shall meet the following CFP Standard and provide evidence of compliance through the documentation requested in the application. In addition, the *certification organization* shall agree to abide by *certification* policies and procedures, which are specified by the CFP Food Protection Manager *Certification* Committee, hereinafter referred to as the FPMC Committee, approved by the CFP, and implemented by the *accrediting organization*.

The *accrediting organization* shall verify and monitor continuing compliance with the CFP Standard through the entire *accreditation* period. The CFP FPMC Committee will work directly with the *accreditation organization* to enhance and maintain *certification* policies and procedures that meet the specific needs of Food Protection Managers while ensuring a valid, reliable and *legally defensible* evaluation of *certification* programs.

The American National Standards Institute (ANSI) was selected as the *accrediting organization* for the CFP Standard for *Accreditation* of Food Protection Manager *Certification* Programs and assumed its duties in January 2003. The CFP FPMC Committee continues to work within the Conference structure to monitor the criteria and selection process for the organization serving as the accrediting body for Food Protection Manager *Certification* Programs.

The CFP strongly encourages regulatory authorities and other entities evaluating credentials for Food Protection Managers to recognize and endorse this Standard and the *accreditation* process. The CFP Standard for *Accreditation* of Food Protection Manager *Certification* Programs provides the framework for universal acceptance of individuals who have obtained their credentials from an *accredited certification program*. In the U.S Food and Drug Administration's Food Code, hereinafter referred to as the FDA Food Code, Section 2-102.20 recognizes Food Protection Manager *certificate*s issued by an*accredited certification program* as one means of meeting the FDA Food Code's "Demonstrationof Knowledge" requirement in Section 2-102.1 and as satisfying the requirement of section
2-102.12 for the Person in Charge to be a Ce~~e~~rtified Ff~~f~~ood P~~p~~rotection M~~m~~anager.

Please note that words that appear in italics are defined terms.

Modifications and Improvements

The FPMC Committee followed the Conference directive to use the 1996 conference working document, Standard for Training, Testing and *Certification* of Food Protection Managers, in the development of accreditation standards. Extensive revision of this document was presented to CFP's 2012 Biennial Meeting of the Conference~~s~~ for Food Protection under the title, Standard for *Accreditation* of Food Protection Manager *Certification* Programs.

The charge to the FPMC Committee from the 2010 Biennial Meeting of the Conference for Food Protection resulted in revisions to the Standard to enhance the integrity of the entire examination process, which included identification and analysis of root causes of security violations and implementation of solutions.

The revision and reformatting of the document were made after a comprehensive FPMC Committee review of each section. This revision of the Standard for *Accreditation* of Food Protection Manager *Certification* Programs:

1. adds and improves definitions that are more precise and more consistent with terminology and definitions used in the *psychometric* community and by *accreditation* organizations;
2. reorganizes the Standard to eliminate duplication and align with purpose;
3. modifies or creates the Standard to better address professional credibility and training of *test administrators/proctors*; handling of examination packages; shipping irregularities; location(site) irregularities; and breach of the *certification organization's test administrators/proctor's* protocols and requirements;
4. uses "*test administrator/proctor*" in the Standard to indicate duties for both "*test administrator*" and "*proctor;*" and
5. adds a standard for management systems.

Annexes

Annex A is the result of the deliberation and recommendations from the FPMCC from the 2016 Biennial Meeting of the Conference for Food Protection, and represents the process and requirements for CFP to recognize a certification body that is accredited by ANSI under the ISO/IEC 17024 STANDARD.

Annex B is not part of the Standard, but provides information to guide those responsible for implementing or reviewing Food Protection Manager *Certification* Programs. This annex provides guidelines for specific responsibilitiesthat affect the effective implementation of the Conference Standard for *Accreditation* of Food Protection Manager *Certification* Programs.

Annex B provides guidance to regulatory authorities that incorporate Food Protection Manager *Certification* as part of their requirements to obtain or retain a permit to operate. The CFP Standard for *Accreditation* of Food Protection Manager *Certification* Programs is designed to be a voluntary unifying mechanism for the universal acceptanceof F~~f~~ood P~~p~~rotection M~~m~~anagers who obtain their *certificate*s from an *accredited certification program*.

Over the past twenty-five years, many regulatory authorities have developed their own Food Protection Manager *Certification* Programs. This has resulted in a variety of standards for *certification* programs. The CFP Standard for universal acceptance of *Certified Food Protection Manager*s provide regulatory authorities consistent and *legally defensible* criteria for evaluating *certification* programs. In addition, they eliminate duplication of testing and additional cost forthe industry.

Regulatory authorities that may not be in a position to eliminate their existing programs are encouraged to recognize F~~f~~ood P~~p~~rotection M~~m~~anagers certified in accordance with this Standard as fulfilling their program requirements. Annex B provides additional guidance, developed through the CFP, for the implementation of these regulatory *certification* programs.

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SECTION 1.0 - DEFINITIONS

1.0 Definitions.

1.1 **Accreditation** means that an *accrediting organization* has reviewed a Food Protection Manager *Certification* Program and has verified that it meets Standards set by the CFP as set forth in this document.

1.2 **Accrediting organization** means an independent organization that determines whether a Food Protection Manager *Certification* Program meets the Standards set by the CFP.

1.3 **Accredited certification program** means a Food Protection Manager *Certification* Program that has been evaluated and listed by an *accrediting organization* as being in conformity with the CFP Standard for such programs asset forth in this document. This does not refer to training functions or educational programs.

1.4 **Algorithm** means a set of procedures or rules pertaining to the selection of questions on an examination.

1.5 **Certificate** means documentation issued by a *certification organization*, verifying that an individual has complied with the requirements of an *accredited certification program*.

1.6 **Certification** means the process wherein a *certificate* is issued.

1.7 **Certification organization** means an organization that provides a *certification* program and issues the *certificate*.

1.8 **Certified Food Protection Manager** means a person who has successfully passed an *accredited food safety certification examination* demonstrating that he/she has the *knowledge, skills and abilities (KSA's)* required to protect the public from foodborne illness.

1.9 **Competency** means a defined combination of *knowledge, skills and abilities (KSA's)* required in the satisfactory performance of a job.

1.10 **Competency examination** means an instrument that assesses whether an individual has attained at least the minimum level of *competency* necessary to perform effectively and safely in a particular occupation or job.

1.11 **Computer-adaptive testing (CAT)** means a method of *computer-based testing* that uses *algorithm*s to select *items* at various difficulty levels to determine an *examinee's* proficiency.

1.12 **Computer-based testing (CBT)** means an examination administered on a computer.

1.13 **Continued proficiency** means a *certification organization's* process or program designed to assess continued *competence* of *Certified FoodProtection Managers*.

1.14 **Demographic data**, in this context, means the geographic distribution, education, credentials, stakeholder representation, and other relevant characteristics of the referenced group.

1.15 **Entry level performance** means carrying out job duties and tasks effectively at a level that does not pose a threat to public safety but not necessarily beyond that level.

1.16 **Equivalency** (in "equivalent examinations") means that two or more versions of a test measure the same constructs in the same ways and are built to the same content and statistical specifications .

1.17 **Examination adaptation** means a process by which an examination is transformedfrom a source language and/or culture into a target language and/or culture.

1.18 **Examination blueprint** means the plan that specifies how many questions fromevery job/task analysis content area must be included on each test form.

1.19 **Examination developers** means the individuals involved in the process of creatingthe Food Safety *Certification* Examination**.**

1.20 **Examination forms** means equivalent, alternate, and differing sets of *items,* compiled according to the same *examination blueprint* and conforming to the same *examination specifications*.

1.21 **Examination Materials** means all materials necessary for creating, disseminating, retrieving, administering, and grading examination items and forms.

1.22 **Examination specifications** means the description of the specific content areas of an examination, stipulating the number or proportion of *item*s for each measured *competency,* the total number of scored and unscored items, the amount of time allotted to complete the exam, and requirements for receiving a passing score.

1.23 **Examination version** means an examination in which the exact set of *item*s in an *examination form* is presented in another order, language, manner, or medium.

1.24 **Examinee** means a person who takes an examination.

1.25 **Exposure plan** means the policies and procedures in place to ensure that examination *item*s and forms are not made available to such a degree that their discrimination value is diminished.

1.26 **Food establishment** means an operation that stores, prepares,packages, serves, vends, or otherwise provides food for human consumption as defined inthe FDA Food Code 2017.

1.27 **Food safety certification examination** means an examination in food safety approved in accordance with the provisions of this program.

1.28 **Instructor** means an individual who teaches a course that includes *competencies* in prevention of foodborne illness. May also be called "educator" or "trainer."

1.29 **Item** means an examination question.

1.30 **Item bank** means all ~~of~~ the *item*s that have been developed for the several forms ofan examination. It includes all the *item*s available to create *examination forms*.

1.31 **Item sequence** means the presentation order of examination *item*s in an examination.

1.32 **Job Task Analysis** means the description of functions or tasks required for an individual to perform to entry-level standards in a specific job or occupation, including information about the attributes required for that performance. It defines the performance dimension of a job and includes *knowledge, skills and abilities (KSA's)* necessary to carryout the tasks.

A. **Tasks** are the individual functions, whether mental or physical, necessary to carry out an aspect of a specific job.

B. **Knowledge, skills, and abilities (KSAs)** include the information and other attributes that the worker shall possess in order to perform effectively and safely. They include information and understanding as well as learned behaviors and natural attributes.

1.33 **Legal entity** means an organization structured in a manner that allows it to function legally and be recognized as a responsible party within the legal system.

1.34 **Legally defensible** means the ability to withstand a legal challenge to the appropriateness of the examination for the purpose for which it is used.

1.35 **Linear Examination Form** means a fixed examination form, in any deliveryformat, where the form does not change or adapt based on the examinee's responses.

1.36 **Overexposure** refers to an *item* that has been selected or viewed to such a degree that its discrimination value is diminished.

1.37 **Exam Candidate** means an individual who may be reasonably expected to take a *food safety certification* examination.

1.38 **Proctor** means a person under the supervision of a *test administrator*, who assists by assuring that all aspects of an examination administration are being carried out with precision, with full attention to security and to the fair treatment of *examinees*.

1. 39 **Psychometric** means scientific measurement or quantification of human qualities, traits, or behaviors.

1.40 **Psychometrician** means a professional with specific education and training in development and analysis of examinations and other assessment techniques and in statistical methods.

1.41 **Regulatory authority** means a government agency that has been duly formed underthe laws of that jurisdiction to administer and enforce the law.

1.42 **Reliability** means the degree to which test scores for a group of test takers are consistent over repeated applications of a measurement procedure and, hence, are inferred to be dependable and consistent for an individual test taker.

1.43 Remote proctoring means supervision of an examinee during testing by a proctor who is in a different location. Examinee behavior is monitored by a human proctor using online monitoring software and artificial intelligence software.

1.443 **Retail food industry** means those sectors of commerce that operate *food establishments*.

1.454 **Test administrator** means the individual at the test site who has the ultimate responsibility for conducting a *food safety certification examination*. The *test administrator* can also be a *proctor*.

1.465 **Validity** means the degree to which accumulated evidence and theory support a specific interpretation of test scores for a given use of a test

SECTION 2.0 – PURPOSE OF CERTIFICATION ORGANIZATIONS

2.0 Purpose of *Certification Organizations.*

2.1 The *certification organization* shall have as a purpose the evaluation of those individuals who wish to secure or maintain Food Protection Manager *Certification* in accordance with the criteria and Standards established through the CFP, and the issuance of *certificates* to individuals who meet the required level of *competency*.

2.2 A *certification organization* responsible for attesting to the *competency* of Food Protection Managers has a responsibility to the individuals desiring *certification*, to the employers of those individuals, and to the public.

2.3 A *certification organization* for Food Protection Manager *Certification* Programs shall not be the *accrediting organization* nor shall the *certification organization* have any conflict of interest with said *accrediting organization.*

SECTION 3.0 – STRUCTURE AND RESOURCES OF CERTIFICATION ORGANIZATIONS

3.0 Structure and Resources of *Certification Organizations.*

3.1 **Structure of *certification organizations*.** The *certification organization* shall be incorporated as a *legal entity* (applies to the parent organization if the *certification organization* is a subsidiary of another organization).

3.2 A *certification organization* shall conform to all CFP Standards for *accreditation* and demonstrate that the relationship between the *certification organization* and any related association, organization or agency ensures the independence of the *certification* program and its related functions.

3.3 If a certification organization provides both education and certification, the certification organization shall at a minimum, demonstrate that the education part of the organization has no undue influence on the certification process. Additionally, the Certification Organization shall demonstrate that the certification process is not financially dependent on the associated education part of the organization.

3.4 **Resources of *Certification Organizations*.** A *certification organization* shall demonstrate.

A. the availability of financial resources to effectively and thoroughly conduct regular and ongoing *certification* program activities.

B. that its employees and any contracted professionals possess the skills and knowledge necessary to conduct the *certification* program activities.

C. that the roles and responsibilities of *certification personnel* are adequately defined.

SECTION 4.0 – FOOD SAFETY CERTIFICATION EXAMINATION DEVELOPMENT

4.0 ***Food Safety Certification Examination*** **Development.**

4.1 *Food safety certification examinations* administered by *accredited certification organizations* shall comply fully with all criteria set by the CFP and shall meet explicit and implicit Standards to protect the public from foodborne illness. The *accredited certification organization* shall provide a *food safety certification examination* that:

A. conforms to all CFP Standards for *Accreditation* of Food Protection Manager *Certification* Programs;

B. has been developed from secure *item bank* that is of the size and compositionto assemble tests that will support the intended use and interpretation of test scores, as well as the legal defensibility of test scores and for paper- or computer-based *linear examination forms*, the number of active items inany given content domain must be a minimum of three (3) times the number of items specified in the *examination blueprint*. For computer adaptive examination programs (*Computer Adaptive Testing*), the number of active items for each content domain mustbe a minimum of six (6) times the number of items specified in the *examination blueprint*.

Type of Form Assembly	**Scaling Factor of Bank vs. Blueprint**
Linear Examination Forms (paper or computer-based)	Minimum of 3 times the number listed in the blueprint
Computer Adaptive Testing	Minimum of 6 times the number listed in the blueprint

C. *Certification organizations* must have a policy that supports the monitoring and controlling of item exposure rates, use of an appropriate and defensible number of concurrent, equivalent *linear examination forms* (for print-based or computer-based), or an item bank of sufficient size and composition to support *computer adaptive testing*.

4.2 The certification organization must demonstrate to the accreditation agency the appropriateness of the policies, procedures, processes, and decisions regarding the following :

a. examination development, maintenance, and delivery;
b. certification decisions;
c. *examination materials* and data storage;
d. reporting;
e. resolution of complaints and appeals;
f. impartiality; and
g. examination security.

4.3 The *certification organization* shall provide complete information about the *food safety certification examination*, including information related to procedures and personnel involved in all aspects of the examination development and analysis. Actual or potential conflicts of interest that might influence judgment or performance of *Examination Developers* shall be disclosed. The information required for *accreditation* will include but is not necessarily limited to:

A. complete description of the scope and usage of the examination;
B. *job task analysis* list, with *knowledge, skills, and abilities(KSAs);*
C. *examination specifications*;
D. evidence that the number of active items in the *item bank* is (1) aligned with the weight specified in the *examination blueprint*, (2) appropriate for the format of the examination, with special consideration for *computer-adaptive testing*, and (3) meets the requirements of the item exposure plan;
E. statistical performance of each *item* in the bank;
F. number of *examination forms* and evidence of their *equivalence* to each other;
G. description of method used to set passing score;
H. copies of all logs, diaries, and personnel lists and descriptions kept as required in the development process;
I. appropriate summary statistics for each *examination ~~form~~*, regardless of assembly or delivery method; and
J. names, credentials, and *demographic* information for all persons involved in the *job task analysis*, *item* writing and review, and setting the passing score.

4.4 ***Job Task Analysis.*** A food safety certification examination shallbe based on a valid job task analysis. The job task analysis shall be developed by qualified individuals, including retail food industry and public health stakeholders and subject matter experts.

4.5 The job task analysis shall provide a complete description of the knowledge, skills, and abilities (KSAs) required to function competently in the occupation of Certified Food Protection Manager, with emphasis on those tasks most directly related to the Certified Food Protection Manager's role in the prevention of foodborne illness and controlling foodborne pathogens.

4.6 The *examination blueprint* shall be derived from a valid study of the *job task analysis. Examination specifications* deriving from the *exam blueprint* shall be publicly available.

4.7 The credential awarded upon passing a food safety certification examination is designed to be recognized nationwide and throughout the *retail food industry*. As such, the certification organization shall regularly evaluate practices in the *retail food industry* to ensure the job task analysis on which its examination is based remains appropriate and relevant. The maximum length of use for any *job task analysis* is five years fromthe date of validation.

4.8 ***Psychometric*** **Standards**. *Food safety certification examination* development, including setting the passing score, shall ~~be~~ follow the most recent edition of Standards for Educational and Psychological Testing, developed jointly by the American Psychological Association, American Educational Research Association and National Council for Measurement in Education, and on all appropriate Federal requirements (for example, Americans with Disabilities Act). *Food safety certification examinations* shall be revised as needed to comply with changes in the Standards for Educational and Psychological Testing or in any of the Federal requirements.

4.9 The *food safety certification examination* development procedures shall ensure that the *competencies* assessed in the *accredited certification program* are those required for *competent entry level performance* in the role of *Certified Food Protection Manager*, as defined by law and industry standards, and that they focus on factors related to the prevention of foodborne illness in the *retail food industry*.

4.10 The*certification organization* shall ensure relative equivalence and reliability across its various *examination forms* and administration methodologies (e.g., paper-pencil, CBT).

4.11 The *food safety certification examination* shall be developed to be as free from bias as possible. Certification organizations shall provide evidence that all examinations are evaluatedfor sensitivity and appropriateness with respect to a diverse population of examinees. .

4.12 When any *food safety certification examination* is translatedor adapted into another language, the *certification organization* shall demonstrate comparability between the source examination and the translated or adapted examination. The *certification organization* is responsible for defending its translation/*adaptation* processes to the accrediting organization. To avoid potential problems in translation of industry-specific terminology, the *certification organization* shall work in consultation with a food safety subject matter expert (SME) who is fluent in both the original language and the target language and who does not pose a conflict of interest or examination security risk.

4.13 *Examination Developers* shall maintain a log and diary of the procedures and a list ofthe qualifications, identities, and *demographic data* of the persons who participated in *item* development, examination development, translations, setting the passing score, and the statistical analyses of the examination *item*s and of the full examination. Those materials shall be provided to the *accrediting organization* on demand.

4.14 **Examination Development Security**. The certification organization will demonstrate that procedures are developed and implemented to ensure that individual items, item banks, food safety certification examinations presented in all media, test answer sheets and examinee scores are and remain secure. The *certification organization* is required to demonstrate how its examination security plan covers each step in the examination development, administration,scoring, and maintenance.

All examinations shall be delivered and administered in a format that ensures the security of the examination ~~(i.e., in a secured environment with a *test administrator/proctor*)~~. Un-proctored examinations are not acceptable regardless of the mode of administration.

4.15 Periodic Review. At least annually, each *certification organization* shall report tothe accrediting organization, providing a review of its *food safety certification examination(s)*.The report will include at minimum the following summary information for all examinations(for each examination used) administered during the preceding 12 months, as well as other information that may be reasonably requested by the *accrediting organization*.

A. number of *food safety certification examinations* administered;
B. mean, corresponding standard deviation, and range of candidate scores;
C. ~~A~~ measure of form-level reliability;
D. ~~A~~ measure of decision consistency;
E. p~~P~~assing rates (both number and percentage of examinees that passed the examinationin the given 12-month period); and
F. s~~S~~ummary statistics for all items used during the preceding 12-month period, which may be presented using classical test theory, item response theory, or similar models.
G. For the purposes of clarity and identifying data trends, annual summary information may need to be presented in concise reports, such as semi-annual or quarterly, to the *accrediting organization.*

4.16 Requirements for Examination Standardization. *Certification organizations* shall specify conditions and procedures for administering all *food safety certification examinations* in a standardized manner to provide examinees with a fair andequitable opportunity to demonstrate competency.

SECTION 5 – FOOD SAFETY CERTIFICATION EXAMINATION ADMINISTRATION

5.0 ***Food Safety Certification Examination*** **Administration.** All sections of the~~se~~ Standard~~s~~ apply to *Computer Based Testing (CBT)* Administration except Section<u>s</u> 5.1, and 5.4B. All sections of these Standards apply to *remote proctoring* except Sections 5.4B, 5.11B, 5.13 C & D.

5.1 **Security for *Examination Materials.***

A. Policies and procedures shall be developed and documented by the *certification organization* to ensure the security of *examination materials*. At a minimum, security provisions shall address:
   1) t~~T~~he type of test materials (i.e<u>.,</u> electronic or paper);
   2) t~~T~~he locations of the test materials (i.e., transportation, electronic delivery, disposal,storage, examination center (when applicable));
   3) t~~T~~he steps in the examination process (e.g.<u>,</u> development, administration, results reporting);
   4) t~~T~~he threats arising from repeated use of examination materials<u>.</u>

B. Packaging by c*ertification organization.*
   1) Each individual examination booklet shall be securely sealed before packing.
   2) Secure tamper-resistant shipping material, such as Tyvek envelopes or similar materials that are designed to reveal any tampering or violation of the package's security, is required for all shipment of materials in all phases.
   3) Packaging must include a packing list that contains:
      a. *examination form* language(s) or version(s) enclosed; and
      b. quantity of examinations enclosed.

C. Shipping to the *test administrator/proctor* from the c*ertification organization.*
   1) Shipping shall be done by certifiable, traceable means, with tracking numbers so that the location can be determined at any given time.
   2) A signature is required upon delivery.
   3) Only an individual authorized by the *test administrator/proctor* may sign for the package.

D. Storage by *test administrator/proctor.*
   The package(s) of examination booklets shall be secured at all times immediately upon delivery. Under no circumstances may examination booklets, *examinee* used answer sheets, or other examination materials be kept where other employees or the public ~~has~~ <u>have</u> access.

E. Shipping to the *certification organization* from the *test administrator/proctor*<u>.</u>
   1) After examination administration, examination booklets and answer sheets shall remain in secure storage until returned to c*ertification organization.*
   2) The following shall be in tamper-resistant shipping material:

a. all used and unused examination booklets for each examination administration;
b. *examinees'* used answer sheets; and
c. all required c*ertification organization* forms.

3) Shipping shall be done within two business days following the examination date by certifiable, traceable means, with tracking numbers so that the location can be determined at any given time.

F. Handling unused examination booklets that have been held for up to ninety days. The *test administrator/proctor* will:
1) ensure that all examination booklets are accounted for;
2) package examination booklets securely as described above; and
3) ship to the certification organization securely packaged and according to these *Standards* and the *Certification Organization*'s instructions.

5.2 Test Site Requirements.

Sites chosen for administering *food safety certification examination*s shall conform to all legal requirements for safety, health, and accessibility for all *examinees*.

A. ~~Additionally, the~~ Aaccommodations, lighting, space, comfort, and workspace for takingthe examination shall reasonably allow *examinees* to perform at their highest level of ability.

B. Requirements at each test site include, but are not limited to:
1) reasonable accommodation requests, in accordance with the requirements of the Americans with Disabilities Act, shall be fulfilled for *examinees*;
2) conformity to all fire safety and occupancy requirements of the jurisdiction in which they are located;
3) sufficient spacing between each *examinee* in the area in which the actual examination is conducted, or other appropriate and effective methods, to preclude any *examinee* from viewing another *examinee's* examination;
4) acoustics allowing each *examinee* to hear instructions clearly, using an electronic audio system if necessary;
5) lighting at each *examinee's* workspace adequate for reading;
6) ventilation and temperature appropriate for generally recognized health and comfort of *examinees*;
7) use of private room(s) where only examination personnel and *examinees* are allowed access during the examination administration; and
8) no further admittance into the test site once examination administration has begun.

5.3 Test Site Language Translation.

A *certification organization* shall have a published, written policy regarding test site language translation of *food safety certification examinations*. If a *certification organization* allows test site language translation of a *food safety certification examination* when an *examination version* is not available in the *examinees'* requested language, the *certification organization* shall have a published, formal application process available to all *potential examinees*. Procedures shall include but not be limited to:

A. An application process for *potential examinees* that includes an evaluation and documentation component to determine the eligibility of the *potential examinee* for test site language translation.,

B. An application process for translators that includes clear and precise qualifications that shall include but not be limited to the following:
   1) being fluent in both languages;
   2) have a recognized skill in language translation;
   3) trained in the principles of objective examination administration;
   4) have no personal relationship with the *examinee* (may not be another *examinee*, may not be a relative or friend of the *examinee* and may not be a co-worker, employer, or an employee of the *examinee*);
   5) not having any vested interest in Food Protection Manager *certification* or conflict of interest;
   6) provide references or other proof attesting to the translator's competencies and professional acumen; and
   7) agree in writing to maintain the security of the examination.

C. A proctored environment where the translator and *examinee* are not a distraction to other *examinees*, and

D. A proctored environment where the translator is not active as the *test administrator*/*proctor*.

5.4 Scoring.

A. Only the *certification organization* may score the examination by nationally accepted scoring methods ~~approvedby the *accrediting organization*~~. No official scoring is to be done at the test site for paper-pencil based examinations.

B. *Food safety certification examination* scores for paper-pencil based examinations will not be released as ~~being~~ official untilverified and approved by the c*ertification organization*.

C. *Examinee* scores will be confidential, available only to the *examinee,* the Certification Organization, the Accrediting Organization, and to persons or organizations approved in writing by the *examinee*.

D. Score reports will be available to *examinees* in a time frame specified in the application, which will not exceed fifteen business days following the administration of the *food safety certification examination*. If there is a delay due to problems in verification or authentication of scores, *examinees and the test administrator/proctor* will be so informed and an approximate date for release of the scores will be announced.

5.5 *Test Administrator/Proctor(s)* Role. *Test administrators/proctors* shall have successfully completed the *certification organization's* specific training in examination administration and security procedures. They shall provide written assurance of maintaining confidentiality of examination contents, of adhering to the *certification organization's*

standards and ethics of secure examination administration, and of agreeing to abide by the *certification organization's* policies, procedures, and rules.

5.6 ***Test Administrator/Proctor*** **Roles and Requirements.** To serve as a *test administrator/proctor* for an accredited *certification organization* the qualified individual shall complete the *certification organization's*:

A. signed Application;

B. Nnon-Disclosure Agreement (NDA);

C. training program for *test administrators/proctors;* and

D. Ceonflict of Interest Disclosure Agreement (can be a part of the NDA).

5.7 ***Test Administrator/Proctor*** **Renewal.** *Test administrators/proctors* shall renew the training program for *test administrators/proctors* and Non-Disclosure Agreement with the *certification organization* a minimum of every three (3) years.

5.8 ***Instructor*** **as** ***Test Administrator/Proctor*****.**
When a person acts as *an instructor* and a *test administrator/proctor*, thatperson relinquishes the role of *instructor* when acting in the role of *test administrator/proctor.*

5.9 ***Test Administrator/Proctor*** **Responsibilities.**
Test Administrators/proctors shall utilize documented procedures provided by the certification body to ensure a consistent examination administration. These include, but are not limited to:

A. Schedule examinations. *Food safety certification examination*s shall be scheduled far enough in advance to allow for timely shipment of supplies or pre-registration for computer-based examinations.

B. The *certification organization's* criteria for conditions for administering examinations shall be followed. Conditions can include, but are not limited to: lighting, temperature, separation of candidates, noise, candidate verification and safety, *test administrator/proctor* conduct and *examination materials* security throughout examination process, etc.

C. Report possible security breaches and examination administration irregularities in compliance with the *certification organization's* policies.

5.10 The number of approved *proctors* assigned to a *test administrator* shall be sufficient to allow each *examinee* to be observed and supervised to ensure conformance to security requirements. The *certification organization* shall develop and justify to the *accrediting organization,* through documented policies, the ratio of test administrator/proctor to

examinees.

5.11 Examination Security.

A. All aspects of *food safety certification examination* administration are to be conducted in a manner that maximizes the security of the examinations, in keeping with the public protection mandate of the CFP. This shall be accomplished in a manner that ensures fairness to all *examinees*.

B. For test site/testing center administered examinations, a~~A~~ll *examinees* shall begin taking the examination at the same time. No *examinee* shall be admitted into the test site/testing center once examination administration has begun.

C. Where reasonable accommodation~~s is~~ are provided for *ex~~x~~aminees* under provisions of the Americans with Disabilities Act, care shall be takento ensure that security of the examination is maintained. Individuals assisting in providing accommodation (Assistants) shall disclose in writing any actual or potentialconflict of interest prior to assisting in any exam administration. The *certification organization* shall address any identified conflicts of interest and maintain a signed nondisclosure agreement with Assistants.

5.12 The *certification organization* shall provide procedures to be followed in any instance where the security of a *food safety certification examination* is, or is suspected to be, breached.

A. Included shall be, at a minimum, specific procedures for handling and for reporting to the *certification organization*, any suspected or alleged:
   1) cheating incidents;
   2) lost or stolen examination materials~~;~~
   3) intentional or unintentional divulging of examination *item*s by *examinees* or examination administration personnel; or
   4) any other incidents perceived to have damaged the security of the examination or any of its individual *item*s.

B. Corrective actions to guard against future security breaches shall be established and implemented.

C. Documentation of corrective actions and their effectiveness shall be made available to the *accrediting organization*.

5.13 *Item* and Examination Exposure.

The *certification organization* shall have an *exposure plan* that:

A. controls for *item* and examination exposure;

B. accounts for the number of times an *examination item*, *examination form,* and

examination version is administered;

C. ensures that no *examination form* is retained by any *examination administration* personnel for more than ninety days;

D. at all times accounts for all copies of all used and unused examination booklets; and

E. systematically and actively demonstrates that every used answer sheet, examination booklet, and any other examination materials and answer keys are accounted for to prevent, reduce, or eliminate examination exposure.

5.14 ***Certification Organization's*** **Responsibility to** ***Test Administrators/Proctors.***

A. The *certification organizations* shall specify the responsibilities of *test administrator/proctor*, set minimum criteria for approval of *test administrators*/ *proctors*, and provide a training program to enable *potential examinees* to meet the approval criteria. Responsibilities, duties, qualifications and training of *test administrators*/*proctors* shall be directed toward assuring standardized, secure examination administration and fair and equitable treatment of *examinees*.

B. The *certification organization* shall define and provide descriptions for the roles of *test administrators/proctors* clearly indicating theresponsibilities for these roles. The *certification organization* shall demonstrate how itensures *administrators/proctors* understand and practice the procedures identified for their roles.

C. *Test administrator/proctor* training programs shall include:
   1) specific learning objectives for all activities of *test administrator/proctor*; and
   2) an assessment component that shall be passed before an *applicant* for *test administrator/proctor* will be approved.

5.15 ***Certification Organization*** **Test Administrator/Proctor Agreements.** The *certification organization* shall enter into a formal agreement with the *test administrator/proctor*. The formal agreement shall at a minimum address:

A. provisions that relate to code of conduct;

B. conflicts of interest; and

C. consequences for breach of the agreement.

5.16 The *certification organization* shall assess and monitor the performance of *test administrators/proctors* in accordance with all documented procedures and agreements.

5.17 The *certification organization* is not permitted to hire, contract with, or use the services of any person or organization that claims directly or indirectly to guarantee passing any certification examination. *Instructors* making such a claim, whether independently or as an employee of another organization making the claim, are not eligible to serve as *test administrators/proctors* for any *certification organization.*

5.18 Policies and procedures for taking corrective action(s) when any *test administrator* or *proctor* fails to meet job responsibilities shall be implemented and documented. *Test administrators/proctors* that have been dismissed by the *certification organization* for infraction of policies or rules, incompetence, ethical breaches, or compromise of examination security will be reported to the *accrediting organization*.

5.19 Examination Administration Manual.
The *certification organization* shall provide each *test administrator/proctor* with a manual detailing the requirements for all aspects of the *food safety certification examination* administration process. The Examination Administration Manual shall include a standardized script for the paper examination *test administrator/proctor* to read to *examinees* before the examination commences. For computer-based tests (CBT), standardized instructions shall be available for *examinees* to read.

5.20 Examination Scripts. Separate scripts/instructions may be created for different delivery channels or *certification organizations*. *Certification organizations* may customize elements of the scripts to fit their particular processes, but each script shall contain the following:

A. Introduction to the Examination Process
   1) composition of the examination (number of questions, multiple choice, etc.);
   2) time available to complete the examination;
   3) role of the *test administrator/proctor*;
   4) process for restroom breaks; and
   5) process for responding to *examinee* comments and questions.

B. Copyright and Legal Responsibilities
   1) ~~(spacing)~~description of what constitutes cheating on the examination;
   2) penalties for cheating; and
   3) penalties for copyright violations.

C. Examination Process
   1) maintaining test site security;
   2) description of examination components unique to the *certification organization* (examination booklet, answer sheet completion, computer process in testing centers, etc.);
   3) instructions for proper completion of personal information on answer sheets/online registration and examination booklets;
   4) instructions on properly recording answers on answer sheets or online; and
   5) instructions on post-examination administration process.

SECTION 6.0 – COMPUTER-BASED TESTING (CBT)

6.0 **Computer-Based Test Development and Administration** All sections of the~~se~~ Standards apply to *Computer Based Testing* (CBT) Administration except Section 5.1.

6.1 **Computer-Based Test Development.** *Examination specifications* for *computer-based testing* shall describe the method for development, including the *algorithm*s used for test *item* selection, the *item* response theory model employed (if any), and examination *equivalency* issues.

6.2 *Item*s shall be evaluated for suitability for computer delivery, be reviewed in the delivery medium, and be reviewed in the presentation delivery medium. Assumptions shall not be made that *item*s written for delivery via a paper/pencil medium are suitable for computer delivery nor should it be assumed that computer test *item*s are suitable for paper/pencil delivery.

6.3 When *examination forms* are computer-generated, whether in *Computer-Adaptive Testing* (CAT) or in a simple linear *algorithm*, the *algorithm* for *item* selection and the number of *item*s in the *item bank* from which the examination is generated shall ensure that the *item*s are protected from *overexposure*. *Item* usage statistics shall be provided for all available *item*s in the pool.

6.4 ***Computer-Based Testing*** **Administration.** ~~Where examination environments differ (for example, touch screen versus mouse) evidence shall be provided to demonstrate equivalence of the *examinee*s' scores.~~The Computer-Based Test designer shall be accountable to assure that the visual representation of the exam questions, the answers, and the directions is clear and generally easy to interpret, allowing the examinee optimal chance to accurately select their desired response to the exam questions.

6.5 Tutorials and/or practice tests shall be created to provide the *examinees* adequate opportunity to demonstrate familiarity and comfort with the computer test environment.

6.6 If the time available for computer delivery of an examination is limited, comparability of scoring outcomes with non-timed delivery of the exam shall be demonstrated. Data shall be gathered and continually analyzed to determine if scoring methods are comparable.

6.7 Evidence of security in the *computer-based testing* environment shall be provided. Factors affecting test security include, but are not limited to, *examinee* workspace, access to personal materials, level of *examinee* monitoring, and *test encryption and decoding*.

6.8 Documentation of precautions to protect *examination forms* and the *item bank* from unauthorized access shall be provided. (Spacing issue with 6.9)

6.9 Policies and procedures regarding the recording and retention of the *item sequence* and *item* responses for each *examinee* shall be developed and followed. Computer examinations using a unique sequence of *item*s for each *examinee* shall record the information necessary to recreate the sequence of *item*s and *examinee* responses on the

computer examination.

6.10 Systems and procedures shall be in place to address technical or operational problems in examination administration. For example, the examination delivery system shall have the capability to recover *examinee* data at the appropriate point in the testing session prior to test disruption. Policies regarding recovery for emergency situations (such as retesting) shall be developed.

6.11 **Due Process.** *Examinees* shall be provided with any information relevant to *computer-based testing* that may affect their performance or score. Examples of such information might include but not be limited to: time available to respond to *item*s; ability to change responses; and instructions relating to specific types of *item*s.

SECTION 7.0 – CERTIFICATION ORGANIZATION RESPONSIBILITIES TO *POTENTIAL EXAMINEES, EXAMINEES* AND THE PUBLIC

7.0 A *certification organization's* Responsibilities to *Examinees* and the Public.

7.1 Responsibilities to *Potential Examinees* and/or *Examinees* for *Certification*. A *certification organization* shall develop and implement policies, which address the following:

A. an overview to *exam candidates* of the process by which one obtains *certification*;

B. ~~a~~ notice to *exam candidates* of non-discrimination.

C. protocols for the periodic review of examination policies and procedures to ensure fairness;

D. procedures for uniform~~ly~~ and prompt reporting of *food safety certification examination* results to *examinees*;

E. procedures for providing *examinees* failing the *food safety certification examination* with information on general areas of deficiency;

F. protocols that assure the confidentiality of each *examinee's food safety certification examination* results; and

G. appeals procedures– for– *exam*– *candidates* regarding any part of the *accredited certification program*.

7.2 Qualifications for Initial *Certification*. To become a *Certified Food Protection Manager* an individual shall pass a *food safety certification examination* from an *accredited certification program* recognized by the CFP. The *certificate* shall be valid for no more than five years.

~~(space)~~

7.3 *Individual Certification* C*ertificates:*

A. Each *certification organization* will maintain a secure system with appropriate backup or redundancy to verify validity of individual *certification certificates*.

B. *Certificates* shall include, at a minimum:
   1) issue date/date examination was taken;
   2) length of time of *certification* validity;
   3) name and *certification* mark of *certification organization;*
   4) *accrediting organization* mark;
   5) name of certified individual;
   6) unique *certificate* number;

7) name of *certification*;
8) contact information for the *certification organization*; and
9) examination form identifier.

C. Replacement or duplicate *certificates* issued through an *accredited certification organization* shall carry the same issue date, or date of examination, as the original *certificate*, and will be documented by the *certification organization*.

7.4 **Discipline of *Certificate* Holders and *Examinees*.** A *certification organization* shall have formal *certification* policies and operating procedures including the sanction or revocation of the *certificate*. These procedures shall incorporate due process.

7.5 ***Continued Proficiency*.** An *accredited certification program* shall include a process or program for assessing continued competence that includes an examination component at an interval of no more than five years. The outcome of the process or program shall demonstrate that the person has maintained the minimum competencies as determined by the job task analysis.

7.6 **Responsibilities to the Public and to Employers of Certified Personnel.** ~~-~~ A *certification organization* shall maintain a registry of ~~individuals~~ certified individuals. Any title, credential, or certificate awarded by the certification organization shall be relevant to the retail food industry and role of Food Protection Manager and not designed to mislead or intentionally confuse *examinees* and other stakeholders.

7.7 **Complaints and Appeals.** Each *certification organization* shall have a published procedure addressing complaints and appeals. Such procedures shall include a stated timeframe for response from the *certification organization*. (spacing issue)

7.8 **Misrepresentation.** Only *certification organizations* that conform to all requirements of the Standard and are *accredited* by the agent selected by the CFP as the *accrediting organization* for such programs are allowed to refer to themselves as being *accredited*. Those programs may not make any other reference to the CFP in their publications or promotional materials in any medium.

SECTION 8.0 – CERTIFICATION ORGANIZATION RESPONSIBILITIES TO THE ACCREDITING ORGANIZATION

8.0 *Certification Organization* Responsibilities to the *Accrediting Organization*.

8.1 Application for *Accreditation*. *A certification organization* seeking *accreditation* for development and/or administration of a *certification* program shall provide at least the following information, as well as other information that might be requested by the *accrediting organization:*

A. the name and complete ownership structure of the *legal entity*;~~.~~

B. the address, telephone/fax number(s) and other contact information of the *certification organization's* headquarters;~~.~~

C. the name, position, address, and telephone/fax/e-mail information of the contact personfor projects related to the CFP Standards for *Accreditation* of Food Protection Manager*Certification* Programs;~~.~~

D. such fiscal information as may be needed to establish evidence of ability to carry out obligations under the~~se~~ Standard~~s~~.

8.2 Summary Information. A *certification organization* shall:

A. provide evidence that the mechanism used to evaluate individual competence is objective, fair, and based on the knowledge and skills needed to function as a *Certified Food Protection Manager* to the extent possible;

~~B.~~ provide evidence that the evaluation mechanism, ~~is based on standards which establish *reliability* and *validity* for each form of the *food safety certification examination*~~ measures to the extent possible:

1. Reliability
2. Intended interpretation
3. Use of test scores

C. provide evidence that the pass/fail levels are established in a manner that is generally accepted in the *psychometric* community ;

D. have a formal policy of periodic review of evaluation mechanisms and shall provide evidence that the policy is implemented to ensure relevance of the mechanism to knowledge and skills needed by a *Certified Food Protection Manager*;

E. provide evidence that appropriate measures are taken to protect the security of all *food safety certification examination*s;

F. publish a comprehensive summary or outline of the information, knowledge, or functions covered by the *food safety certification examination*;

G. make available general descriptive materials on the procedures used in examination construction and validation and the procedures of administration and reporting of results; and

H. compile at least annually a summary of *certification* activities, including numberof *examinees*, number tested, number passing, number failing, and number certified.

8.3 Responsibilities to the *Accrediting Organization*. The *certification organization* shall:

A. make available upon request to the *accrediting organization* copies of all publications related to the *certification* program;~~,~~

B. notify the *accrediting organization* of any proposed changes in structure or activities of the *certification organization*;~~,~~

C. advise the *accrediting organization* of substantive change in *food safety certification examination* administration;~~,~~

D. advise the *accrediting organization* of any major changes in testing techniques or in the scope or objectives of the *food safety certification examination*;~~,~~

E. annually complete and submit to the *accrediting organization* information requested on the current status of the Food Protection Manager *Certification* Program and the *certification organization*;~~,~~

F. submit to the *accrediting organization* the report requirements information specified for the Food Protection Manager *Certification* Program;~~,~~ and

G. be re-accredited by the *accrediting organization* at least every five years.

SECTION 9.0 – MANAGEMENT SYSTEMS

9.0 Management Systems.

9.1. Each c*ertification* o*rganization* shall have a formal management system in place to facilitate continuous quality improvement and produce preventive and corrective actions. The management system shall contain the following three components.

A. Document control to include:
   1) lists of all documents pertaining to the *certification organization*;
   2) dates for documents approved for implementation by the *certification organization*;
   3) the person(s) within the *certification organization* responsible for the documents; and
   4) listing of individuals who have access to the documents.

B. Internal audits to include:
   1) identification of critical activities;
   2) data collection process and evaluation schedule;
   3) audit methodology and evaluation process;
   4) the person(s) authorized to perform audits; and
   5) report audit findings and identify corrective action required.

C. ~~A~~ Management Review that includes:
   1) a documented annual review of internal audit results;
   2) a management group that conducts the review;
   3) a review of the audit results to determine corrective actions needed;
   4) a review of the audit results to determine preventive actions needed; and
   5) the effectiveness of corrective and preventive actions taken.

ANNEX A

Conference for Food Protection

Conference for Food Protection Requirements for Certification Organizations to Provide Food Protection Manager Certifications using the ISO/IEC 17024 Personnel Certification Standard

The requirements described in this document shall be applied in conjunction with the ISO/IEC 17024 standard(International Organization for Standardization/ International Electrotechnical Commission). All clauses of ISO/IEC 17024 standard continue to apply. This document provides supporting criteria to that standard for certification bodies that want to be recognized by the CFP.

SECTION 1.0 – CONFERENCE FOR FOOD PROTECTION ACCEPTANCE OF ISO/IEC 17024 ACCREDITED PROGRAMS

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document(including any amendments) applies. A) ISO/IEC 17024 Standard, B) FDA Food Code.

A1.0 Conference for Food Protection acceptance of *ISO/IEC 17024* accredited Food Protection Manager Certification programs.

A1.1 Wherein, the Conference for Food Protection ("CFP") maintains the *Standards for Accreditation of Food Protection Manager Certification Programs* ("CFP Standard");

A1.2 And, the CFP recognizes *ISO/IEC 17024, Conformity assessment – General requirements for bodies operating certification of persons* ("ISO/IEC 17024 Standard") as an alternative personnelcertification standard to the CFP Standard;

A1.3 And, that the recognition of ISO/IEC 17024 Standard does not impact the CFP Standard;

A1.4 And, that the CFP recognizes that certification organizations accredited under either the CFP Standard or ISO/IEC 17024 Standard may offer Food Protection Manager Certifications;

A1.5 So long as organizations seeking accreditation to provide Food Protection Manager Certifications using the ISO/IEC 17024 Standard abide by the requirements listed herein.

SECTION 2.0 – DEFINITIONS

A2.0 Definitions

A2.1 For definitions, please refer to *FDA Food Code, section 1-201.10*.

SECTION 3.0 – SCHEME

A3.0 Scheme

A3.1 **Purpose**. The Purpose of the ISO 17024 Standard, as it relates to the CFP Food Protection Manager Certification is to ensure that:

> "…the competencies assessed in the accredited certification program are those required for competent entry level performance in the role of Certified Food Protection Manager, as defined by (United States) law and industry standards, and that they focus on factors related to the prevention of foodborne illness in the retail food industry," (CFP Standard Section 4.10).

A3.2 A food protection manager as addressed in *FDA Food Code, section 2-102.12* and *FDA Food Code, section 2-102.20*.

A3.3 A Certified Food Protection Manager may work in a "food establishment" as defined in *FDA Food Code, section 1-201.10*.

A3.4 **Scope.** The Food Protection Manager Certification is based on the *FDA Food Code*. Certification organizations must update their programs to the latest *FDA Food Code* version within five (5) years of its release.

A3.5 **Geographic Limitations.**

- **A.** The scope of this personnel certification is based on the United States FDA Food Code; therefore, it is inherently for individuals working in the United States or those who utilize itsFDA Food Code;
- **B.** So long as an applicant outside of the United States is certified through an accredited program adhering to the requirements set forth in this document, the CFP recognizes that certification as a Food Protection Manager Certification.

A3.6 **Job Task Analysis.** Certification organizations must complete a job task analysis using the requirements defined in CFP Standard, section 4.4-4.76.

SECTION 4.0 – PRE-REQUISITES

A4.0 Pre-requisites

A4.1 There are no training or other pre-requisites for Food Protection Manager Certification candidates.

SECTION 5.0 – TRANSLATOR/TRANSLATION REQUIREMENTS

A5.0 Translator/Translation Requirements

A5.1 **Application Process.** In the event a personnel certificate candidate requires an onsite translator, the application process for translators must include clear and precise qualifications for those translators.

A5.2 **Test Site Language Translation.** Certification organizations must follow the requirements set forth in CFP STANDARD, section 5.3.

SECTION 6.0 – REPRESENTATION

A6.0 Representation

A6.1 **Certificates.** All certificates delivered upon the successful passing of a certification exam accredited under the ISO 17024 Standard must include the Conference for Food Protection logo and the ANSI accreditation mark.

SECTION 7.0 – DOCUMENT REFERENCES

A7.0 The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies:

A. FDA Food Code.

B. CFP Standard

C. ISO 17024.

ANNEX B

Guidelines for Regulatory Authorities Implementing Food Protection Manager Certification Programs

B1. Each permitted *food establishment* should have a minimum of one designated *Certified Food Protection Manager* who is accountable for food safety.

Documentation of *certification* of *Certified Food Protection Manager*(s) should be maintained at each *food establishment* and shall be made available for inspection by the *regulatory authority* at all times.

B2. A *Certified Food Protection Manager* is responsible for:

1) identifying hazards in the day-to-day operation of a *food establishment*;

2) developing or implementing specific policies, procedures or standards aimed at preventing foodborne illness;

3). coordinating training, supervising or directing food preparation activities and taking corrective action as needed to protect the health of the consumer; and

4) conducting in-house self-inspection of daily operations on a periodic basis to see that policies and procedures concerning food safety are being followed.

B3. **Qualifications for *Certification*.** To become a *Certified Food Protection Manager*, an individual shall pass a *food safety certification examination* from an accredited *certification organization* recognized by the CFP. The CFP recognizes the importance and need for the provision of food safety training for all food employees and managers. The CFP recommends the content of food protection manager training be consistent with paragraph 2-102.11 (C) of the most recent FDA Food Code. The CFP promotes the information contained in the FDA Food Code as well as content outlines based on job tasks analyses, provided on the CFP website, which may be of value in developing or evaluating training.

B4. Regulatory authorities should work with the *certification organization* on a mutually agreeable format, medium and time frame for the submission of score reports pertaining to the administration of *food safety certification examinations*.

FOOD PROTECTION CERTIFICATION COMMITTEE
Minutes of the Meeting | December 1, 2021 | 2-4 PM eastern

Attendance ~~strikethrough~~ indicates absence

Chairs/Voting: Chair Quam, Vice Chair Daniel, ~~Allen~~, Anderson, Burns Savage, Chapman, Ciarimboli, Corchado Torres, ~~Derr~~, ~~Dolhanyk~~, ~~Dunleavy~~, Dwyer, Eastwood, Halbrook, Hawley, Huffman, Jackson, Koester, Luebkemann, Paster Cammarata, Piche, Reich, Roughan, Smith, Straughn, Sweet, Wiedmeyer, Wilson, Woods, Wynne [25 voting members present]

Non-voting: Morris, ~~Albrecht~~, Baker, Conley, Duggins, Gillam, Johnson, Krishna, ~~Morrison~~, ~~Pollock~~, Rivas, Unkart, Williams, Wittry

Interested Parties & Guests:

Agenda Items

1. Welcome & Introduction of Committee Members
2. CFP Anti-trust Statement
3. Committee orientation - powerpoint deck
4. Committee administration and constituencies
   a. Standing committee, reports to Executive Board
   b. Purpose of Committee
   c. 6 constituencies: academic, certification, consumer/Independent, industry (food service, retail), regulatory (local, state, federal), training providers
   d. Roles of Chair (non-voting), Vice-chair (voting), 30 voting members, alternates
   e. Advisors/consultants, non-voting: ACAC, ANSI, FDA/USDA, psychometrician
   f. Meeting procedures
   g. Voting procedures
5. Election of New Committee Chair
6. Committee Bylaws
7. Food Protection Manager Certification Standards
8. Charges from CFP
9. Formation of Workgroups (Standards, Bylaws)
10. Meeting Schedule: Next Meeting – 2/2/22, 2-4:00 pm (eastern)

Minutes

Items 1-4: Acting Chair Jeff Hawley convened the meeting in "virtual" format at 2 PM eastern, and explained he would be Acting Chair as a result of Sharon Wood's retirment, only until elections occur later in the meeting. The anti-trust statement was read, attendance was recorded, and a quorum established. Chair Hawley then presented committee orientation and administration information.

Allen Reich inquired as to whether members would receive any background information on committee issue II-004 "Limit CPFM accredited exam certificate validity to four years," submitted by Lars Johnson. Chair Hawley advised that at the appropriate time the submitter would be recognized to explain the issue.

Item 5: Chair Hawley called for Chair and Vice Chair nominations. Luebkemann and Huffman nominated Susan Quam for Chair, and Justin Daniel for Vice Chair for the remainder of the 2021-23 biennium. No additional nominations were advanced.

Motion
Luebkemann moved and Huffman seconded that: Susan Quam be elected Chair and Justin Daniel be elected Vice Chair for the remainder of the biennium. Motion carried with unanimous consent.

Susan Quam assumed the Chair and presided over the remainder of the meeting.

Item 6-9:
Chair Quam summarized the work the committee would undertake, and called for establishment of and volunteers for two workgroups to perform routinely-charged maintentance: FPMCC Bylaws - Jeff Hawley, Chair; and Food Protection Manager Certification Standards ("Standards") - Kate Piche, Chair.

Item 10:
Chair Quam reminded members FPMCC meetings are currently set to recur every other month on the first Wednesday, with the following 2022 dates scheduled: Feb. 2, Apr. 4, Jun. 1, Aug. 3, Oct. 5, Dec. 7.

Next meeting will convene virtually on Feb. 2, 2022, 2-4 PM eastern.

Motion
Corchado Torres moved and Dwyer seconded adjournment. Motion carried with unanimous consent.

Meeting adjourned at 3:37 PM eastern.

FOOD PROTECTION CERTIFICATION COMMITTEE
Minutes of the Meeting | February 2, 2022 | 2-4 PM eastern

Attendance ~~strikethrough~~ indicates absence

Chairs/Voting: Chair Quam, Vice Chair Daniel, ~~Allen~~, Anderson, Burns Savage, Chapman, Ciarimboli, Corchado Torres, ~~Derr~~, ~~Dolhanyk~~, ~~Dunleavy~~, Dwyer, Eastwood, Halbrook, Hawley, Huffman, ~~Jackson~~, Koester, Luebkemann, Paster Cammarata, Piche, Reich, Roughan, Smith, Straughn, Sweet, Wiedmeyer, Wilson, Woods, Wynne [25 voting members present]

Non-voting: Morris, ~~Albrecht~~, Baker, Conley, Duggins, Gillam, Johnson, Krishna, ~~Morrison~~, Pollock, Rivas, Unkart, Williams, ~~Wittry~~

Interested Parties & Guests:

Agenda Items

1. Welcome & Introduction of Committee Members, Attendance
2. CFP Anti-trust Statement
3. Formation of Workgroups - Standards, Bylaws
4. Overview of discussion format: speaker recognition, voting
5. Issue 2020 II-004
   a. Issue Background – Lars Johnson, issue submitter
   b. Identify impacts and feasibility questions
      - to facilitate future discussion, the committee will develop a "10,000-foot level" list of impacts and feasibility to be further discussed at the April meeting
      - committee leadership will organize the list for deeper discussion beginning in April
6. Meeting Schedule: next meeting April 6, 2022, 2-4 PM eastern

   FPMCC meetings recur every even month on the first Wednesday, 2-4 PM eastern
   Meeting Zoom link: https://us02web.zoom.us/j/87071250980
   Meeting ID: 870 7125 0980
   One tap mobile: +13126266799,,87071250980# US (Chicago)
   +16468769923,,87071250980# US (New York)

Quam Notes for Discussion of Issue II-004 4-Year Exam Validity / Areas of impact and feasibility

- Time lapse between CFP/FDA/Code publication
  - Test provider impact – what is the date of implementation
- Will the change reduce the number of risk factor violations – is there studies behind it
- Providers are already able to have shorter time period, with five as the max
- Is it legally justifiable
- Impact on update timelines and justification for changes and taking different methodologies into consideration
- Impact on the CFP Standard
- What is the frequency of the JTA? Some may already be less than 5 years
- Does existing work done by providers already capture and address the issue
- Financial impact – shorter timeline increases frequency
- E.g. Rhode Island operated on 3 year basis – do they have data on impact of more frequency - change in seat time requirements. Utah has 3 year frequency as well
- Need for research to justify change
- How does this impact time lines outlined in state statute and local ordinance

- Timing of exam vs timing of FC release
- Practical day to day knowledge vs no hands on experience
- Is this aligning with FC or is this justifiable as a way to improve food safety
- How many jurisdictions have times other than 5 years
- 2017 FC update to have CFPM on duty at all times, already impacts industry, will this requirement make it greater
- Different ways to "recertify" other than by exam. Is there a bigger issue to address relating to best ways to recertify
- Pandemic related delays to recertification
- Why was 5 years chosen in the first place
- Financial impact on industry

Minutes

Items 1-2: Chair Susan Quam convened the meeting in "virtual" format at 2 PM eastern, the anti-trust statement was referenced, attendance was recorded, and a quorum established.

Items 3: Chair Quam then called for volunteers for the Standards and Bylaws workgroups and the following groups were formed:

Standards, Chair Kate Piche - Allen Reich, April Rivas, Lars Johnson, Laura Koester, Laurie Williams, Lindy Wiedmeyer, Liz Corchado Torres, Nikki Burns Savage, Sean Dunleavey, Sharon Unkart, Tara Dwyer, Yolanda Woods

Bylaws, Chair Jeff Hawley - Bryan Chapman, Evelin Pollock, Justin Daniels, Laurie Williams, Nick Eastwood, Tara Paster Cammarata, Troy Huffman

Item 4: Chair Quam explained how discussion and voting would proceed in context of the virtual meeting format.

Item 5: Chair Quam introduced charged issue 2020 II-004, "Limit CPFM accredited exam certificate validity to four years," and Lars Johnson, the issue submitter. Mr. Johnson was recognized and stated objectives of the issue include: alignment of the CFPM certificate with the Food Code publication cycle; reduce the number of people that could miss a Food Code update without need to be recertified; improve manager knowledge at "little to no cost" to certificate holders.

Chair Quam then called for committee input on impacts and feasibility, with these responses:

- Williams asked if Johnson considered two-year supplemental Food Code updates, which can be significant
- Johnson stated a change to 4-year certification would capture all changes in a cycle
- Anderson asked if Johnson considered increased costs to exam providers; Johnson stated he did not
- Corchado Torres asked what the required response time is for FDA to act on CFP Biennial Meeting recommendations; Williams responded CFP has 45 days to transmit recommendations after the Biennial meeting, then FDA has 60 days to respond
- Corchado Torres asked about implementation time for certifying organizations to incorporate FDA's changes to Food Code; Huffman stated the issue proposed has no effect on exam content updates
- Huffman asked if there is any available science on the impact to food safety risk in changing from a 5-year to a 4-year credential expiration; Johnson stated there to be a dearth of data in this regard
- Chapman stated the certifying organizations must justify to ANSI the credential expiration; 5 years is a current maximum, but less is optional
- Krishna states this change will impact certifying organizations legal defensibility, and could have JTA implications, i.e., whether the exam is demonstrating job competence; he further stated that JTAs would need to align with changed expiration dates which has a cost, and there could be impacts to the Standards and exam validity

- Roughan stated the assumption this change would come at “little to no cost” is not accurate
- Dwyer stated that Rhode Island had experience with shorter expirations and associated instruction time required of exam candidates, but no associated data with regard to food borne illness risk reduction had been gathered
- Koester stated Utah requires training and examination every three years
- Reich stated the proposed change in credential expiration should be based on research rather than anecdote, and how to implement alignment of credential expiration with Food Code updates is unclear
- Anderson stated this matter is not as simple as “4 is better than 5,” and that considering the proposal should include a demonstration of efficacy versus simple alignment
- Burns Savage stated that Southern Nevada Health District uses a 5-year expiration
- Piche stated that the National Restaurant Association tracks jurisdictions that depart from 5-year expirations and can make that information available to the committee
- Johnson stated that in addition to some regulatory jurisdiction varying from 5-year expirations, some private sector organizations do also
- Chapman stated increased adoption of the 2017 Food Code and its increased CFPM “onsite” requirement has already disproportionately increased costs for small / independent operators
- Ciarimboli stated Hy-Vee has adopted a three-year expiration due to a Minnesota state requirement
- Rivas asked what the basis for the 5-year standard is; discussion ensued that FDA and or John Marcello may have information in this regard
- General discussion ensued that this change may more appropriately within the purview of regulatory jurisdictions, and nothing prohibits them from adopting shorter expirations

Chair Quam asked for the members to email her their comments on impact, feasibility, cost, stakeholder impacts by sector (certifying organizations, trainers, food operators, or others).

The meeting was adjourned at 3:22 PM by unanimous acclimation.

###

FOOD PROTECTION CERTIFICATION COMMITTEE
Minutes of the Meeting | April 6, 2022 | 2-4 PM eastern

Attendance ~~strikethrough~~ indicates absence

Chairs/Voting: Chair Quam, Vice Chair Daniel, Allen, Anderson, Burns Savage, Chapman, Ciarimboli, Corchado Torres, Derr, ~~Dolhanyk~~, ~~Dunleavy~~, Dwyer, ~~Eastwood~~, Halbrook, Hawley, Huffman, Jackson, Koester, Luebkemann, Paster Cammarata, Piche, Reich, ~~Roughan~~, ~~Smith~~, Straughn, ~~Sweet~~, Wiedmeyer, ~~Wilson~~, Woods, Wynne [21 voting members present]

Non-voting: Morris, ~~Albrecht~~, Baker, Conley, Duggins, ~~Gillam~~, Johnson, ~~Krishna~~, ~~Morrison~~, Pollock, Rivas, ~~Unkart~~, Williams, Wittry

Interested Parties & Guests:

Agenda Items

1. Welcome & Roll Call
2. CFP Anti-trust Statement
3. Workgroup reports
   a. Standards
   b. Bylaws
4. Overview of discussion format
   a. Speaker recognition – raise hand virtually
   b. Voting – roll call vote
5. Issue 2020 II-004
   a. Discussion begins on each issue raised by the committee at the last meeting
   b. Handout: *0322 FPMCC 4 Year Impact List Word Doc*
   c. Handout: *State Food Protection Manager Recertification certification timeframe PDF*
   d. Discussion will resume at June meeting for issues not covered in this meeting
6. Meeting Schedule: Next Meeting – 06.01.22, 2-4:00 pm EDT

   FPMCC meetings recur every even month on the first Wednesday, 2-4 PM eastern
   Meeting Zoom link: https://us02web.zoom.us/j/87071250980
   Meeting ID: 870 7125 0980
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   +16468769923,,87071250980# US (New York)

   FPMCC April 6, 2022 Meeting Packet (Attachments inserted at end of Minutes):

Attachment 1	FPMCC Roster
Attachment 2	Agenda and Issue 2020 II-004 discussion topics
Attachment 3	Issue 2020 II-004 additional discussion topics
Attachment 4	Recertification frequencies by jurisdiction (source: National Restaurant Assoc.)
Attachment 5	John Marcello, FDA - historical narrative re Five-year certification term
Attachment 6	Laurie Williams, FDA - historical narrative re Food Code publication frequency
Attachment 7	Glenda Lewis, FDA - historical narrative re Food Code publication terminology
Attachment 8	FPMCC Progress Report April 2022

Handout: *0322 FPMCC 4 Year Impact List Word Doc*
Issue II-004 4-Year Exam Validity - Areas of impact and feasibility
For committee discussion April 6, 2022 (Agenda Item 5.b.)

I. Financial Impact - Industry/Providers/Regulatory Agencies

1. At what frequencies are the providers updating their JTAs?
    a. Some may already be updating at less than five years, by addressing the Food Code changes, whenever they are released
    b. If so, do these JTA updates already capture and address the concern of keeping up with Food Code changes?
    c. Does the time lapse between CFP Issue approval/FDA acceptance/Food Code publication impact the JTA process?
2. Shorter certification validity increases frequency
    a. Providers must process and issue certificates more frequently
        - How does this impact providers financially?
    b. Will industry ultimately pay more as employees recertify more frequently?
        - How many industry employees need to be recertified after five years now?
        - Does industry turnover impact this?
    c. The 2017 Food Code update requires CFPM on duty at all times, already impacts industry, will this requirement make it greater?
3. Impact on the CFP Standard
    a. Will this financially impact the CFP?

II. Statutory Implications

1. Is changing the exam validity legally justifiable?
    a. Can a candidate or regulatory authority challenge the change?
    b. Is this justifiable as a way to improve food safety?
2. How does this impact time lines outlined in state statute and local ordinance? *(Please refer to the accompanying State Food Protection Manager Recertification certification timeframe PDF)*
    a. If a statute or ordinance specifies five years, how many jurisdictions are willing to change their laws to four years?
    b. If a jurisdiction does not change, what takes precedence? Law or the certification expiration?
3. Why was five years chosen in the first place? *(Chair Quam is communicating with John Marcello to discuss history and will hopefully have information by meeting time)*

III. Other Issues

1. Some states allow different ways to “recertify” other than by exam. Is there a bigger issue to address relating to best ways to recertify?
2. Will the change reduce the number of risk factor violations – are there studies behind it?
3. Should the committee ask for research to justify change?

Minutes

Items 1-2: Chair Susan Quam convened the meeting in "virtual" format at 2:04 PM eastern, the anti-trust statement was referenced, attendance was recorded, and a quorum established.

Item 3: Chair Quam called for reports from the workgroups. Standards has not met yet, Piche has not received the roster. Bylaws Chair Hawley reported and recommended the following:

Recommendation 1 - this recommendation is made in recognition of difficulty filling regulator seats.

Revisions to Article VI, Section3, Subsection 1.
Subsection 1. Nine (9) representatives from regulatory agencies with food safety responsibilities:
a. ~~Two (2)~~ Three (3) from State regulatory agencies;
b. ~~Two (2)~~ Three (3) from local regulatory agencies; and
~~c. Two (2) from federal government agencies; and~~
c. Three (3) "At Large" appointments. (*At large selections may include federal government agencies, state regulatory agencies and local regulatory agencies with food safety responsibilities.)

Williams stated this recommendation may need edits due to some federal agencies being implicated in, but having no formal retail food safety role or involvement.

Motion
Huffman moved and Jackson seconded that: Recommendation 1 be accepted as submitted, with Jeff Hawley authorized to make necessary clerical edits reflecting federal agency retail food responsibility. Motion carried without objection.

Recommendation 2
Delete Article VII, Section 5, Subsection 3.

Subsection 3. All certification organizations accredited by the Conference's accreditation process participating on the Committee shall not to exceed a total of five (5) votes.
• If more than five (5) certification organizations volunteer to participate on the Committee, the five (5) votes allocated to certification organizations shall be fractionalized (evenly divided).
• The voting fraction shall be determined when the final committee membership is approved by the Board and shall remain in effect until the next biennial Conference meeting.
• Each certification organization shall be allowed no more than one (1) vote or one (1) voting fraction at any meeting.

Fractionalized approach is difficult to manage and not practical. Bylaws workgroup recommends deletion of Article VII, Section 5, Subsection 3. If there are more than five certification organizations who want to participate on the committee the additional ones would be At-large committee members. As a reminder, At-large committee members can participate fully in all committee meetings, except they would not have voting privileges.

Additional information on committee membership:
Article VI, Section 3, Subsection 3 says "Five (5) total votes for certification organizations that are accredited by the Conference's accreditation process. Although there is no limit to the number of accredited certification organizations, this constituency shall have a maximum of five (5) votes."

Halbrook asked how voting would be allocated if more than five certifying bodies were to participate; the Chair replied that recommendations would be made to the Executive Board by the Chair and Vice Chair for final action by the Executive Board. Certifying organization members Anderson and Chapman indicated no objection to this.

Motion
Huffman moved and Jackson seconded that: Recommendation 2 be accepted as submitted, with Jeff Hawley authorized to make necessary clerical edits reflecting federal agency retail food responsibility. Motion carried without objection.

Items 4-5: discussion of Issue II-004 4-Year Exam Validity - Areas of impact and feasibility

I. Financial Impact: Industry/Providers/Regulatory Agencies

1. a. Discussion: At what frequencies are the providers updating their JTAs?
Corchado-Torres - update JTA every five years, change if/when significant Food Code changes occur.
Chapman - Major changes every five years unless Food Code changes warrant otherwise.
Piche - JTA five years unless Food Code changes warrant otherwise.
Anderson - Same for us.
Sharon Unkart – Exams updated as soon as Food Code changes are published.

2.a. Discussion: Shorter certification validity increases frequency
Anderson - Updating exam content and JTAs are separate from certification validity. Beneficial for providers, but increased cost to industry. The question should be "does greater frequency support better food safety?" Unkart and Chapman expressed agreement.
Unkart – Exam content is updated as soon as the food code is published.
Corchado-Torres – Is the expectation that when the Food Code changes, the testing agencies update content? It takes time to update content for testing, so there is still a lag after Food Code updates.
Johnson – The point is not to accelerate testing, but keep pace with the Food Code regular flow.

The question of whether training should be required of exam candidates, and the committee was reminded this is beyond the scope of the standards and the committee's current charges.

2.b. Discussion: Will industry ultimately pay more as employees recertify more frequently?
Halbrook - costs could be significant to businesses footing the bill, with employees numbering in the hundreds of thousands. Increased frequency increases costs, with no known increase in food safety.
Paster Cammarata – It depends on what each state is doing; could be difficult to small businesses. More care should be on retention of the information.

3. General discussion concluded that if the frequency standard is reduced to four years, no financial impact is expected to CFP.

Chair Quam called for any additional questions from the committee, none were heard.

II. Statutory Implications

1. Discussion: Is changing the exam validity legally justifiable?
Quam - Any change must be legally defensible.
Johnson - Some jurisdictions currently have less than five years.

2. Discussion: How does this impact time lines outlined in state statute and local ordinance? *(see PDF: State Food Protection Manager Recertification certification timeframe)*
Luebkemann – Laws, whether local, state, or federal override the Standards.
Johnson – Minnesota requires three years and renewal with CEU's, managed by the state.

Huffman – State statute may not recognize shorter certification expirations in the Standards, creating inconsistency and conflicting guidance. A minority of states have less than five year frequencies.
Pollock – Texas does not require renewal, just a current FPM.

The was much general discussion with concern expressed for creating conflict or inconsistency with existing laws. Huffman stated that a law or ordinance could create a shorter frequency without impacting the Standards, but not vice versa.

3. Discussion: Why was five years chosen in the first place?
Meeting Packet Attachments 5, 6, and 7 provide related background:

Attachment 5	John Marcello, FDA - historical narrative re Five-year certification term
Attachment 6	Laurie Williams, FDA - historical narrative re Food Code publication frequency
Attachment 7	Glenda Lewis, FDA - historical narrative re Food Code publication terminology

III. Other Issues

1. Discussion: Some states allow different ways to "recertify" other than by exam. Is there a bigger issue to address relating to best ways to recertify?
Luebkemann – This is tangential to the substance of the charge, and is a government prerogative.
Hawley – Recertification is not addressed in the Standards, and may vary by locality and action of the authority having jurisdiction.

2. Discussion: Will the change reduce the number of risk factor violations – are there studies behind it?
General committee discussion concluded awareness of no studies available regarding exam frequency requirements and an associated impact to food borne illness risk factors.

3. Discussion: Should the committee ask for research to justify change?
General committee discussion concluded that a change in frequency should be based on or informed by an associated impact to risk factors. The question was raised as to whether the FDA Risk Factor Studies may have relevant information, with Williams responding they do not. The question was raised regarding effect on jurisdictions that currently have a five-year certification codified into law or rule, with the response being that a law or rule overrides the Standards. Dwyer stated research should be part of the decision making process.

The question was raised as to the sense of the committee on this issue, and if a straw poll may be in order; discussion ensued indicating that members may need more time to consider the question, and additional discussion is scheduled for the June 1, 2022 FPMCC meeting.

Item 6:
Chair Quam reminded members FPMCC meetings are currently set to recur every other month on the first Wednesday, with the following 2022 dates scheduled: June 1, Aug. 3, Oct. 5, Dec. 7.

Next meeting will convene virtually on June 1, 2022, 2-4 PM eastern.

Motion
Luebkemann moved and Corchado Torres seconded adjournment. Motion carried without objection.

Meeting adjourned at 3:35 PM eastern.

###

ATTACHMENT 1

Committee Name: FOOD PROTECTION MANAGER CERTIFICATION revised 12.09.2021

Last Name	First Name	Position	Vote / Non-vote	Constituency	Employer	City	State	Telephone	Email	Notes
Quam	Susan	Chair	Non Voting	Industry - Support At Large	Wisconsin Restaurant Association	Madison	WI	608-216-2875	squam@wirestaurant.org	
Daniel	Justin	Vice Chair	Voting	Regulator - Local	Lincoln-Lancaster County Health Department	Lincoln	NE	402-441-8033	jdaniel@lincoln.ne.gov	
Sweet	Bridget	Member	Voting	Academia	Johnson & Wales University	Providence	RI	774-434-5146	bridget.sweet@jwu.edu	
Reich	Allen	Member	Voting	Academia	Northern Arizona University	Flagstaff	AZ	928-853-6340	allen.reich@nau.edu	
Wilson	David	Member	Voting	Consumer	After School Matters	LaGrange	IL	708-582-0022	d.wilson180@my.chicago.chefs.edu	
Dolhanyk	Anne	Member	Voting	Consumer	STOP Foodborne Illness	West Linn	OR	360-601-4264	adolhanyk@gmail.com	
Luebkemann	Geoffrey	Member	Voting	Industry - Food Service	Florida Restaurant & Lodging Association	Tallahassee	FL	850-224-2250	gluebkemann@frla.org	
Halbrook	Courtney	Member	Voting	Industry - Food Service	Topgolf	Dallas	TX	704-236-0890	courtney.halbrook@topgolf.com	
Wynne	Rebecca	Member	Voting	Industry - Food Service	Darden	Denver	CO	303-895-4042	rwynne@darden.com	
Dwyer	Tara	Member	Voting	Industry - Retail Food	Dave's Marketplace	East Greenwich	RI	401-4748905	tarad@davesmarketplace.com	
Allen	Consuelo	Member	Voting	Industry - Retail Food	Whole Foods Market	Austin	TX	512-426-8709	consuelo.allen@wholefoods.com	
Hawley	Jeff	Member	Voting	Industry - Retail Food	Harris Teeter	Matthews	NC	704-844-3098	jhawley@harristeeter.com	
Koester	Laura	Member	Voting	Industry - Retail Food At Large	Harmons	Salt Lake City	UT	801-957-8472	laurakoester@harmonsgrocery.com	
Ciarimboli	Ellen	Member	Voting	Industry - Retail Food At Large	Hy-Vee, Inc.	West Des Moines	IA	515-453-2789	eciarimboli@hy-vee.com	
Corchado Torres	Liz	Member	Voting	Industry - Support Certification Org	National Registry of Food Safety Professionals	Orlando	FL	407.999.8126	lcorchado@nrfsp.com	
Piche	Kate	Member	Voting	Industry - Support Certification Org	National Restaurant Association / ServSafe	Chicago	IL	312-261-5348	kpiche@restaurant.org	
Chapman	Bryan	Member	Voting	Industry - Support Certification Org	StateFoodSafety	Orem	UT	801-494-1879	bchapman@statefoodsafety.com	
Eastwood	Nick	Member	Voting	Industry - Support Certification Org	Always Food Safe	St. Paul	MN	612.203.4872	nick.eastwood@alwaysfoodsafe.com	
Anderson	Tom	Member	Voting	Industry - Support Certification Org	360 Training	Austin	TX	512-212-7343	tom.anderson@360training.com	
Derr	Samuel	Member	Voting	Industry - Support Training	Elite Food Safety Training	Naperville	IL	630-776-3430	sderr@elitefoodsafety.com	

Paster Cammarata	Tara	Member	Voting	Industry - Support Training	Paster Training, Inc.	Gilbertsville	PA	610-970-1776	tara.paster@pastertraining.com
Roughan	George	Member	Voting	Industry - Support Training	TAP Series	Westlake Village	CA	818-889-8799 x 101	gr@tapseries.com
Straughn	Ki	Member	Voting	Regulator - Local	Public Health Seattle & King County	Bellevue	WA	206-263-8088	kstraughn@kingcounty.gov
Wiedmeyer	Lindy	Member	Voting	Regulator - Local At Large	City of West Allis Health Department	West Allis	WI	414-302-8654	lwiedmeyer@westalliswi.gov
Woods	Yolanda	Member	Voting	Regulator - Local At Large	Shelby County Government	Memphis	TN	901-222-9190	yolanda.woods@shelbycountytn.gov
Burns Savage	Nikki	Member	Voting	Regulator - Local At Large	Southern Nevada Health Districtg	Las Vegas	NV	702-686-7691	ntburns@cox.net
Jackson	Jeff	Member	Voting	Regulator - State	Arkansas Department of Health	Little Rock	AR	870-847-7619	jeff.jackson@arkansas.gov
Huffman	Troy	Member	Voting	Regulator - State (Federal replacement)	Colorado Department of Public Health & Environment	Denver	CO	303-692-3664	troy.huffman@state.co.us
Smith	Colleen	Member	Voting	Regulator - State (Federal replacement)	NH DHHS	Concord	NH	603-271-4858	colleen.smith@dhhs.nh.gov
Dunleavy	Sean	Member	Voting	Regulator - State	Michigan Department of Agriculture and Rural Development	Lansing	MI	517-243-8895	dunleavys@michigan.gov
Non-voting									
Morrison	Sheri	Member	Non-Voting	ACAC Representative	Pennsylvania Department of Agriculture	Harrisburg	PA	717-787-5289	shmorris@pa.gov
Albrecht	Julie	Member	Non-Voting	ACAC Representative	Dept. of Nutrition and Health Sciences, University of Nebraska - Lincoln	Lincoln	NE	402-464-2702	jalbrecht1@unl.edu
Krishna	Vijay	Consultant	Non-Voting	ANAB Representative	ANAB	Washington	DC	202-331-3614	vkrishna@ansi.org
Wittry	Beth	Consultant	Non-Voting	Federal Govt	CDC	Atlanta	GA	770-488-7333	Xks5@cdc.gov
Williams	Laurie	Consultant	Non-Voting	Federal Govt	FDA	College Park	MD	240-402-2938	laurie.williams@fda.hhs.gov
Duggins	Quwanza	Consultant - alternate	Non-Voting	Federal Govt	FDA	Oklahoma City	OK	240-535-5969	quwanza.duggins@fda.hhs.gov
Baker	Michael	Alternate	Non-Voting	Industry - Support Certification Org	National Registry of Food Safety Professionals	Chicago	IL	312-651-5783	mbaker@restaurant.org
Conley	Mark	Alternate	Non-Voting	Industry - Support Certification Org	National Restaurant Association / ServSafe	Chicago	IL	312.583.9853	MConley@restaurant.org
Johnson	Lars	Alternate	Non-Voting	Industry - Support Training	LAJ Consulting/ FoodSafetyGuy	San Jose	CA	507-990-5129	fsg@foodsafetyguy.com
Morrison	Laura	Alternate	Non-Voting	Industry - Support	Ohio Restaurant Association	Columbus	OH	614-246-0205	lmorrison@ohiorestaurant.org

Gillam	Tim	Alternate	Non-Voting	Industry - Food Service	Subway Restaurants	Milford	CT	570-688-3310	gillam_t@subway.com
Rivas	April	Alternate	Non-Voting	Industry - Support Training	ATC Food Safety	Pfafftown	NC	707-363-6032	april.rivas@atrainingcompany.com
Pollock	Evelin	Alternate	Non-Voting	Regulator - Local	Harris County Public Health	Houston	TX	713-248-5691	evelin.pollock@phs.hctx.net
Unkart	Sharon	Alternate	Non-Voting	Regulator - State	NEHA	Denver	CO	720-802-2142	sdunkart@neha.org

ATTACHMENT 2

Food Protection Manager Certification Committee (FPMCC)
April 4, 2:00-4:00 pm EDT

- Welcome & Roll Call

- CFP Anti-trust Statement

- Workgroup reports
  - Standards
  - Bylaws

- Overview of discussion format
  - Speaker recognition – raise hand virtually
  - Voting – roll call vote

- Issue 2020 II-004
  - Discussion begins on each issue raised by the committee at the last meeting
  - Handout: *0322 FPMCC 4 Year Impact List Word Doc*
  - Handout: *State Food Protection Manager Recertification certification timeframe PDF*
  - Discussion will resume at June meeting for issues not covered in this meeting

- Meeting Schedule: Next Meeting – 06.01.22, 2-4:00 pm EDT

Issue II-004 4-Year Exam Validity
Areas of impact and feasibility

- Time lapse between CFP/FDA/Code publication
  - Test provider impact – what is the date of implementation
- Will the change reduce the number of risk factor violations – is there studies behind it

ATTACHMENT 2

- Providers are already able to have shorter time period, with five as the max
- Is it legally justifiable
- Impact on update timelines and justification for changes and taking different methodologies into consideration
- Impact on the CFP Standard
- What is the frequency of the JTA? Some may already be less than 5 years
- Does existing work done by providers already capture and address the issue
- Financial impact – shorter timeline increases frequency
- E.g. Rhode Island operated on 3 year basis – do they have data on impact of more frequency - change in seat time requirements. Utah has 3 year frequency as well
- Need for research to justify change
- How does this impact time lines outlined in state statute and local ordinance
- Timing of exam vs timing of FC release
- Practical day to day knowledge vs no hands on experience
- Is this aligning with FC or is this justifiable as a way to improve food safety
- How many jurisdictions have times other than 5 years
- 2017 FC update to have CFPM on duty at all times, already impacts industry, will this requirement make it greater
- Different ways to “recertify” other than by exam. Is there a bigger issue to address relating to best ways to recertify
- Pandemic related delays to recertification
- Why was 5 years chosen in the first place
- Financial impact on industry

ATTACHMENT 3

Issue II-004 4-Year Exam Validity
Areas of impact and feasibility
For committee discussion April 6, 2022

I. Financial Impact - Industry/Providers/Regulatory Agencies

1. At what frequencies are the providers updating their JTAs?
   a. Some may already be updating at less than 5 years, by addressing the Food Code changes, whenever they are released
   b. If so, do these JTA updates already capture and address the concern of keeping up with Food Code changes?
   c. Does the time lapse between CFP Issue approval/FDA acceptance/Food Code publication impact the JTA process?
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3. Impact on the CFP Standard
   a. Will this financially impact the CFP?

II. Statutory Implications

1. Is changing the exam validity legally justifiable?
   a. Can a candidate or regulatory authority challenge the change?
   b. Is this justifiable as a way to improve food safety?
2. How does this impact time lines outlined in state statute and local ordinance? *(Please refer to the accompanying State Food Protection Manager Recertification certification timeframe PDF)*
   a. If a statute or ordinance specifies 5 years, how many jurisdictions are willing to change their laws to 4 years?
   b. If a jurisdiction does not change, what takes precedence? Law or the certification expiration?
3. Why was 5 years chosen in the first place? *(Chair Quam is communicating with John Marcello to discuss history and will hopefully have information by meeting time)*

III. Other Issues

1. Some states allow different ways to “recertify” other than by exam. Is there a bigger issue to address relating to best ways to recertify?
2. Will the change reduce the number of risk factor violations – are there studies behind it?
3. Should the committee ask for research to justify change?

ATTACHMENT 4

Food Protection Manager Certification Recertification*

State	Certs valid	Certification Required?	State	Certs valid	Certification Required?	State	Certs valid	Certification Required?
DC	3 years	Yes	IA	5 years	Yes	NJ	5 years	Yes
MN	3 years	Yes	ID	5 years	Yes	NM	5 years	Yes
MT	3 years	Yes	IL	5 years	Yes	NV	5 years	Yes
RI	3 years	Yes	IN	5 years	Yes	NY	5 years	Yes
UT	3 years	Yes	KS	5 years	Demonstration of Knowledge	OK	5 years	City/County Requirements
SD	4 years	Yes	KY	5 years	Yes	OR	5 years	Demonstration of Knowledge
AK	5 years	Yes	LA	5 years	Yes	PA	5 years	Yes
AL	5 years	Yes	MA	5 years	Yes	SC	5 years	Yes
AR	5 years	Yes	MD	5 years	City/County Requirements	TN	5 years	Demonstration of Knowledge
AZ	5 years	City/County Requirements	ME	5 years	Yes	TX	5 years	Yes
CA	5 years	Yes	MI	5 years	Yes	VA	5 years	Yes
CO	5 years	Yes, except Denver	MO	5 years	City/County Requirements	WI	5 years	Yes
CT	5 years	Yes	MS	5 years	Yes	WV	5 years	Yes
DE	5 years	Yes	NC	5 years	Yes	WY	5 years	City/County Requirements
FL	5 years	Yes	ND	5 years	City/County Requirements	VT	5 years	Demonstration of Knowledge
GA	5 years	Yes	NE	5 years	City/County Requirements	WA	5 years	Yes- Effective 3/1/23
HI	5 years	Demonstration of Knowledge	NH	5 years	Yes	OH	No expiration	Yes

* ordered by shortest to longest recertification timeframes and at the state level

ATTACHMENT 5

From: Marcello, John <John.Marcello@fda.hhs.gov> **Marcello email response re 5-year certification term**
Sent: Friday, March 25, 2022 3:21 PM **2022-03-25**
To: Susan Quam <SQuam@wirestaurant.org>
Cc: 'jdaniel@lincoln.ne.gov' <jdaniel@lincoln.ne.gov>; Geoff Luebkemann <gluebkemann@FRLA.org>; Lewis, Glenda R <Glenda.Lewis@fda.hhs.gov>; Williams, Laurie (CFSAN) <Laurie.Williams@fda.hhs.gov>; Cartagena, Mary <Mary.Cartagena@fda.hhs.gov>; Pierce, Andre <Andre.Pierce@fda.hhs.gov>; O'Malley, Elizabeth <Elizabeth.OMalley@fda.hhs.gov>; Smith, Chris <Chris.Smith@fda.hhs.gov>; Destromp, Kimberly <Kimberly.Destromp@fda.hhs.gov>; Duggins, Quwanza <Quwanza.Duggins@fda.hhs.gov>; DelMundo, Katherine <Katherine.DelMundo@fda.hhs.gov>
Subject: Marcello response re 5-year certification term

Susan:

Good to hear from you!! Hope all is well!! Your request implies that I can provide some historical background on this subject which means I'm old.

I do have some insights to provide. It is helpful to start with the genesis of best practices for developing and delivering Food Protection Manager Certification. In the late 1970s – early 1980's the National Institute for the Food Service Industry (NIFI) developed the first manager certification coursebook titled – *Applied Foodservice Sanitation*. One of the primary resources used to develop the content of this coursebook is the *1976 Food Service Sanitation Manual including A Model Food Service Sanitation Ordinance, 1976 Recommendations of the Food and Drug Administration.*

This certification textbook becomes the early foundation upon which both industry and regulatory agencies begin to build Food Protection Manager certification programs. At this time, there is not a single recognized standard for developing and providing food protection manager certification programs. The Education Foundation of the National Restaurant Association (NRA) obtains the NIFI rights to the *Applied Food Sanitation Textbook* and begins to develop its Food Protection Manager certification program which ultimately evolves into the ServSafe program. The NRA develops "best practices" for their program – one of them being that their certification be valid for no more than three years. Keep in mind that this time frame was based on a considered "best practice" and not based on any recognized standard. A significant number of other certification providers, including regulatory agencies, adopt the same recertification time frame but other chose different time frames (four years; five years, etc.). This was just one of many examples of differences in certification providers requirements. This fragmentation created an environment that presented disincentives to certification due to lack of recognition and reciprocity of certificates accepted within the regulatory community which in turn resulted in duplicative cost and staff resources for the industry trying to meet the varied certification requirements of regulatory jurisdictions.

From 1994 through 2002, the CFP's Food Protection Manager Certification Committee did extensive work to develop a national standard. This resulted in what today is known as the *CFP Standards for Accreditation of Food Protection Manager Certification Programs*. During this same period, FDA issues the 1993 FDA Food Code (the first edition in the current format) and commits to a process to update the Code every four years. During this same period, The FDA *Food Code* begins to incorporate provisions related to Food Protection Manager Certification.

NOTE: Laurie Williams had previously submitted an e-mail on the background history related to the naming and cycle of Food Code publications. Glenda Lewis has also provided some additional information on this process. Both of these resources are included as attachments to my response

It is at this point in time that the CFP Committee recognizes the needs to address the issue you raised below regarding time frame for certification length. There are some important points to keep in mind as part of this discussion, including how CFP defines a certification program.

Section 1.0 of the Accreditation Standards defines what an accredited certification program is:

- **1.3 Accredited certification program** means a Food Protection Manager Certification Program that has been evaluated and listed by an accrediting organization as being in conformity with the CFP Standards for such program as set forth in this document. This does not refer to training functions or educational programs.

The current FDA Food Code definition of 'accredited certification program' is consistent with CFP. One of the primary responsibilities of a Food Protection Manager certification provider is the development of an examination that conforms with sound psychometric standards and is valid, reliable, and legally defensible. At its core, the certification examination must be based on a job task analysis,

- **4.4 Job Task Analysis** – A food safety certification examination shall be based on a valid job task analysis. The job task analysis shall be developed by qualified individuals, including retail food industry and public health stakeholders and subject matter experts.

The connection of the Job Task Analysis (JTA) to the current version of the Food Code is implied in Section 4.5 of the Standards. Keep in mind that the Food Code is only one of several technical resources that can be used to base the JTA.

- **4.5** The job task analysis shall provide a complete description of the knowledge, skills, and abilities (KSAs) required to function completely in the occupation of CFPM with the emphasis on those tasks most directly related to the CFPM's role in prevention of foodborne illness and controlling foodborne pathogens.

I've underlined the second half of this provision because of the importance of the Food Code as a source for the JTA.

Now here is where the rationale for the 5-year certification period originates. It is based on the CFP Standard's requirement for the JTA to be updated every five years per Section 4.7:

- **4.7** The credential awarded upon passing a food safety certification examination is designed to be recognized nationwide and throughout the retail food industry. As such, the certification organization shall regularly evaluate practices in the retail food industry to ensure the job task analysis on which the examination is based remains appropriate and relevant. **The maximum length of use for any job task analysis is five years from the date of its validation.**

So the 5 year certification period referenced in Section 7.2 of the CFP Standards is set to align with when the certification provider is required to update their job task analysis.

- **7.2 Qualifications for Initial Certification** – To become a Certified Food Protection Manager an individual shall pass a food safety examination from an accredited certification program by the Conference for Food Protection. **The certification shall be valid for no more than 5 years.**

The FDA Food Code does not specify any specific time frame for certification length. Rather **Section 2-102.20 Food Protection Manager Certification. Paragraph (B)** refers back to the CFP Standards:

> (B) A FOOD ESTABLISHMENT that has a PERSON IN CHARGE that is certified by a FOOD protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs is deemed to comply with Section 2-202.12.

Section 2-102.12 Certified Food Protection Manager:

> (A) The PERSON IN CHARGE shall be a certified food protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM

With all of this, there still may be some discussion within the CFP Committee relative to reducing the validation period to 4 years to align with the planned updated versions of the Food Code. It is important to keep in mind that FDA works very closely with CFP to identify and assess areas in the Food Code that may need to be updated. The normal frequency for publication of the full edition of the Food Code is a 4-year period, with Supplements issued in the interim 2-years. In addition, some SLTT stakeholders have expressed a desire for the period between release of full editions to be lengthen due to their challenges with following the dedicated process for Food Code Adoption in their states.

Even more importantly, for the CFP CFPM Committees I had the honor to Co-Chair, the members recognized that the certification providers could not turn on a dime as soon as the new Food Code was published and produce an updated examination(s). They first needed to conduct the JTA and validate the results. This would then have to be followed with an examination development process that included item writing, fairness reviews, passing score reviews, etc. This is a process in its own right that needs time and resources to be conducted correctly and in accordance with sound psychometric standards.

In summary, it has been 20 years since I have been directly engaged with the CFP CFPM Committee but I would think any recommendation to change the certification length in the Standards needs to take into consideration:

- What problem is the change in length of certification time frame seeking to address? How will such a change impact the regulatory community, industry, and certification providers? There is always a cost-benefit assessment that needs to be weighed.
- The current process certification organizations have in place for updating their job task analysis every 5 years. The 5-year time frame was based on nationally recognized psychometric practices for maintaining up-to-date assessments of professional practices. Is this still the standard within the psychometric community? ANSI may be able to provide some perspective.
- What has been the certification organizations experience with the scope of changes that may occur during the 5-year period of their JTAs that may result in changes to the technical content in their certification examination focus on the KSAs for food protection managers?
- What economic impact would any change in length have on a certification organizations efforts to update their JTAs and examinations?
- In turn, what might the impact of changing the certification have on industry's access to updating examinations? Would their be any increased in costs for the retail food and foodservice industries.

I hope this helps! Please let me know if you have any questions or need additional information.

John

John A. Marcello
Senior Advisor to the OSCP Director

ORA/OHAFO/Office of State Cooperative Programs (OSCP)
U.S. Food and Drug Administration
Tel: 480-829-7396 ext. 2035 Cell: 602-402-9227
John.marcello@fda.hhs.gov

From: Susan Quam <SQuam@wirestaurant.org>
Sent: Wednesday, March 23, 2022 9:52 AM
To: Marcello, John <John.Marcello@fda.hhs.gov>
Cc: 'jdaniel@lincoln.ne.gov' <jdaniel@lincoln.ne.gov>; Geoff Luebkemann <gluebkemann@FRLA.org>
Subject: [EXTERNAL] CFPM

Good morning John,

I am hoping you can reach back in to your memory and give me some insight on how the FPMCC reached consensus on a 5-year certification length. I was participating in committee meetings when the Standard was first developed, but I cannot remember any discussion regarding the certification timing.

As you know, the FPMCC is looking at the impact of moving to a 4-year certification. Knowing the history of why it is five years now will be helpful.

WRA has your back.
Susan Quam, CAE, IOM
Executive Vice President
Wisconsin Restaurant Association
direct: 608.216.2875 • mobile: 608.217.4513
squam@wirestaurant.org
wirestaurant.org

From: Williams, Laurie (CFSAN)
To: Susan Quam; jdaniel@lincoln.ne.gov
Cc: Duggins, Quwanza; DelMundo, Katherine; Cartagena, Mary
Subject: FPMCC - Food Code
Date: Friday, February 4, 2022 8:51:00 AM
Attachments: image003.png

ATTACHMENT 6

Greetings Susan and Justin,

I sent an email to John Marcello asking if he would be so kind as to provide input to the historical background for the 5-year examination renewal for the food protection manager certification. He would be happy to help! He asks that Susan contact him and fill him in on what is needed. His contact information is: John.marcello@fda.hhs.gov

In addition, I did a little research on the change in publication intervals of the Food Code from 2 years to 4 years with the Supplement and I am sharing language to that effect:

Issue 00-I-065 Periodicity of the FDA Food Code

The Conference recommends that an ad hoc committee be established under Council 1 to develop a Conference paper to explore the impact of changing the periodicity of the Food Code, with equal representation of stakeholders, prior to the next Conference. The Committee shall report back to Council 1 at the 2002 Conference.

Issue 2002-II-022 Periodicity of the Food Code was accepted as amended. The recommended solution: That new editions of the Food Code be published every four (4) years instead of two (2) years except that issues of public health significance should be acted upon immediately. Council Recommendation: Accept as amended. Assembly Action: Affirm.

The very first Supplement was FDA 2001 Food Code Supplement which published August 29, 2003. This Supplement was introduced with the following language:

“The Food and Drug Administration (FDA) is pleased to issue this Supplement to the 2001 Food Code (hereafter referred to as Supplement). This Supplement updates the 2001 Food Code to address several recommendations made by the 2002 Conference for Food Protection (CFP) with which the FDA, Centers for Disease Control and Prevention (CDC), and United States Department of Agriculture (USDA) concur. The changes contained in this Supplement reflect the current science and emerging food safety issues, and imminent health hazards related to food safety.

From 1993 through 2001, the complete Food Code has been issued every two years. With the support of the Conference for Food Protection, FDA has decided to move to a four-year interval between complete Food Code revisions. The next complete revision of the Food Code will be published in 2005. Until that time, this Supplement allows several changes upon which there is substantial concurrence among the Federal Agencies and the other stakeholders to be incorporated into the Food Code. The Supplement ensures that the most current food safety provisions are available to agencies planning to initiate rule-making activities prior to 2005.

This Supplement provides other users of the Food Code, such as educators, trainers, and the food service, retail food, and vending industries, with up-to-date information of how to best mitigate risk factors that contribute to foodborne illness.”

FDA 2001 Food Code Supplement

The Food Code Supplement is intended to keep the Food Code up to date and provides the most current food safety provisions to agencies planning to initiate rule-making activities before the next edition of the Food Code. As evidenced in the present FDA Food Code starting on page iv, the Food Code is updated every 2 years with the Supplement included.

If you have any questions or require additional information please do not hesitate to contact me.

ATTACHMENT 7

From: Marcello, John
To: Marcello, John
Subject: FW: Review requested - Response to a question received from the CFP Certification of Food Protection Managers Committee
Date: Friday, March 25, 2022 7:34:14 AM

From: Lewis, Glenda R <Glenda.Lewis@fda.hhs.gov>
Sent: Thursday, March 24, 2022 11:17 PM
To: Marcello, John <John.Marcello@fda.hhs.gov>; Williams, Laurie (CFSAN) <Laurie.Williams@fda.hhs.gov>; Cartagena, Mary <Mary.Cartagena@fda.hhs.gov>; Lewis, Glenda R <Glenda.Lewis@fda.hhs.gov>
Cc: Farmer, Laurie <Laurie.Farmer@fda.hhs.gov>; Pierce, Andre <Andre.Pierce@fda.hhs.gov>; O'Malley, Elizabeth <Elizabeth.OMalley@fda.hhs.gov>; Destromp, Kimberly <Kimberly.Destromp@fda.hhs.gov>; Smith, Chris <Chris.Smith@fda.hhs.gov>; Duggins, Quwanza <Quwanza.Duggins@fda.hhs.gov>; DelMundo, Katherine <Katherine.DelMundo@fda.hhs.gov>; Lewis, Glenda R <Glenda.Lewis@fda.hhs.gov>
Subject: RE: Review requested - Response to a question received from the CFP Certification of Food Protection Managers Committee

John,

Thanks for sharing and the opportunity to review. You did an excellent job laying out the history. In the email that Laurie sent to the CFP Committee referring the question to you, she provides a nice summation of the CFP history for the change in the publication cycle of the Food Code. I add to that here with some additional notes on the naming and cycle of Food Code publication. You may want to include this aspect in your response when describing the Food Code history.

The language used in 2003 for naming the Supplement, 'FDA 2001 Food Code – Supplement' has evolved to be, 'Supplement to the 2001 Food Code'. This has carried through to each Supplement that has been released since 2003 and they are named as, 'Supplement to the [date year] Food Code.

We now also refer to the 4 year version as a 'full edition' Food Code whereas in 2001 we called it 'complete Food Code'. In later years questions arose around the 'complete Food Code description' and we landed on 'full edition' to characterize/make a separation from the Supplement and the full edition.

Below is the description of the Food Code cycle, excerpted from the Food Code Adoption Annual Report 2020.

Between 1993 and 2001, the FDA Food Code was issued every two years. The 2005 Food Code was the first full edition published on the new four-year interval. During the interim period between full editions, FDA may publish one Food Code Supplement that updates, modifies, or clarifies certain provisions. As of December 31, 2020, the 2017 Food Code (https://www.fda.gov/media/110822/download) is the most recent full edition published by FDA, and it was followed by the Supplement to the 2017 Food Code (https://www.fda.gov/media/133749/download), which was published in 2019. . . This Report may use two terms to describe the FDA Food Code – 'version' and 'edition'. The term 'version' is associated with the year of publication/ release and the term 'edition' is associated with the number of times the Code has been published in its current format. So, the 1993 version is the 1st edition, the 1995 version is the 2nd edition, the 1997 version is the 3rd edition, the 1999 version is the 4th edition, the 2001 version is the 5th edition, the 2005 version is the 6th edition, the 2009 version is the 7th edition, the 2013 version is the 8th edition and the 2017 version is the 9th edition.

ATTACHMENT 8

Conference for Food Protection – Committee Progress Report

Committee Progress Reports are considered DRAFT until accepted by the Executive Board
Approved 7/13/21

The Conference Chair, Executive Director, Council Chair, or Issue Chair may return committee reports, Issues, or attached documents requesting edits to improve understanding, or to include missing information.

Committee-submitted documents may impact the image, credibility, and integrity of the Conference as an organization. With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, documents) become the property of the Conference.

COMMITTEE NAME:

DATE OF REPORT: ☐ ***Initial fall progress report*** X ***Spring progress report*** ☐ ***Second fall progress report***
Date submitted: *04.01.2022* **Date amended (if applicable):** *Click here to enter a date.* **Date accepted by Executive Board:** *Click here to enter a date.*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** X ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: **Susan Quam and Justin Daniel**

COMMITTEE CHARGE(S):

Issue # **2020 II-001**

1. Food Protection Manager Certification Committee (FPMCC) is to carry out charges assigned via the Conference Issue process and from the Conference Executive Board relating to food protection manager certification and to adopt sound, uniform accreditation standards and procedures that are accepted by the Conference while ensuring that the conference Standards for Accreditation for Food Protection Manager Certification programs and the accreditation process are administered in a fair and responsible manner.
2.

Issue # **2020 II-004**

1. The Food Protection Manager Certification Committee is to review the impact and feasibility of changing the frequency of required certification examination to a time period not to exceed four years from date of issuance, aligning knowledge demonstration by examination with the routine four-year update and publication of the FDA Retail Food Code.
2.

COMMITTEE WORK PLAN AND TIMELINE: It is anticipated that this Committee will meet regularly via virtual platform and, if possible, in-person.

COMMITTEE ACTIVITIES:

1. ***Dates of committee meetings or conference calls:***
   The following are our scheduled virtual meeting dates. All meetings are from 2:00-4:00 p.m. Eastern time. All meetings have been virtual so far. We are still considering a face to face meeting in late summer/early fall
   December 1, 2021
   February 2, 2022
   April 6, 2022
   June 1, 2022
   August 3, 2022
   October 5, 2022
   December 7, 2022

2. ***Overview of committee activities:***
   The committee held its first meeting on December 1. Interim chair Hawley led the committee through an orientation session and reviewed the committee's charges. The committee elected Susan Quam and Justin Daniel as chair and vice chair respectively. Jeff Hawley was appointed chair of the Committee Bylaws workgroup and Kate Piche was appointed chair of the Standard workgroup. Volunteers for both groups were also recruited.

   At the February 2 meeting, the committee reviewed Issue II-004 and identified potential impacts and feasibility issues related to changing the validity of certification from 5 years to 4 years.

   The committee will begin discussing each of the impacts/feasibility issues at its April 6 meeting. We anticipate it will take at least two meetings to fully vet all points, and possibly discover any that were missed in the initial discussion.

3. ***Charges COMPLETED and the rationale for each specific recommendation:***
   a. No charges completed at this time

b.

4. ***Status of charges still <u>PENDING</u> and activities yet to be completed:***

   a. **2020 II-001 Both the Bylaws and Standard workgroups have just begun their work reviewing their respective committee documents**

   b. **2020 II-004 As reported above, the committee will begin discussion on the 4-year vs 5-year certification at its April meeting**

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

X Board Action is NOT required and therefore the report can be placed on the consent calendar for Board review and acceptance.

□ Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.

ATTACHMENTS:

1. ***Content Documents:***

   a. ***Committee Member Roster:*** ☐ ***See changes noted above under "requested action"*** *"Committee Members Template" (Excel) available at: www.foodprotect.org/work/report.*

   X ***No changes to previously approved roster*** *Committee roster to be submitted as a PDF attachment to this report.*

   b. ***Committee Generated Content Documents (OPTIONAL):*** X ***No draft content documents submitted at this time***

2. ***Supporting Attachments (OPTIONAL):*** ☐ ***Not applicable***

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FOOD PROTECTION CERTIFICATION COMMITTEE
Minutes of the Meeting | June 1, 2022 | 2-4 PM eastern

Attendance ~~strikethrough~~ indicates absence

Chairs/Voting: Chair Quam, Vice Chair Daniel, ~~Allen~~, Anderson, Burns Savage, Ciarimboli, ~~Corchado Torres~~, ~~Derr~~, ~~Dolhanyk~~, Dwyer, Eastwood, Halbrook, Hawley, Huffman, Jackson, Koester, ~~Luebkemann~~, Paster Cammarata, ~~Piche~~, ~~Reich~~, ~~Roughan~~, Smith, Straughn, ~~Sweet~~, Wiedmeyer, ~~Wilson~~, Woods, Wynne [17 of 27 voting members present]

Non-voting: Morris, ~~Albrecht~~, Baker, Conley, Duggins, ~~Gillam~~, ~~Johnson~~, Krishna, ~~Morrison~~, ~~Pollock~~, Rivas, ~~Unkart~~, Williams, Wittry

Interested Parties & Guests:

Agenda Items

1. Welcome & Roll Call
2. CFP Anti-trust Statement
3. Approval of Minutes
4. Workgroup reports
   a. Standards
   b. Bylaws (if needed)
   c. ANAB Contract
5. Overview of discussion format
   a. Speaker recognition – raise hand virtually
   b. Voting – roll call vote
6. Issue 2020 II-004
   a. Straw Poll
      I. What is the will of the committee?
      II. Motion needed to determine direction of the committee's response
   b. Discussion/vote
   c. Formation of work group to craft final response
7. Meeting Schedule: Next Meeting – 08.03.22, 2-4:00 pm EDT

Minutes

Items 1-2: Welcome & Roll Call – Chair Quam called the meeting to order at 2:03 PM eastern on a virtual meeting platform; roll was called and quarum established. Members Bryan Chapman and Sean Dunleavey are no longer voting members due to changes in their constituency status. The anititrust statement was referenced.

Item 3: Jeff Hawley moved approval of the minutes, Jeff Jackson seconded, motion passed unanimously.

Item 4: Workgroup reports

a. Standards – Burns Savage reported the group met, member feedback was solicited, and is being reviewed.
b. Bylaws – work is completed.

c. ANAB Contract - Hawley led a workgroup to review the ANAB contract, which was 20 years old, and needing updating. Input from ACAC is pending. An updated contract has been approved bu the CFP Executive Board and sent to ANAB. Vijay Krishna requested the revised contract, and gave an update on ANAB accreditation process.

Item 5: An overview of committee discussion and voting in the virtual environment was presented to inform the members and faciltate effective discussion in this format.

Item 6: Action to date on Issue 2020 II-004 was reviewed by Chair Quam and asked for the will of the Committee. Hawley recommended no change to the current five-year certification term, as the Committee has been presented no compelling basis for the change. Anderson, Eastwood, and Wynne concurred. Krishna offered information on the process to accredit certification organizations, including that JTAs supporting the exam validity must be periodically updated at a frequency that would keep exams aligned with changes to the Food Code.

A straw poll was called for to gauge the sense of the Committee. Hawley moved and Halbrook seconded that the Committee formulate a response statement that the Committee does not support the proposed change to a four-year certification term; motion passed unanimously with 17 yeas, 0 nays, 0 abstentions.

Discussion ensued and it was determined a workgroup would form to draft the response.

Item 7: Meeting Schedule – the next meeting is scheduled for August 3, 2022, from 2-4 PM east. Members were reminded to save the dates for the 2023 Biennial Meeing in Houston, and to stay alert for Council formation notices in May or June, and Council applications in July.

The meeting adjourned at 2:46 PM eastern by unaimous acclimation.

###

FOOD PROTECTION CERTIFICATION COMMITTEE
Minutes of the Meeting | August 3, 2022 | 2-4 PM eastern

Attendance ~~strikethrough~~ indicates absence

Chairs/Voting: Chair Quam, Vice Chair Daniel, ~~Allen~~, Anderson, Burns Savage, Ciarimboli, Corchado Torres, ~~Derr~~, ~~Dolhanyk~~, Dwyer, Eastwood, Halbrook, Hawley, ~~Huffman~~, ~~Jackson~~, ~~Koester~~, Luebkemann, Paster Cammarata, Piche, Reich, ~~Roughan~~, Smith C., Smith M., Straughn, ~~Sweet~~, Wiedmeyer, ~~Wilson~~, Woods, ~~Wynne~~ [18 of 28 voting members present].

Non-voting: Morris, ~~Albrecht~~, Baker, Conley, ~~Duggins~~, ~~Gillam~~, Johnson, Krishna, ~~Morrison~~, Pollock, ~~Rivas~~, Unkart, Williams, Wittry.

Interested Parties & Guests: Tiffany Vowell.

Agenda Items

1. Welcome & Roll Call
2. CFP Anti-trust Statement
3. Approval of Minutes
4. Workgroup reports
   a. Standards
   b. Issue II-004 Response
5. Issue development
   a. Committee Report
   b. Changes to the Standard
   c. Changes to Committee Bylaws
   d. Issue II-004
6. Discussion format
   a. Speaker recognition – raise hand virtually
   b. Voting – roll call vote
7. Next Meeting – 10-05-2022, 2-4:00 pm EDT

Minutes

Items 1-2: Welcome & Roll Call – Chair Quam called the meeting to order at 2:00 PM eastern on a virtual meeting platform; roll was called, and a quorum established. Melissa Smith has been added to the FPMCC voting roster representing State Food Safety and succeeding Bryan Chapman. The antitrust statement was referenced, and made available in the “chat” feature.

Item 3: Minutes will be reviewed and approved at a later date.

Item 4: Workgroup reports

a. Standards – Piche advised the Committee that the workgroup has met, is developing changes, and will present them at the October FPMCC meeting.
b. Issue II-004 Response – a workgroup was formed and drafted a response to this issue (inserted below); Chair Quam presented the draft response, minor edits were suggested by the committee members, and a final draft completed and approved by the committee.

Item 5: Issue development – Chair Quam reported the following items will be developed / finalized for review by the FPMCC then submitted to the CFP Executive Board:

a. Committee Report
b. Changes to the Standard
c. Changes to Committee Bylaws
d. Issue II-004 response

Item 6: An overview of committee discussion and voting in the virtual environment was presented to inform the members and facilitate effective discussion in this format.

Item 7: Meeting Schedule – the next meeting is scheduled for

The meeting adjourned at 2:41 PM eastern by unanimous consent.

Draft FPMCC Response to 2020 II-004
Issue 2020 II-004

The Food Protection Manager Certification Committee is to review the impact and feasibility of changing the frequency of required certification examination to a time period not to exceed four years from date of issuance, aligning knowledge demonstration by examination with the routine four-year update and publication of the FDA Retail Food Code.

Public Health Significance

The FPMCC committee thoroughly reviewed the impact and feasibility of reducing the maximum to four years and concluded that no change to the current maximum of five years for certification validity is warranted. The committee met four times to discuss the pros and cons of reducing the period to four years and found the negative impact a change would have on the industry, and jurisdictions where CFPMs are mandated, to be significant. These negative impacts included:

1. Staff shortages within the Food Industry coupled with the increased expense associated with maintaining certification for retail food facilities may place an undue burden on foodservice owners/operators.

2. Insufficient evidence exists that more frequent Food Manager Certification renewals would lead to fewer food borne illness outbreaks or improved public health outcomes.

3. Given the delay in FDA Model Food Code adoption by State/Territorial/Local jurisdictions as well as the time necessary to modify course materials and examinations, increasing the recertification timeframe to four years may be an impossible task.

Recommended Solution: The Conference recommends…
No change to the frequency of required certification examination from the current maximum of five years.

###

FOOD PROTECTION CERTIFICATION COMMITTEE
Minutes of the Meeting | October 5, 2022 | 2-4 PM eastern

Attendance ~~strikethrough~~ indicates absence

Chairs/Voting: Chair Quam, Vice Chair Daniel, ~~Allen~~, Anderson, Burns Savage, Ciarimboli, Corchado Torres, ~~Derr~~, ~~Dolhanyk~~, ~~Dwyer~~, Eastwood, Halbrook, Hawley, Huffman, Jackson, Koester, ~~Luebkemann~~, Paster Cammarata, Piche, ~~Reich~~, Roughan, Smith C., Smith M., ~~Straughn~~, ~~Sweet~~, Wiedmeyer, ~~Wilson~~, Woods, Wynne [20 of 28 voting members present]

Non-voting: ~~Morris~~, ~~Albrecht~~, Baker, Conley, Duggins, ~~Gillam~~, ~~Johnson~~, Krishna, Morrison, Pollock, ~~Rivas~~, Unkart, Williams, Wittry

Interested Parties & Guests:

Agenda Items

1. Welcome & Roll Call
2. CFP Anti-trust Statement
3. Standard workgroup report – review Standards updates proposed by the workgroup
4. CFP ACAC Representative
5. Issue development
   a. Committee Report
   b. Changes to the Standard
   c. Changes to Committee Bylaws
   d. Issue II-004
6. Discussion format
   a. Speaker recognition – raise hand virtually
   b. Voting – roll call vote
7. Next Meeting – 12-07-2022, 2:00-4:00 pm EDT

Minutes

Items 1-2: Welcome & Roll Call – Chair Quam called the meeting to order at 2:05 PM eastern on a virtual meeting platform; roll was called, and a quorum established. The antitrust statement was referenced in the "chat" feature. An overview of committee discussion and voting in the virtual environment was presented to inform the members and facilitate effective discussion in this format (**Item 6**).

Item 3: Standard Workgroup report – workgroup Chair Piche thanked the members of the group and referenced the proposed changes (see separate attachment) that were emailed to the FPMCC in September for review. Piche presented the changes as a whole, and hearing no comments offered when called for, Hawley moved and Paster Cammarata seconded acceptance of all changes; motion approved by unanimous consent using "hands raised" and audio in the virtual platform.

In other Standards business, Vijay Krishna requested some clarifications on behalf of ANAB (inserted below).

Item 4: CFP ACAC Representative – Chair Quam advised that the current CFP ACAC members Julie Albrecht and Sherri Morris. Albrecht is retiring and seeks to be replaced. Krishna offered comments on the role of ACAC representative, the time commitment, meeting cadence, and typical agenda items such as matters of non-compliance or non-conformities to the Standard, and that the nominee must avoid

conflicts of interest with the certifying bodies. Chair Quam advised that Jeff Hawley has volunteered to take on this role; Hawley referenced his over 20-year involvement on the FPMCC committee, work with the Standard, expressed willingness to serve as CFP ACAC representative, and as he is retiring from his constituency he would welcome the opportunity to remain involved with the FPMCC.

Halbrook moved, Roughan seconded Hawley's nomination as CFP ACAC representative; role call vote resulted in 18 yeas and 1 abstention (Hawley) for unanimous approval

Item 5: Issue development – Chair Quam advised these four issues will be presented at the 2023 Biennial Meeting, and committee will be provided review drafts for review prior to submission:

a. Committee Report
b. Changes to the Standard
c. Changes to Committee Bylaws
d. Issue II-004

Unagendaed New Business Item 1:
The FPMCC was advised that during its October 4, 2022 meeting the CFP Executive Board discussed Prometric's voluntary withdrawal from ANAB accreditation, that Prometric ceased CFPM exam administration at the end of August 2022, and that communication from CFP may be appropriate in this regard. The Executive Board requested FPMCC input on this, including addressing validity of Prometric certificates issued prior to termination of their ANAB accreditation.

Discussion ensued, and it was suggested that information for the public would be helpful, including linking to Prometric's voluntary withdrawal notice posted on the ANAB website and that certain Prometric certifications remain valid. Chair Quam will appoint a workgroup draft to an explanation of this matter for posting on the CFP website, and report back to the Executive Board; George Roughan volunteered for the workgroup.

Unagendaed New Business Item 2:
Chair Quam reported that the final updated ANAB contract was presented to the Executive Board during its October 4, 2022 meeting and approved. Chair Quam thanked Jeff Hawley for successfully leading the contract update workgroup. The Executive Board also approved the FPMCC Fall Progress Report, roster changes, and vote regarding Issue II-004.

Item 7: Meeting Schedule – the next meeting is scheduled for

The meeting adjourned at 2:48 PM eastern by unanimous consent.

###

Conference for Food Protection Standard for Accreditation of Food Protection Manager Certification Programs (2021): ANAB Feedback/Requests for Clarification

Conference for Food Protection Manager Certification Committee responses in red text.

Clause	ANAB Feedback/Request for Clarification
1.20	The 2021 revision removed the requirement of "at least 25% alternate questions" between examination forms. Why was this removed? Is there no longer a maximum overlap requirement? What is considered acceptable overlap? Please revise for clarity. This is a definition, not a standard and previously it was indicated we should not be too prescriptive and to allow this type of specificity to be provided in a guidance document that ANAB would create to accompany the Standard.
1.25 and 1.36	Does just checking for discrimination suffice as checking for exposure/cheating? Are there additional checks that should be required? Please revise for clarity. This is a definition, not a standard and previously it was indicated we should not be too prescriptive and to allow this type of specificity to be provided in a guidance document that ANAB would create to accompany the Standard.
1.30, 4.1 B., 4.3 D.	We understand "available items" and "active items" to mean items that have been pretested and are usable (i.e., they have acceptable stats). However, certification organizations may understand "available" and "active" to mean items that have been written but not necessarily pretested/have acceptable stats. Please revise for clarity. We will revise in the next certification committee cycle
1.8, 1.9, 1.32, 1.32 B., 4.3 B., 4.5	Are knowledge, skills, and abilities required (all 3)? Or are just knowledge areas acceptable? Please clarify and revise as needed. We will revise in the next certification committee cycle
1.34	We understand "legally defensible" to include being "psychometrically sound" (valid and reliable). Please revise for clarity. We will revise in the next certification committee cycle
5.4 A.	ANAB as the accreditation organization does not approve scoring methods. We suggest revising "by methods approved by the accrediting organization" to "by nationally accepted scoring methods." This will be completed this committee period.
5.4 A. and B.	We understand the requirements that "no official scoring is to be done at the test site" and "scores will not be released as being official until verified and approved" to apply to paper/pencil tests. Computer-based testing (at a test site or via remote proctoring) that uses an algorithm to score the exam is acceptable. Please revise for clarity. This will be completed this committee period.
5.11 B.	We interpret this requirement to apply only to test sites/test centers (not remote proctoring). Please revise for clarity. This will be completed this committee period.
5.13 C. and D.	We interpret these requirements to apply only to test sites/test centers (not remote proctoring). Please revise for clarity. This will be completed this committee period.
Overall	Replace references to ANSI with references to ANAB throughout. We will revise in the next certification committee cycle
Overall	Please fix spacing issues and other typos throughout. This will be completed this committee period.

Template approved: 7/13/2021

Standing Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME *Constitution Bylaw & Procedures Committee*

DATE OF FINAL REPORT: *11/18/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: **Davene Sarrocco-Smith and Sean Dunleavy**

COMMITTEE CHARGE(S):

1. ***Issue # 2020 II-006***
   - **a.** These governing documents be reviewed on a recurrent basis every biennium, prioritized in this manner: 1. Constitution 2. Biennial Meeting/CFP Procedures document 3. Position descriptions 4. Policy documents
2. Since Issue ***# 2020 II-006*** mandated reoccurring review this language needs to be incorporated into the Constitution.

3. ***Issue #2020 II-010***

a. Representation from the Constitution and ByLaws Committee on the Local Regulatory Representation Committee.

4.Item 1.8.3 from April 2022 Executive Board meeting

a. Constitution, Bylaws, and Procedures (CB&P) Committee to update the "CFP Biennial Meeting/Conference Procedures" document with the policy change regarding membership effective dates and submit the revised document for Board review and approval.

b. CB&P Committee to draft an Issue for the 2023 Biennial Meeting to amend the governing documents to reflect the membership effective date change.

5. Item 1.8.3 from April 2022 Executive Board meeting

a. Constitution and Bylaws/Procedures Chair to work with the Executive Assistant to ensure concerns addressed on pages 3-4 in the Executive Assistant's report are merged with activities related to document review and retention. (record retention)

b.CB&P Committee to start review of Policy documents prior to Position Descriptions so that

they can provide assistance and direction to the Ad Hoc Committee that will be created April
2023.

c. At the April 2023 Board Meeting, an ad hoc committee is to be created for the 2023-2025 biennium to address concerns regarding document retention.

6. Provide clarifying Constitutional language for Article XV Section 1, Subsection 2 regarding Committees and Federal partners.

Committee Work Plan and Timeline:

1. Harmonize the Biennial Meeting CFP Procedures document with the 2021 delegate approved Constitution and ByLaws.
2. Evaluate current policies (2) regarding record retention. Develop CFP document spreadsheet and evaluate those documents pursuant to record retention and provide recommendations.
3. Vice Chair participation on the Local Regulatory Representation Committee.

Committee Activities: Dates of committee meetings or conference calls: 2/1,2/15, 3/1, 3/15, 3/29, 4/5, 4/19, 5/3, 5/17, 6/7, 6/21, 7/5, 7/19, 8/2, 8/16, 8/30, 9/20, 10/18, and 11/1/22. Committee votes occurred via email.

1. ***Overview of committee activities:***
   - **1.a.** Started by wordsmithing the CFP Biennial Meeting and Procedures document. Reached a point and found the organization within the document to be jumbled; the Procedures document did not flow with the proceedings of the Biennial Meeting. CB & P Committee took a step back and reorganized existing contents of document. Started wordsmithing again and adding clarity to content. The CB & P Committee formatted and reorganized the CFP Biennial Meeting/Conference Procedures document as well as harmonized with the current version of the CFP Constitution and Bylaws. The completed draft is a step-by-step process of the CFP's Biennial Meeting and Conference Procedures that a new member could use and understand what and how things take place. Our objective was to provide clarity while being explanatory in this functional procedural document.

   - **1.b.** Looked at 2 current policies regarding record retention. Developed CFP document spreadsheet using Executive Assistants Board report list. Created standard 8 questions for evaluation of each document on the spreadsheet. Created policy for policies and policy template. Collected recommendations throughout the process to aid in developing final recommendations.

   - **1.c.** Chair and Vice Chair conferred on item 1.8.3 regarding registration policy change provided to Conference Chair & Vice Chair June 3, 2022.

   - **1.d.** Vice Chair attended 5-6-22, 6-3-22, 7-15-22, 8-5-22 Local Regulatory Representation Committee meetings.

2. ***Charges COMPLETED and the rationale for each specific recommendation:***

A.a. Constitutional language for Article XVI Section 3 Subsection 1, regarding CB & P duties, added and approved by Executive Board on May 17, 2022.

A.b. Draft version of CFP Biennial Meeting/Conference Procedures document completed and unanimously approved by committee and approved by Executive Board on October 5, 2022, and became effective then.

A.c. Item 1.8.3 registration Constitutional language change for Article III Section 4, regarding registration and membership, approved by Executive Board on November 18, 2022.

A.d. Vice Chair participated on Local Regulatory Representation Committee.

A.e. Constitutional language for Article XV Section 1, Subsection 2, regarding Committees and Federal partners, approved by Executive Board on November 11, 2022.

3. ***Charges INCOMPLETE and to be continued:***

3.a. Report with final recommendations to the Executive Board regarding Record Retention to be provided at Spring 2023 Board meeting.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☐ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☒ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

1. *After the Assembly approves Constitutional changes, those changes be automatically sent to the Constitution and ByLaws Committee. The CB & P will review the CFP Constitution and ByLaws and CFP Biennial Meeting/Conference Procedures document and update all sections that would apply to the changes the Assembly of Delegates approved. Reasoning: to attempt to keep the two governing documents updated and consistent with each other.*

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. *Issue #1: Report – Committee Name:* List of content documents submitted with this Issue: *Committee Member Roster:*

☐ ***See attached revised roster PDF*** ☐ ***No changes to previously approved roster***

"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) *Other content documents: CFP Biennial Meeting/Conference Procedures document*

b. List of supporting attachments: ☐ ***Not applicable***

(b.i.1)

1. ***Committee Issue #2***: CB & P duties; Constitution Article XVI
2. ***Committee Issue #3***: Federal partners and Committee membership; Constitution Article XV

3. ***Committee Issue#4***: Membership; Constitution Article III

Committee Nam	Constitution, Bylaws and Procedures							
Last Name	**First Name**	**Position (Chair/Member)**	**Constituency**	**Employer**	**City**	**State**	**Telephone**	**Email**
Sarrocco-Smith	Davene	Chair	Emeritus		Dallas	GA	440-476-2429	davenesarrocco@yahoo.com
Dunleavy	Sean	Vice Chair	Emeritus		Howell	MI	517-861-7991	sdunleavy67@gmail.com
Bacon	Brenda	voting	Emeritus 7-22					baconbc@outlook.com
Sanchez	Angela	voting	Industry Retail Food	Amazon	Nashville	TN		ajaynethomas@yahoo.com zanglas@amazon.
Woodbury	Thomas	Voting	Industry Support	ComplianceMate	Holladay	UT	801-330-9511	thomas.g.woodbury@gmail.com
Sparks	Christopher	voting	Local Regulatory	Houston Health Dept.	Houston	TX		christopher.sparks@houstontx.gov
Burns-Savage	Nikki	voting	Local Regulatory	Southern Nevada Health District	Las Vegas	NV		ntburns@cox.net
Cartagena	Mary	FDA Consultant	Federal Regulatory				240-402-2937	**Mary.Cartagena@fda.hhs.gov**
Lewis	Glenda	FDA Alternate	Federal Regulatory				240-402-2150	**Glenda.Lewis@fda.hhs.gov**
Hazard	Tennetta	USDA Consultant	Federal Regulatory					Tennetta.hazard@usda.gov

Constitution & Bylaws	governing
Biennial Meeting/Conference Procedures	governing
Position Descriptions	
EXECUTIVE Administration Positions	
Board Member	governing
Director	governing
Executive Treasurer	governing
Executive Assistant	governing
LEADERSHIP Positions	
Conference Chair	governing
Conference Vice Chair	governing
Immediate Past Chair	governing
COUNCIL Positions	
Council Chair	governing
Vice Chair	governing
Council Member	governing
Council Scribe	governing
Council Runner	governing
Parliamentarian	governing
App Liaison	governing
STANDING Committee Positions	
Audit Committee Chair	governing
Constitution & Bylaws Committee Chair	governing
Finance Committee Committee Chair	governing
Food Protection Manager Certification Committee Chair	governing
Issue Committee Committee Chair	governing
Nominating Committee Chair	governing
Program Committee Chair	governing
Program Standards Committee Chair	governing
Publications Committee Chair	governing
Resolutions Committee Chair	governing
Strategic Planning Committee Chair	governing
Committee Chair Handbook	governing
Policies	
Antitrust Policy	governing
Archiving CFP Documents	governing
Audit Policy	governing
Commercialism & Comity Policy	governing
Crumbine Award Policy	governing

Late Issue Submission Policy	governing
Open Meeting Policy	governing
Record Retention Policy	governing
Travel Subsidy Policy	governing
Conference Spokesperson Policy	governing
Invoice Approval Policy	governing
Privacy Policy	governing

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COMMITTEE NAME Program Standards Committee (PSC)

DATE OF FINAL REPORT: *11/18/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☐ ***Council II*** ☐ ***Council III*** ☒ ***Executive Board***

REPORT SUBMITTED BY: Angie Wheeler, Chair; Kenesha Williamson, Co-Vice Chair; DeBrena Hilton, Co-Vice Chair

COMMITTEE CHARGE(S):

Issue # __2020 II-017_____

1. Identify inconsistencies in language between all Standards in the Retail Program Standards
2. Continue review of initiatives (existing, new or under development) involving the training, evaluation and/or certification of food safety inspection officers to ensure the sharing of information and eliminate unnecessary redundancy in the creation of work products or assignments of tasks/responsibilities
3. Maintain the "Crosswalk – Requirements for Foodborne Illness Training Programs" document as a resource for content baseline for foodborne illness training

Issue # __2020 II-023_____

1. The Program Standards committee and FDA staff continue to explore the feasibility of incorporation of plan review functions into the standards either as a stand-alone standard or inserted into the existing standards in the Voluntary National Retail Food Regulatory Program Standards
2. Acknowledgement of the Preliminary Plan Review Proposal document to be utilized as a starting point for the Program Standards Committee work on this issue

Issue # __2020 II-033_____

1. Conduct a thorough review of Standard 5 "Foodborne Illness and Food Defense Preparedness and Response of the FDA Voluntary National Retail Food Regulatory Program Standards (VNRFRPS).
2. The review should include comparing the Standard to other similar FDA standards in food.
3. Review the "Description of Requirements" to ensure the requirements provide program flexibility and include items generally part of a retail food program.
4. Review Standard 5 "Data Review and Analysis" from a sampling of jurisdictions to determine if certain data analysis requirements typically have no or such limited data to make the information not valuable.
5. Review the Center for Disease Control and Prevention's National Environmental Assessment Reporting System (NEARS), Environmental Assessment Training Series (EATS), and Council to Improve Foodborne Outbreak Response (CIFOR) to consider inclusion of specific components.
6. Propose amendments to Standard 5 of the VNRFRPS.
7. Report back committee findings and recommendations to the next Biennial Meeting.

Subcommittee #5 Retail Program Standards Symposium

This subcommittee worked to develop the agenda and identify speakers for a 2 ½ day virtual meeting in 2022 focused on sharing information about the Retail Program Standards. The co-chairs of the subcommittee, as well as other Program Standards Committee members, worked with NEHA on the symposium. The dates of the symposium were June 7-9, 2022.

COMMITTEE WORK PLAN AND TIMELINE: The assigned charges were divided into 5 subcommittees. Each subcommittee set their workplan and timeline with a goal for all subcommittees to complete their work by 10/31/22 and then draft issues for pre-submittal.

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

a. PSC leadership met on November 3, 2021.

b. Full PSC meeting was held on November 16, 2021. Members interest in a specific subcommittee

was gathered. Subcommittee co-chairs were assigned in December 2021.

c. PSC leadership met on January 6, 2022, to discuss the subcommittee assignments.

d. Subcommittee 2 co-chairs met on January 6, 2022, to discuss the charges, develop a base plan for meeting charges, meeting dates, meeting platforms and set agenda for the first meeting.

e. Subcommittee 1 met on January 13, 2022, February 17, 2022, March 15, 2022, April 19, 2022, May 31, 2022, June 28, 2022, August 24, 2022, and September 8, 2022.

f. Subcommittee 2 met on January 18, 2022, February 15, 2022, March 15, 2022, April 19, 2022, and July 19, 2022.

g. PSC leadership met with FDA to discuss the Standard 6 worksheet as well as other changes to the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) on January 24, 2022.

h. Subcommittee 3 met on January 25, 2022, February 8, 2022, February 28, 2022, April 11, 2022, April 25, 2022, September 8, 2022 and October 25, 2022. Additional meetings have been also held with the FDA, PSC Chair and subcommittee co-chairs during the preparation of the Issue documents to ensure that FDA is aware of what is being submitted.

i. Subcommittee 4 met on February 23, 2022, March 21, 2022, April 18, 2022, May 25, 2022, June 22, 2022, July 27, 2022, August 31, 2022, September 23, 2022 and October 20, 2022.

j. Subcommittee 5 met bi-weekly beginning on February 4, 2022, through June 6, 2022.

k. Full PSC met on March 1, 2022, and August 18, 2022. A full committee meeting is also planned for December 2022 to review the Issues submitted.

l. Subcommittee 5 co-chairs, NEHA and the PSC Chair and Co-Vice Chairs met with FDA representatives on March 24, 2022 to discuss the needs for the Retail Program Symposium in June 2022.

m. Subcommittee 5 chair met with FDA consultants on March 30, 2022 to further discuss support needs for the Retail Program Symposium.

n. The PSC leadership, along with subcommittee 1 co-chairs, met with representatives from FDA on June 23, 2022 to discuss re-standardization requirements for those that don't standardize others.

o. The subcommittee co-chairs, along with the PSC leadership met on May 3, 2022, and August 18, 2022.

p. Subcommittee 1 leadership, subcommittee members, the PSC Chair and FDA met on August 23, 2022 to discuss Issue 2020 II-31. It was determined that this subcommittee would look further at this issue as part of their charges even though it was not assigned to the PSC for action.

q. The PSC chair attended a meeting of the Clearinghouse Workgroup on September 8, 2022 to get instructions for pilot testing a new Retail Program Standards reference system database that's being developed for the interpretations.

r. The PSC chair provided feedback on two items sent to the Clearinghouse Workgroup for an interpretation on 10/5/22.

s. The chair, co-vice chair and some of the PSC members attended a meeting with FDA on 11/10/22 to be briefed on VNRFRPS related activities that the FDA is considering. Issue documents from the PSC related to what was discussed during the meeting was also shared with FDA.

2. ***Overview of committee activities:***

a. The Chair and Co Vice-Chairs developed the committee roster from those who expressed interest in participating on the PSC. There has been turnover of members, including the local representative serving as the Co-Vice Chair. Additional members were solicited and added to the roster. Five subcommittees were formed to work on the charges. Microsoft Teams folders were created for each of the subcommittees. All the subcommittees have been routinely meeting to work on their assigned charges.

b. Issue 2020 II-17 Charges 1 and 2 (subcommittee #1) reviewed the committee charges,

determined the timeline for addressing charges and decided to use Microsoft Teams for document sharing. A preliminary discussion of the VNRFRPS and review of poll responses regarding initial feedback on any known gaps within the VNRFRPS was conducted. Charge 2 was addressed during the February 3, 2022 call, and a list of training, evaluation and/or certification courses available to food safety inspection officers was reviewed based on the draft created during the last biennium. Starting February 17, 2022, the committee started work on edits to the list of training, evaluation and/or certification courses. The addition and removal of entries to the list of courses was completed through screen sharing. Committee members provided feedback on their review assignments. Changes to member assignments were made based on the feedback and overall experience with the VNRFRPS.

At the request of our FDA consultants, a special meeting was held on March 15, 2022 for Standard 6 to discuss the Standardized Key Crosswalk to the 2017 FDA Food Code and the Compliance and Enforcement worksheet. For this discussion, we hosted issue submitter Dan Joseph from State of Colorado. The conference call on April 19, 2022 was another special session which focused on Standard 8. Issue submitter Jo Ann Monroy presented at the meeting to review their staffing model pilot study on Standard 8 – Program Resources. On May 31, 2022 the committee began discussing the updates from the workgroups to review their assigned Standards. As each workgroup presented, the group screenshared the notes and discussions within the CFP Microsoft Teams folder. On June 28, 2022, the workgroups screenshared notes within the CFP Microsoft Teams folders and discussed possible Issues to be drafted for Standard 2 and 3 in the coming months.

c. Issue 2020 II-17 Charge 3 and Issue 2020 II-33 Charge 5 (subcommittee #2): During each meeting, members were assigned sections of the Crosswalk-Requirements for Foodborne Illness Training Programs to evaluate and report updates and changes at the next meeting. Subcommittee members has reviewed NEARS, EATS and CIFOR to consider including additional components in VNRFRPS Standard 5. The subcommittee review has been finalized with no major changes or revisions noted. They do recommend adding a reference/resource information regarding the Crosswalk document to VNRFRPS Standards 2 and 5 to bring more awareness to the document as a resource. They will also be recommending cleanup of the documents on the CFP website so only the current version of the Crosswalk is available to reduce confusion.

d. Issue # 2020 II-023 (subcommittee #3) Issue documents have been drafted to incorporate plan review within Standard 3 as a new element seven as well as adding the new element to the self-assessment/verification audit form. Another Issue document has been drafted as well as to re-create the Plan Review Committee to update the CFP Plan Review Guidance document to include requirements in the current food code as well as incorporating food safety management system elements within the plan review document.

e. Issue 2020 II-33 Charges 1-4 & 6-7 (subcommittee #4) reviewed the charges, compared the VNRFRPS Standard 5 with the Manufactured Food Regulatory Program Standard 5 to determine if they can be aligned to achieve the desired outcomes. The committee solicited input from enrolled jurisdictions about concerns with VNRFRPS Standard 5 and possible guidance on solutions. They looked at whether the VNRFRPS need to be more flexible to achieve the intent of Standard 5. The committee determined that, at this time, Standard 5 was aligned with achieving the best approach to respond to foodborne illness outbreaks but a Road Map to assist jurisdictions on how to meet the standard would be a resource to include in the Standard. The Road Map would provide steps to set up relationships with other agencies involved with outbreak response and tools to collect and track data. They also determined that they would like to continue to work on charges 3, 4 & 5 from the Issue in the next biennium and an Issue has been drafted for this.

f. Subcommittee 5 co-chairs attended multiple meetings weekly and bi-weekly with stakeholders to develop the agenda, speakers, symposium layout, registration, and website development for a Retail Program Standards Symposium (RPSS). An initial Save the Date was developed, as well as a website. A timeline was developed as well as identification of the responsible individual(s) for each task. The registration announcement was drafted and registration for the symposium opened on March 24, 2022. An agenda grid was developed, and speakers and moderators were contacted. The final agenda and speaker information was completed on March 30, 2022. The RPSS was held June 7-9, 2022. Planning for the next RPSS in 2024 is underway.

3. ***Charges <u>COMPLETED</u> and the rationale for each specific recommendation:***
   a. Issue #2020 II-017 charges have been completed and Issue documents have been drafted recommending revisions to the VNRFRPS.
   b. Issue #2020 II-023 charges have been completed and Issue documents have been drafted to incorporate plan review within Standard 3 as well as to re-create the Plan Review Committee to update the CFP Plan Review document to the current food code as well as incorporating food safety management system elements within the plan review document.
   c. The Retail Program Standards Symposium (RPSS) was held in June 7-9, 2022. 958 individuals registered (not including speakers) for the RPSS, while 755 individuals attended the symposium. A complete breakdown of attendance is provided in the RPSS Post Event Data document. Planning for the next RPSS in 2024 has begun.
   d. Issue 2020 II-33 charges were completed but subcommittee members felt that charges 3, 4 & 5 could be explored further in the next biennium, so a continuation issue was drafted. The subcommittee also feels that a roadmap to assist jurisdictions on how to meet the standard would be a good resource to include in VNRFRPS Standard 5. An issue to continue work on developing the roadmap has been drafted.
4. ***Charges <u>INCOMPLETE</u> and to be continued to next biennium:***
   a. Issue 2020 II-33 charges 3, 4 & 5.
   b. Standing committee charges to review and update the VNRFRPS as well as the ongoing review and updating of the Crosswalk – Requirement for Foodborne Illness Training Programs Based on Standard 5

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***
☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1) ***Issue #1: Report – Program Standards Committee (PSC):*** **List of content documents submitted with this Issue:** ***Committee Member Roster: Program Standards Committee Roster***

☐ ***See attached revised roster PDF*** ☒ ***No changes to previously approved roster***

Other content documents:

(1) PSC6 Draft Program Standard 2 – NCS Added
(2) PSC7 Program Standards 2022 Standard 3 Requirements
(3) PSC7 Program Standards 2022 Standard 3 Self-Assessment and VA form edits
(4) PSC9 Program Standards 2022 Standard 5 Edits
(5) PSC9 Program Standards 2022 Definitions Edits
(6) PSC10 Draft Standard 6 Establishment File Worksheet Food Code Form 3A Based
(7) PSC11 Draft Standard 6 Standardized Key Crosswalk to the 2017 FDA Food Code
(8) PSC13 Draft Program Standard 2 Additional Exam Based on NCS
(9) PSC15 Proposed Revised Program Standards 3 SA VA Form to Include Plan Review
(10) PSC15 Proposed Revised Program Standard 3 Requirement to Include Plan Review
(11) PSC16 Standard 5 Roadmap Draft 10 22
(12) PSC16 Standard 5 Data Collection Template
(13) PSC17 Program Standards 2022 Standard 2 with Crosswalk added
(14) PSC17 Program Standards 2022 Standard 5 with Crosswalk added

2) **List of supporting attachments:** ☐ ***Not applicable***

a. PSC Subcommittee 1 Final Report
b. PSC Subcommittee 2 Final Report
c. PSC Subcommittee 3 Final Report
d. PSC Subcommittee 4 Final Report
e. PSC Subcommittee 1 Final Report Charge 2 supporting attachment
f. RPSS Post Event Data_Part1
g. RPSS Post Event Data_Part2
h. RPSS Post Event Data_Part3
i. RPSS Post Event Data_Part4
j. PSC2 2022 Program Standards Standard 1 Regulatory Foundation
k. PSC2 CFP Issue 2020 II-031
l. PSC3 & PSC5 2022 Program Standard 2 Appendix B-1
m. PSC4, PSC13 & PSC17 2022 Program Standards 2 Trained Regulatory Staff
n. PSC5 Course Descriptions and Objectives - FDA38 FDA39
o. PSC5 AFDO – Risk-Based Inspection Methods in Retail FD218
p. PSC6 & PSC13 National Curriculum Standard
q. PSC7 2022 Program Standards 3 Inspection Program Based on HACCP Principles
r. PSC7 RPS 2022 Standard 3 Self-Assessment and Verification Audit form
s. PSC8 RPS Standard 2 Trained Staff Instructions and Worksheet for a VA
t. PSC8 RPS Standard 6 Compliance Enforcement Inst and Worksheet for a VA
u. PSC9 & PSC17 Standard 5 FBI and Food Defense Preparedness and Response
v. PSC9 2022 Program Standards Definitions
w. PSC12 2022 Program Standards 8 Program Support and Resources
x. PSC12 Issue 2020 II-017 Packet
y. PSC4, PSC13 & PSC17 2022 Program Standards 2 Trained Regulatory Staff
z. PSC13 IFSS Framework Basic Advanced Feb 2021 first tab
aa. PSC13 IFSS Framework Basic Advanced Feb 2021 Color Chart
bb. PSC13 IFSS Framework Basic Advanced Feb 2021 Descriptors tab
cc. PSC14 & PSC15 Plan Review for Food Establishments Guide 2016
dd. PSC15 Annex 3 Ch. 8 Comp and Enf Const Insp and Approval 8-201.12 & 8-203.10
ee. PSC18 www.foodprotect.org – Crosswalk Screenshot
ff. PSC19 Issue 2020 II-033

2) ***Committee Issue #2***: PSC2 Assign 2020 II-031 to Program Standards Committee
3) ***Committee Issue #3***: PSC3 Tracking Versions Standard 2 Appendix B-1
4) ***Committee Issue #4***: PSC4 Re-standardization Frequency for staff not standardizing others
5) ***Committee Issue #5***: PSC5 Add FD218 to Standard 2 Post Curriculum
6) ***Committee Issue #6***: PSC6 Reference National Curriculum Standard in VNRFRPS Standard 2
7) ***Committee Issue #7***: PSC7 Std 3 Requirements and Self-Assessment & Verification Audit Form Edits
8) ***Committee Issue #8***: PSC8 Create Standard 4 Verification Audit Instructions
9) ***Committee Issue #9***: PSC9 Edits to Standard 5 and Definitions
10) ***Committee Issue #10***: PSC10 Standard 6 Establishment File Worksheet Form 3A
11) ***Committee Issue #11***: PSC11 Standard 6 Crosswalk Update
12) ***Committee Issue #12***: PSC12 Defining Standard 8 Verification Audit Parameters
13) ***Committee Issue #13***: PSC13 Add NCS Exam Option to Standard 2
14) ***Committee Issue #14***: PSC14 Recreate Plan Review Committee
15) ***Committee Issue #15***: PSC15 Incorporation of Plan Review into VNRFRPS Standard 2
16) ***Committee Issue #16***: PSC16 Development of a Roadmap for the requirements in VNRFRPS Standard 5
17) ***Committee Issue #17:*** PSC17 Referencing Crosswalk – Requirements for Foodborne Illness Training Program

18) ***Committee Issue #18:*** PSC18 Requirements for Foodborne Illness Training Program Crosswalk Content User Accessibility

19) ***Committee Issue #19:*** PSC19 Continuation of Issue 2020 II-033 Charges 3 4 & 5

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STANDARD 2 TRAINED REGULATORY STAFF

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STANDARD 2 TRAINED REGULATORY STAFF

This Standard applies to the essential elements of a training program for regulatory staff.

Requirement Summary

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have the knowledge, skills, and ability to adequately perform their required duties. These knowledge, skills, and abilities (i.e. competencies) are outlined in the FDA National Curriculum Standard (NCS). The NCS identifies the competencies needed by FSIOs for successful job performance. The NCS has been developed through Cooperative Agreements with FDA, by subject matter experts representing local, state, and federal jurisdictions. Several courses have been developed based on the competencies in the NCS, specifically the "GenEds". The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

STEP 1
Completion of curriculum courses designated as "Pre" in Appendix B-1 prior to conducting and independent routine inspections.

STEP 2
Completion of the following:

- A minimum of 25 joint field training inspections (or a sufficient number of joint inspections determined by the trainer and verified through written documentation that the FSIO has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments); and
- Successful completion of the jurisdiction's FSIO Field Training Plan similar to the process outlined in *Appendix B-2: Conference for Food Protection (CFP) Field Training Manual*.

STEP 3
Completion of the following:

- A minimum of 25 independent inspections; and
- Remaining course curriculum (designated as "post" courses) outlined in *Appendix B-1: Curriculum for Retail Food Safety Inspection Officers*.

STEP 4
Completion of a standardization process similar to the FDA standardization procedures.

STEP 5
Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

Description of Requirement

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have successfully completed the required elements of the 5-step training and standardization process:

- Steps 1 through 4 within 24 months of hire or assignment to the retail food regulatory program.
- Step 5 every 36 months after the initial 24 months of training.

Step 1: Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in pre-requisite courses designated with a "Pre" in Appendix B-1, for the following curriculum areas:

1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
2. Public Health Principles;
3. Food Microbiology; and
4. Communication Skills.

There are two options for demonstrating successful completion of the pre-inspection curriculum.

OPTION 1: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- FDA ORA U pre-requisite courses identified as "Pre" in Appendix B-1; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances.

Note: *The estimated contact time for completion of the FDA ORA U pre-requisite ("Pre") courses is 42 hours.*

OPTION 2: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- Successful completion of courses deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the FDA ORA U pre- requisite (Pre") courses; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances; and
- Successful passing of one of the four written examination options (described later in this Standard) for determining if a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the listed ORA U courses are available from the web site link at: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

Note: *While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:*

- *Logs/records that are completed based on sign-in sheets; or*
- *Information validated from the certificate at the time-of-issuance; or*
- *A college transcript with a passing grade or other indication of successful completion of the course; or*
- *Automated attendance records, such as those currently kept by some professional associations and state agencies, or*
- *Other accurate verification of actual attendance.*

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORAU courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the four written examination categories specified herein.

1. The Certified Food Safety Professional examination offered by the National Environmental Health Association; or

2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable; or

3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or

4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

Note: *Written examinations are part of a training process, not a standardization/certification process. The examinations listed are not to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.*

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer who has successfully completed all training elements (Steps 1 – 3) of this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "training" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

If the trainer determines that the FSIO has successfully demonstrated the required performance elements and competencies, a lower minimum number of joint field training inspections can be established for that FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan in Appendix B-2, to support the exception.

Note: *The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."*

Demonstration inspections are those in which the jurisdiction's trainer takes the lead and the candidate observes the inspection process. Training inspections are those in which the candidate takes the lead, and their inspection performance is assessed and critiqued by the trainer. The jurisdiction's trainer is

responsible for determining the appropriate combination of demonstration and training inspections based on the candidate's food safety knowledge and performance during the joint field inspections.

The joint field inspections must be conducted using a field training process and forms similar to ones presented in the *CFP Field Training Manual* included as Appendix B-2. The *CFP Field Training Manual* consists of a training plan and log, trainer's worksheets, and procedures that may be incorporated into any jurisdiction's retail food training program. It is a national model upon which jurisdictions can design basic field training and provides a method for FSIOs to demonstrate competencies needed to conduct independent inspections of retail food, restaurant, and institutional foodservice establishments.

Jurisdictions are not required to use the forms or worksheets provided in the *CFP Field Training Manual*. Equivalent forms or training processes can be developed. To meet the intent of the Standard, documentation must be maintained that confirms FSIOs are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments.

Note: *The CFP Field Training Manual is designed as a training approach providing a structure for continuous feedback between the FSIO and trainer on specific knowledge, skills, and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.*

- *The CFP Field Training Manual is NOT intended to be used for certification or licensure purposes.*
- *The CFP Field Training Manual is NOT intended to be used by regulatory jurisdictions for administrative purposes such as job classifications, promotions, or disciplinary actions.*

FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2013 *FDA Food Code*). The jurisdiction's trainer/food program manager can determine if the FSIO is ready to conduct independent inspections of risk category 1 establishments (as defined in Appendix B-3) at any time during the training process.

Note: *The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can in lieu of the 25 joint field inspections:*

- *Include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement; and*
- *The supervisor/training officer must observe experienced FSIOs conduct inspections to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.*

Step 3: Independent Inspections and Completion of ALL Curriculum Elements

Within 24 months of hire or assignment to the regulatory retail food program, Food Safety Inspection Officers must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1, for the following eight curricula areas, must be completed within this 24-month time frame.

1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
2. Public health principles (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
3. Communication skills (Step 1);
4. Food microbiology (some of the courses for this element are part of the pre-requisite curriculum outlined in Step 1);
5. Epidemiology;
6. Hazard Analysis Critical Control Points (HACCP);
7. Allergen Management
8. Emergency Management

All courses for each of the curriculum areas must be successfully completed within 24 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

> **Note:** *The estimated contact time for completion of the FDA ORA U "post" courses is 26 hours. The term "post" refers to those courses in Appendix B-1 that were not included as part of the pre-requisite coursework. This includes all the courses in Appendix B-1 that do not have the designation "Pre" associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.*

As with the pre-requisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses listed under each curriculum area OR by completing courses, deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the listed ORA U courses are available from the FDA website: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners.

Step 4: Food Safety Inspection Officer – Field Standardization

Within 24 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the "FDA Standardization Procedures." The jurisdiction's "training standard" must have met all the requirements for conducting field standardizations as presented in the definition section of these Standards. The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years.

Note: *The field standardization and continuing standardization (re-standardization) criteria described in Step 4 is intended to provide a jurisdiction the flexibility to use their own regulation or ordinance. In addition, the reference to using standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers, is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written standardization protocol must include the five performance areas outlined above in Step 4.*

It is highly beneficial to use the FDA Food Code, standardization forms and procedures even when a jurisdiction has adopted modifications to the Food Code. Usually, regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge, and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA's standardization procedures are based on a minimum of 8 inspections. However, to meet Standard 2, a minimum of 4 standardization inspections must be conducted.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel versed in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate

consistent evaluation of all candidates.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors and communicates vital information about the inspection in a way that can be received, understood, and acted upon by retail food management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to both the regulatory agency and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard 2 criteria within the 24- month time frame, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5: Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (24 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer.

Training on any changes in the regulatory agency's prevailing statutes, laws and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine activities that are related specifically to food safety or food inspectional work:

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local);
4. Food safety related conferences and workshops; and
5. Distance learning opportunities that pertain to food safety, such as:
    - Web based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and
    - Satellite Broadcasts.

A maximum of ten (10) contact hours may be accrued from the following activities:

1. Delivering presentations at professional conferences;
2. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
3. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period[1].

Note: *Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.*

A maximum of four (4) contact hours may be accrued for:

1. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- transcripts from a college or university;
- a letter from the administrator of the continuing education program attended;
- a copy of the peer-reviewed article or presentation made at a professional conference; or
- documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

Note: *The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of employee's continuing education activities, maintains the training records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses.*

Outcome

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);

2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process similar to that presented in Appendix B-2. **NOTE:** The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."
4. Certificates or other records showing proof of satisfactory standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successful completed the training and education steps outlined in this Standard.
7. Date of hire records or assignment to the retail food program; and
8. Summary record of employees' compliance with the Standard.

The *Standard 2: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 2.

STANDARD 3
INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

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STANDARD 3
INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

This standard applies to the utilization of HACCP principles to control risk factors in a retail food inspection program.

Requirement Summary

An inspection program that focuses on the status of risk factors, determines, and documents compliance, and targets immediate- and long-term correction of out-of-control risk factors through active managerial control.

Description of Requirement

Program management:

1. Implements the use of an inspection form that is designed for:
    a) The identification of risk factors and interventions.
    b) Documentation of the compliance status of each risk factor and intervention (i.e., a form with notations indicating IN compliance, OUT of compliance, Not Observed, or Not Applicable for risk factors)
    c) Documentation of all compliance and enforcement activities and
    d) Requires the selection of IN, OUT, NO, or NA for each risk factor.
2. Develops and uses a process that groups food establishments into at least three categories based on potential and inherent food safety risks.
3. Assigns the inspection frequency based on the risk categories to focus program resources on food operations with the greatest food safety risk.
4. Develops and implements a program policy ***that requires:
    a) On-site corrective actions* as appropriate to the type of violation.
    b) Discussion of long-term control** of risk factor options, and
    c) Follow-up activities.
5. Establishes and implements written policies addressing code variance requests related to risk factors and interventions.
6. Establishes written policies regarding the ~~verification and~~ validation <u>and verification</u> of HACCP plans when a plan is required by the code.

Outcome

The desired outcome of this standard is a regulatory inspection system that uses HACCP principles to identify risk factors and to obtain immediate- and long-term corrective action for recurring risk factors.

Documentation

The quality records needed for this standard include:

1. Inspection form that requires the selection of IN, OUT, NO, or NA,
2. Written process used for grouping establishments based on food safety risk and the inspection frequency assigned to each category,

3. Policy for on-site correction and follow-up activities,
4. Policy for addressing code variance requests related to risk factors and interventions,
5. Policy for verification and validation of HACCP plans required by code, and
6. Policy requiring the discussion of food safety control systems with management when out of control risk factors are recorded on subsequent inspections.

*Note: **On-site** corrective action as appropriate to the violation would include such things as:

a. Destruction of foods that have experienced extreme temperature abuse,
b. Embargo or destruction of foods from unapproved sources,
c. Accelerated cooling of foods when cooling time limits can still be met,
d. Reheating when small deviations from hot holding have occurred,
e. Continued cooking when proper cooking temperatures have not been met.
f. Initiated use of gloves, tongs, or utensils to prevent hand contact with ready-to-eat foods, or
g. Required hand washing when potential contamination is observed.

Note: **Long-term control of risk factors requires a commitment by managers of food establishments to develop effective monitoring and control measures or system changes to address those risk factors most often responsible for foodborne illness. Risk control plans, standard operating procedures, buyer specifications, menu modification, HACCP plans and equipment or facility modification may be discussed as options to achieve the long-term control of risk factors.

***Note: Consideration of the elements outlined in Standard 4 will ensure a strong foundation for a quality and uniform inspection program.

STANDARD 3 – INSPECTION PROGRAM BASED ON HACCP PRINCIPLES INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

Program Self-Assessment & Verification Audit Form

The *Standard 3: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 3. The form is included at the end of these instructions. Whether one is performing a program self-assessment or conducting a verification audit, it is recommended that the form be available as a reference to the Standards 3 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self-Assessment

Jurisdictions conducting a self-assessment of Standard 3 must indicate on the form if each of the listed criteria is met. These responses are recorded under the column "Jurisdiction's Self-Assessment."

Jurisdictions are not obligated to use this form. An equivalent form or process is acceptable provided that the results of the jurisdiction's self-assessment for the specific Standard 3 criteria listed on this form are available for review.

The *Standard 3: Program Self-Assessment and Verification Audit Form* is the only form a jurisdiction needs to use to record the results of their self-assessment. Standard 3 requires inspection policies to be established, written, and implemented. A policy without documentation of implementation does not meet the Standard 3 criteria.

The *Standard 3: Program Self-Assessment and Verification Audit Form* divides the Standard 3 criteria into six steps:

1. Inspection Form Design
    a. The jurisdiction's inspection form identifies foodborne illness risk factors and *Food Code interventions*.
    b. The jurisdiction's inspection form documents actual observations using the convention IN, OUT, NA, and NO.
    c. The jurisdiction's inspection form documents compliance and enforcement activities.
2. Risk Assessment Categories
    a. A risk assessment is used to group food establishments into at least 3 categories based on their potential and inherent food safety risks.
3. Inspection Frequency
    a. The jurisdiction's inspection frequency is based on assigned risk categories.
4. Corrective Action Policy
    a. The jurisdiction has a written and implemented policy that requires on-site corrective action for foodborne illness risk factors observed to be out of compliance.
    b. The jurisdiction has a written and implemented policy that requires discussion for long- term control of foodborne illness risk factors.
    c. The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations.
5. Variance Request Policy
    a. The jurisdiction has a written and implemented policy on variance requests related to foodborne illness risk factors and *Food Code* interventions.

6. ~~Verification and~~ Validation and Verification of HACCP Plan Policy
    a. The jurisdiction has a written and implemented policy for the ~~verification and~~ validation and verification of HACCP plans, when a HACCP plan is required by the *Food Code*.

The self-assessor must review each Standard 3 criterion and determine if the jurisdiction's source documents confirm that the Standard criteria are met. If the criteria are met, the self-assessor must place an "X" in the "YES" box under the "Jurisdiction's Self-Assessment" column of the *Standard 3: Program Self-Assessment and Verification Audit Form*.

If a review of the jurisdiction's source documents does not confirm that the Standard 3 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdiction*'s Self-Assessment" column of the* Standard 3: Program Self-Assessment and Verification Audit Form. The self-assessor may specify why the criteria are not met in the box provided.

The self-assessor should review the findings on the *Standard 3: Program Self-Assessment and Verification Form* to ensure accuracy. The jurisdiction will be required to provide the auditor with their completed *Standard 3: Program Self-Assessment and Verification Audit Form* and any documents used to support and demonstrate that the Standard 3 criteria have been met.

Once all the criteria have been reviewed and documented on the form, the self-assessor must complete the Program Self-Assessment Summary section on page one of the *Standard 3: Program Self-Assessment and Verification Audit Form*. The self-assessor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 3 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 3 criteria.

Documenting the Findings from the Verification Audit
The jurisdiction requesting the verification audit must provide their completed *Standard 3: Program Self-Assessment and Verification Audit Form* to the auditor for review. The auditor must indicate on the *Standard 3: Program Self-Assessment and Verification Audit Form* if the criteria were met.

If a review of the jurisdiction's source documents confirms the self-assessment conclusion that the Standard criteria are met, the verification auditor places an "X" in the "YES" box under the "Auditor's Verification" column of the form.

If a review of the jurisdiction's source documents does not confirm the self-assessment conclusion that the Standard criteria are met, the verification auditor places and "X" in the "NO" box under the "Auditor's Verification" column of the form. The verification auditor must specify why the criterion is not met in the box provided. Supplemental pages may be used to explain findings.

The jurisdiction must meet all six program performance criteria outlined in Standard 3.

The verification auditor must discuss their findings with the program manager or their appointed representative and provide constructive feedback at the conclusion of the on-site visit. In particular, any

Standard 3 criteria for which the auditor cannot confirm through a review of the self-assessment should be thoroughly discussed. Ample time should be allotted to ensure that there is a clear understanding of the reasons for the "non-conforming" finding. The auditor should be prepared to identify the elements required for the jurisdiction to meet the Standard.

Once the close out interview has been conducted, the auditor must complete the Verification Audit Summary section located on the first page of the *Standard 3: Program Self-Assessment and Verification Audit Form*. The auditor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 3 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 3 criteria if the auditor does not confirm the self-assessment findings.

Standard 3: Inspection Program based on HACCP Principles
Program Self-Assessment and Verification Audit Form

PROGRAM SELF-ASSESSMENT SUMMARY

Printed Name of the Person who conducted the Self-Assessment:	
Self-Assessor's Title:	
Jurisdiction Name:	
Jurisdiction Address:	
Phone:	
Fax:	
E-mail:	
Date the Standard 3 Self-Assessment was Completed:	
Self-Assessment indicates that the Jurisdiction MEETS the Standard 3 criteria (indicate YES/NO):	
I affirm that the information represented in the Self-Assessment of Standard 3 is true and correct. **Signature of the Self-Assessor:**	

VERIFICATION AUDIT SUMMARY

Printed Name of the Person who conducted the Verification Audit:	
Verification Auditor's Title:	
Auditor's Jurisdiction Name:	
Auditor's Jurisdiction Address:	
Phone:	
Fax:	
E-mail:	
Date the Verification Audit of Standard 3 was Completed:	
Verification Audit indicates that the Jurisdiction MEETS the Standard 3 criteria (indicate YES/NO):	
I affirm that the information represented in the Verification Audit of Standard 3 is true and correct. **Signature of the Verification Auditor:**	

Standard 3: Inspection Program based on HACCP Principles
Program Self-Assessment and Verification Audit Form

Jurisdiction Name: _____

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
1. Inspection Form Design	a) The jurisdiction's inspection form identifies foodborne illness risk factors and Food Code interventions						
1. Inspection Form Design	b) The jurisdiction's inspection form documents actual observations using the convention (IN, OUT, NO, and NA).						
1. Inspection Form Design	c) The jurisdiction's inspection form documents compliance and enforcement activities.						
2. Risk Assignment Categories	a) A risk assessment is used to group food establishments into at least 3 categories based on their potential and inherent food safety risks.						
3. Inspection Frequency	a) The jurisdiction's inspection frequency is based on the assigned risk categories.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
4. Written and Implemented Corrective Action Policy	a) The jurisdiction has a written and implemented policy that requires on-site corrective actions for foodborne illness risk factors observed to be out of compliance.						
4. Written and Implemented Corrective Action Policy	b) The jurisdiction has a written and implemented policy that requires discussion for long-term control of foodborne illness risk factors.						
4.Written and Implemented Corrective Action Policy	c) The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations.						
5. Variance Requests	a) The jurisdiction has a written and implemented policy on variance requests related to foodborne illness risk factors and Food Code interventions.						
6. ~~Verification and~~ Validation and Verification of HACCP Plans	a) The jurisdiction has a written and implemented policy for the ~~verification and~~ validation and verification of HACCP plans, when a HACCP plan is required by the Code.						

GENERAL NOTES PERTAINING TO THE PROGRAM SELF-ASSESSMENT OR THE VERIFICATION AUDIT

Voluntary National Retail Food Regulatory Program Standards

DEFINITIONS

The following definitions apply in the interpretation and application of these Standards.

1) **Active Managerial Control** – The purposeful incorporation of specific actions or procedures by industry management into the operation of a business to attain control over foodborne illness risk factors.
2) **Auditor** – Any authorized city, county, district, state, federal, tribal, or other third-party person who has no responsibilities for the day-to-day operations of that jurisdiction and is charged with conducting a verification audit, which confirms the accuracy of the self-assessment.
3) **Baseline Survey** – See Risk Factor Study.
4) **Candidate** - A regulatory officer whose duties include the inspection of retail food establishments.
5) **Compliance and Enforcement** – Compliance includes all voluntary or involuntary conformity with provisions set forth by the regulatory authority to safeguard public health and ensure that food is safe. Enforcement includes any legal and/or administrative procedures taken by the regulatory authority to gain compliance.
6) **Confirmed Foodborne Disease Outbreak** – means a foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiologic analysis implicates the food as the source of the illness or epidemiological analysis alone implicates the food as the source of the illness.
7) **Direct Regulatory Authority (DRA) –** The organizational level of government that is immediately responsible for the management of the retail program. This may be at the city, county, district, state, federal, territorial, or tribal level.
8) **Enforcement Actions –** Actions taken by the regulatory authority such as, but not limited to, warning letters, revocation or suspension of permit, court actions, monetary fines, hold orders, destruction of food, etc., to correct a violation found during an inspection.
9) **Follow-up Inspection –** An inspection conducted after the initial routine inspection to confirm the correction of a violation(s).
10) **Food Code Interventions** – the preventive measures to protect consumer health stated below:
    1. management's demonstration of knowledge;
    2. employee health controls;
    3. controlling hands as a vehicle of contamination;
    4. time / temperature parameters for controlling pathogens; and
    5. consumer advisory.
11) **Food-Related Injury** – Means an injury from ingesting food containing a physical hazard such as bone, glass, or wood.
12) **Foodborne Disease Outbreak** – The occurrence of two or more cases of a similar illness resulting from the ingestion of a common food. Foodborne Disease Outbreaks include both Suspect Foodborne Outbreaks and Confirmed Foodborne Disease Outbreaks.
13) **Good Retail Practices (GRP's)** – Preventive measures that include practices and procedures to effectively control the introduction of pathogens, chemicals, and physical objects into food, that are prerequisites to instituting a HACCP or Risk Control Plan and are not addressed by the *FDA Food Code* interventions or risk factors.
14) **Hazard** – A biological, chemical, or physical property that may cause food to be unsafe for human consumption.

15) **National Registry of Retail Food Protection Programs (National Registry) – A** listing of retail food safety programs that have voluntarily enrolled as participants in the *Voluntary National Retail Food Regulatory Program Standards*.
16) **Person in charge (PIC)** – The individual present at a food establishment who is responsible for the operation at the time of inspection.
17) **Program Element –** One of the program areas for which a National Standard has been established such as regulations, training, inspection system, quality assurance, foodborne illness investigation, compliance and enforcement, industry and consumer relations, and program resources.
18) **Program Manager** – The individual responsible for the oversight and management of a retail food regulatory program.
19) **Quality Records –** Documentation of specific elements of program compliance with the National Standards as specified in each Standard.
20) **Risk Control Plan (RCP)** – a concisely written management plan developed by the retail or food service operator with input from the health inspector that describes a management system for controlling specific out-of-control risk factors.
21) **Risk Factors** – the improper employee behaviors or improper practices or procedures in retail food and food service establishments stated below which are most frequently identified by epidemiological investigation as contributing to foodborne illness or injury:
    1. improper holding temperature;
    2. inadequate cooking;
    3. contaminated equipment;
    4. food from unsafe source; and
    5. poor personal hygiene.
22) **Risk Factor Study** (formerly Baseline Survey) – A study on the occurrence of foodborne illness risk factors within institutional, foodservice, restaurants, and retail food facility types under a jurisdiction's regulatory authority. Criteria for a Risk Factor Study are detailed in Standard 9, including at a minimum:
    1. Data Collection, analysis, and a written report;
    2. A collection instrument with data items pertaining to the five foodborne illness risk factors;
    3. A collection instrument that uses the convention of IN, OUT, NA and NO to document observations;
    4. All facility types identified by FDA's national study that are under the jurisdiction's regulatory authority; and
    5. Studies subsequent to the initial study repeated at 5-year intervals.
23) **Routine Inspection – A** full review and evaluation of a food establishment's operations and facilities to assess its compliance with Food Safety Law, at a planned frequency determined by the regulatory authority. This does not include re-inspections and other follow-up or special investigations.
24) **Self-Assessment** – An internal review by program management to determine whether the existing retail food safety program meets the *Voluntary National Retail Food Regulatory Program Standards*.
25) **Self-Assessment Update** – Comparison of one or more program elements against the *Voluntary National Retail Food Regulatory Program Standards* between the required 60-month periodic self-assessment.

26) **Standardization Inspection** – An inspection used to demonstrate a candidate's knowledge, communication skills, and ability to identify violations of all regulatory requirements and to develop a risk control plan for identified, uncontrolled risk factors.
27) **Suspect Foodborne Outbreak** – Means an incident in which two or more persons experience a similar illness after ingestion of a common food or eating at a common food establishment/gathering that did not meet the definition of a Confirmed Foodborne Disease Outbreak.
28) **Trainer** – An individual who has successfully completed the following training elements as outlined in Steps 1 – 3, Standard 2, and is recognized by the program manager as having the field experience and communication skills necessary to train new employees.
    1. Satisfactory completion of the prerequisite curriculum;
    2. Completion of a field training process similar to that contained in Appendix B-2; and
    3. Completion of a minimum of 25 independent inspections and satisfactory completion of the remaining course curriculum.
29) **Training Standard** – An individual who has successfully completed the following training elements AND standardization elements in Standard 2 and is recognized by the program manager as having the field experience and communication skills necessary to train new employees. The training and standardization elements include:
    1. Satisfactory completion of the prerequisite curriculum;
    2. Completion of a field training process similar to that contained in Appendix B-2;
    3. Completion of a minimum of 25 independent inspections and satisfactory completion of the remaining course curriculum;
    4. Successful completion of a standardization process based on a minimum of eight inspections that includes development of HACCP flow charts, completion of a risk control plan, and verification of a HACCP plan, similar to the FDA standardization procedures;
    5. Completion of a minimum of 20 contact hours of continuing education in food safety every 36 months after the initial training is completed as outlined in Standard 2; and
    6. Standardization maintained every three (3) years as outlined in Standard 2.
30) **Verification Audit** – A systematic, independent examination by an external party to confirm the accuracy of the Self-Assessment.

STANDARD 5
FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

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STANDARD 5
FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

This standard applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies, either unintentional or deliberate, which results in illness, injury, and outbreaks.

Requirement Summary

The program has an established system to detect, collect, investigate, and respond to complaints and emergencies that involve foodborne illness, injury, and intentional and unintentional food contamination.

Description of Requirement

1. Investigative Procedures

a. The program has written operating procedures for responding to and /or conducting investigations of foodborne illness and FOOD-RELATED INJURY. The procedures clearly identify the roles, duties, and responsibilities of program staff and how the program interacts with other relevant departments and agencies. The procedures may be contained in a single source document or in multiple documents.

b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, FOOD-RELATED INJURY or contamination of food.

c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties, and responsibilities of each party.

d. The program maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, FOOD-RELATED INJURY or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in or linked to the establishment record for retrieval purposes.

e. Program procedures describe the disposition, action or follow-up and reporting required for each type of complaint or referral report.

f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.

g. The program has established procedures and guidance for collecting information on the suspect food's preparation, storage or handling during on-site investigations of food-related illness, FOOD- RELATED INJURY, or outbreak investigations.

h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.

i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.

2. Reporting Procedures

a. Possible contributing factors to the food-related illness, FOOD-RELATED INJURY or intentional food contamination are identified in each on-site investigation report.

b. The program shares final reports of investigations with the state epidemiologist and reports of CONFIRMED FOODBORNE DISEASE OUTBREAKS with CDC.

3. Laboratory Support Documentation

a. The program has a letter of understanding, written procedures, contract, or MOU acknowledging, that a laboratory(s) is willing and able to provide analytical support to the jurisdiction's food program. The documentation describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.

b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).

4. Trace-back Procedures

a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak, or intentional food contamination. The trace-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.

5. Recalls

a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak, or intentional food contamination.

b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed.

c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.

6. Media Management

a. The program has a written policy or procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.

7. Data Review and Analysis

a. At least once per year, the program conducts a review of the data in the complaint log or database and the foodborne illness and FOOD-RELATED INJURY investigations to identify trends and possible contributing factors that are most likely to cause foodborne illness or FOOD-RELATED INJURY. These periodic reviews of foodborne illnesses may suggest a need for further investigations and may suggest steps for illness prevention.

b. The review is conducted with prevention in mind and focuses on, but is not limited to, the following:

1) FOODBORNE DISEASE OUTBREAKS, SUSPECT FOODBORNE OUTBREAKS and CONFIRMED FOODBORNE DISEASE OUTBREAKS in a single establishment;
2) FOODBORNE DISEASE OUTBREAKS, SUSPECT FOODBORNE OUTBREAKS and CONFIRMED FOODBORNE DISEASE OUTBREAKS in the same establishment type;
3) FOODBORNE DISEASE OUTBREAKS, SUSPECT FOODBORNE OUTBREAKS and CONFIRMED FOODBORNE DISEASE OUTBREAKS implicating the same food;
4) FOODBORNE DISEASE OUTBREAKS, SUSPECT FOODBORNE OUTBREAKS and CONFIRMED FOODBORNE DISEASE OUTBREAKS associated with similar food preparation processes;
5) Number of CONFIRMED FOODBORNE DISEASE OUTBREAKS;
6) Number of FOODBORNE DISEASE OUTBREAKS and SUSPECT FOODBORNE DISEASE OUTBREAKS;
7) Contributing factors most often identified;
8) Number of complaints involving real and alleged threats of intentional food contamination; and
9) Number of complaints involving the same agent and any complaints involving unusual agents when agents are identified.

c. In the event that there have been no food-related illness or FOOD-RELATED INJURY outbreak investigations conducted during the twelve months prior to the data review and analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate response to an actual CONFIRMED FOODBORNE DISEASE OUTBREAK and include on-site inspection, sample collection and analysis. A mock investigation must be completed at least once per year when no FOODBORNE DISEASE OUTBREAK investigations occur.

Note: *Regulatory Programs are encouraged to also participate in the CDC National Environmental Assessment Reporting System (NEARS). NEARS is designed to provide a more*

comprehensive approach to foodborne disease outbreak investigation and response and will provide a data source to measure the impact of food safety programs to further research and understand foodborne illness causes and prevention. (The following link provides additional information regarding NEARS: http://www.cdc.gov/nceh/ehs/nears/index.htm)

Outcome

A food regulatory program has a systematic approach for the detection, investigation, response, documentation, and analysis of alleged food-related incidents that involve illness, injury, unintentional or deliberate food contamination.

Documentation

The quality records required to meet this standard include:

1. Logs or databases of alleged food-related illness and FOOD-RELATED INJURY complaints maintained and current.
2. Collection forms specified in the operating procedures.
3. Investigation reports of alleged food-related illness, FOOD-RELATED INJURY, or incidents. Reports are retrievable by implicated establishment name.
4. The written procedures, contracts, or MOUs with the supporting laboratories.
5. The procedure addressing the trace-back of food products implicated in an illness, outbreak, or contamination event.
6. 21 CFR, Part 7, or written procedures equivalent to 21 CFR, Part 7 for recalls.
7. Completed copies of the annual review and analysis (after 12 months of data).
8. Current written media policy/procedure and contact person.
9. The contact list for communicating with all relevant agencies.
10. Portions of any emergency response relevant to food safety and security.

STANDARD 6: COMPLIANCE AND ENFORCEMENT
ESTABLISHMENT FILE WORKSHEET
Based on FDA Food Code Form 3A

File Number: _____ Establishment Name: _____ Permit Number: _____ Inspection Date (Start Point): _____

Risk Factor and Public Health Interventions

	Supervision	Employee Health	Good Hygienic Practices	Preventing Contamination by Hands	Approved Source	Protection from Contamination	Time/Temperature Control for Safety	Consumer Advisory	HSP Populations	Food Color Additives and Toxic Substances	Conformance with Approved Procedures
Reference to local inspection items	1, 2	3, 4, 5	6, 7	8, 9, 10	11, 12, 13, 14	15, 16, 17	18, 19, 20, 21, 22, 23, 24	25	26	27, 28	29
Start Point Inspection Violations											
Was on-site corrective action taken?											
Was follow-up corrective action taken?											
Was enforcement action taken?											

Note: Each column in which a violation is noted must receive a yes response to one of the three questions in order for the file to pass. Additionally, written procedures must have been followed

Was the Written Procedure Followed? _____ YES _____ NO

Jurisdiction's definitions of acronyms and notations used to reflect follow-up action

Acronym /Notation	Definitions	Acronym /Notation	Definitions	Acronym/Notation	Definitions

File Meets the Standard 6 Criteria: _____ YES _____ NO

Standardized Key Crosswalk to the 2017 FDA Food Code

This crosswalk is intended to assist jurisdictions in making comparisons with their code against the 2017 FDA Food Code. The Form 3-A Food Inspection Report Item numbers are based on the model FDA inspection form found in Annex 7 of the 2017 FDA Food Code. Completion of the crosswalk is intended to assist jurisdictions completing Standard 6 documentation which identifies major risk factors and public health interventions on the jurisdiction's inspection report form. Annex 5 contains additional information regarding the content of Form 3-A.

FBI Risk Factors and Interventions	Food Establishment Inspection Report (Form 3-A) Item Number	Applicable 2017 FDA Food Code References
Supervision		
PIC	1	2-101.11; 2-102.11(A), (B), (C)(1), (4)-(16); 2-103.11 (A), (P)
CFPM	2	2-102.12(A)
Employee Health		
Management	3	2-102.11(C)(2), (3), (17); 2-103.11(O); 2-201.11(A), (B), (C), (E)
Restriction and Exclusion	4	2-201.11(D), (F); 2-201.12; 2-201.13
Vomit and Diarrheal events	5	2-501.11
Good Hygienic Practices		
Eating, Tasting and Drinking	6	2-401.11; 2-301.12
Discharge from eyes, nose, and mouth	7	2-401.12
Preventing Contamination by Hands		
Hands Clean and Properly Washed	8	2-301.11; 2-301.12; 2-301.14; 2-301.15; 2-301.16
No Bare Hand Contact with RTE Foods	9	3-301.11; 3-801.11(D)
Adequate handwashing sinks	10	5-202.12; 5-203.11; 5-204.11; 5-205.11; 6-301.11; 6-301.12; 6-301.13; 6-301.14
Approved Source		
Food obtained from approved source	11	3-201.11-17; 3-202.13-14; 3-202.110; 5-101.13
Food Received at proper temperature	12	3-202.11
Food in good condition, safe and unadulterated	13	3-101.11; 3-202.15
Required records available, shellstock tags, parasite destruction	14	3-202.18; 3-203.12; 3-402.11; 3-402.12
Protection from Contamination		
Food Separated and Protected	15	3-302.11; 3-304.11; 3-304.15(A); 3-306.13(A)
Food Contact surfaces; cleaned and sanitized	16	4-501.111-115; 4-601.11(A); 4-602.11-12; 4-702.11; 4-703.11

FBI Risk Factors and Interventions	Food Establishment Inspection Report (Form 3-A) Item Number	Applicable 2017 FDA Food Code References
Proper disposition or returned, previously served, reconditioned and unsafe food	17	3-306.14; 3-701.11
Time/Temperature Control for Safety		
Cooking	18	3-401.11; 3-401.12; 3-401.14
Reheating	19	3-403.11
Cooling	20	3-501.14
Hot Holding	21	3-501.16(A)(1)
Cold Holding	22	3-501.16(A)(2), (B)
Date marking	23	3-501.17; 3-501.18
Time as Public Health Control	24	3-501.19
Consumer Advisory		
Consumer Advisory provided for raw/undercooked foods	25	3-603.11
HSP Populations		
Pasteurized foods used; prohibited foods not offered	26	3-801.11(A), (B), (C), (E), (G)
Food Color Additives and Toxic Substances		
Food Additives approved and properly used	27	3-202.12; 3-302.14
Toxic substances identified, stored, and used	28	7-101.11; 7-102.11; 7-201.11; 7-202.11; 7-202.12; 7-203.11; 7-204.12; 7-204.13; 7-204.14; 7-205.11; 7-206.11; 7-206.12; 7-206.13; 7-207.11; 7-207.12; 7-208.11; 7-209.11; 7-301.11
Conformance with Approved Procedures		
Compliance with variance/specialized process/HACCP	29	3-404.11; 3-502.11; 3-502.12; 4-204.110(B); 8-103.12; 8-201.13; 8-201.14

*Item numbers listed in this column refer to the item numbers within FDA's Food Establishment Inspection Report (Form 3-A, found in Annex 7).

STANDARD 2 TRAINED REGULATORY STAFF

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STANDARD 2 TRAINED REGULATORY STAFF

This Standard applies to the essential elements of a training program for regulatory staff.

Requirement Summary

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have the knowledge, skills, and ability to adequately perform their required duties. The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

STEP 1
Completion of curriculum courses designated as "Pre" in Appendix B-1 prior to conducting and independent routine inspections.

STEP 2
Completion of the following:

- A minimum of 25 joint field training inspections (or a sufficient number of joint inspections determined by the trainer and verified through written documentation that the FSIO has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments); and
- Successful completion of the jurisdiction's FSIO Field Training Plan similar to the process outlined in *Appendix B-2: Conference for Food Protection (CFP) Field Training Manual*.

STEP 3
Completion of the following:

- A minimum of 25 independent inspections; and
- Remaining course curriculum (designated as "post" courses) outlined in *Appendix B-1: Curriculum for Retail Food Safety Inspection Officers*.

STEP 4
Completion of a standardization process similar to the FDA standardization procedures.

STEP 5
Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

Description of Requirement

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have successfully completed the required elements of the 5-step training and standardization process:

- Steps 1 through 4 within 24 months of hire or assignment to the retail food regulatory program.
- Step 5 every 36 months after the initial 24 months of training.

Step 1: Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in pre-requisite courses designated with a "Pre" in Appendix B-1, for the following curriculum areas:

1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
2. Public Health Principles;
3. Food Microbiology; and
4. Communication Skills.

There are two options for demonstrating successful completion of the pre-inspection curriculum.

OPTION 1: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- FDA ORA U pre-requisite courses identified as "Pre" in Appendix B-1; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances.

Note: *The estimated contact time for completion of the FDA ORA U pre-requisite ("Pre") courses is 42 hours.*

OPTION 2: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- Successful completion of courses deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the FDA ORA U pre- requisite (Pre") courses; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances; and
- Successful passing of one of the ~~four~~ five written examination options (described later in this Standard) for determining if a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the listed ORA U courses are available from the web site link at: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

> **Note:** *While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:*
>
> - *Logs/records that are completed based on sign-in sheets; or*
> - *Information validated from the certificate at the time-of-issuance; or*
> - *A college transcript with a passing grade or other indication of successful completion of the course; or*
> - *Automated attendance records, such as those currently kept by some professional associations and state agencies, or*
> - *Other accurate verification of actual attendance.*

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORAU courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the ~~four~~ five written examination categories specified herein.

1. The Certified Food Safety Professional examination offered by the National Environmental Health Association; or

2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable; or

3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or

4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

5. A food protection certification examination based on the National Curriculum Standard that is developed using methods that are psychometrically valid and reliable.

Note: *Written examinations are part of a training process, not a standardization/certification process. The examinations listed are not to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.*

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer who has successfully completed all training elements (Steps 1 – 3) of this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "training" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

If the trainer determines that the FSIO has successfully demonstrated the required performance elements and competencies, a lower minimum number of joint field training inspections can be established for that FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan in Appendix B-2, to support the exception.

Note: *The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."*

Demonstration inspections are those in which the jurisdiction's trainer takes the lead and the candidate observes the inspection process. Training inspections are those in which the candidate takes the lead, and their inspection performance is assessed and critiqued by the trainer. The jurisdiction's trainer is

responsible for determining the appropriate combination of demonstration and training inspections based on the candidate's food safety knowledge and performance during the joint field inspections.

The joint field inspections must be conducted using a field training process and forms similar to ones presented in the *CFP Field Training Manual* included as Appendix B-2. The *CFP Field Training Manual* consists of a training plan and log, trainer's worksheets, and procedures that may be incorporated into any jurisdiction's retail food training program. It is a national model upon which jurisdictions can design basic field training and provides a method for FSIOs to demonstrate competencies needed to conduct independent inspections of retail food, restaurant, and institutional foodservice establishments.

Jurisdictions are not required to use the forms or worksheets provided in the *CFP Field Training Manual*. Equivalent forms or training processes can be developed. To meet the intent of the Standard, documentation must be maintained that confirms FSIOs are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments.

Note: *The CFP Field Training Manual is designed as a training approach providing a structure for continuous feedback between the FSIO and trainer on specific knowledge, skills, and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.*

- *The CFP Field Training Manual is NOT intended to be used for certification or licensure purposes.*
- *The CFP Field Training Manual is NOT intended to be used by regulatory jurisdictions for administrative purposes such as job classifications, promotions, or disciplinary actions.*

FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2013 *FDA Food Code*). The jurisdiction's trainer/food program manager can determine if the FSIO is ready to conduct independent inspections of risk category 1 establishments (as defined in Appendix B-3) at any time during the training process.

Note: *The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can in lieu of the 25 joint field inspections:*

- *Include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement; and*
- *The supervisor/training officer must observe experienced FSIOs conduct inspections to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.*

Step 3: Independent Inspections and Completion of ALL Curriculum Elements

Within 24 months of hire or assignment to the regulatory retail food program, Food Safety Inspection Officers must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1, for the following eight curricula areas, must be completed within this 24-month time frame.

1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
2. Public health principles (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
3. Communication skills (Step 1);
4. Food microbiology (some of the courses for this element are part of the pre-requisite curriculum outlined in Step 1);
5. Epidemiology;
6. Hazard Analysis Critical Control Points (HACCP);
7. Allergen Management
8. Emergency Management

All courses for each of the curriculum areas must be successfully completed within 24 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

> **Note:** *The estimated contact time for completion of the FDA ORA U "post" courses is 26 hours. The term "post" refers to those courses in Appendix B-1 that were not included as part of the pre-requisite coursework. This includes all the courses in Appendix B-1 that do not have the designation "Pre" associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.*

As with the pre-requisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses listed under each curriculum area OR by completing courses, deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the listed ORA U courses are available from the FDA website: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners.

Step 4: Food Safety Inspection Officer – Field Standardization

Within 24 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the "FDA Standardization Procedures." The jurisdiction's "training standard" must have met all the requirements for conducting field standardizations as presented in the definition section of these Standards. The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years.

Note: *The field standardization and continuing standardization (re-standardization) criteria described in Step 4 is intended to provide a jurisdiction the flexibility to use their own regulation or ordinance. In addition, the reference to using standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers, is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written standardization protocol must include the five performance areas outlined above in Step 4.*

It is highly beneficial to use the FDA Food Code, standardization forms and procedures even when a jurisdiction has adopted modifications to the Food Code. Usually, regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge, and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA's standardization procedures are based on a minimum of 8 inspections. However, to meet Standard 2, a minimum of 4 standardization inspections must be conducted.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel versed in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate

consistent evaluation of all candidates.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors and communicates vital information about the inspection in a way that can be received, understood, and acted upon by retail food management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to both the regulatory agency and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard 2 criteria within the 24- month time frame, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5: Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (24 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer.

Training on any changes in the regulatory agency's prevailing statutes, laws and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine activities that are related specifically to food safety or food inspectional work:

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local);
4. Food safety related conferences and workshops; and
5. Distance learning opportunities that pertain to food safety, such as:
    - Web based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and
    - Satellite Broadcasts.

A maximum of ten (10) contact hours may be accrued from the following activities:

1. Delivering presentations at professional conferences;
2. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
3. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period[1].

Note: *Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.*

A maximum of four (4) contact hours may be accrued for:

1. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- transcripts from a college or university;
- a letter from the administrator of the continuing education program attended;
- a copy of the peer-reviewed article or presentation made at a professional conference; or
- documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

Note: *The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of employee's continuing education activities, maintains the training records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses.*

Outcome

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);

2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process similar to that presented in Appendix B-2. **NOTE:** The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."
4. Certificates or other records showing proof of satisfactory standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successful completed the training and education steps outlined in this Standard.
7. Date of hire records or assignment to the retail food program; and
8. Summary record of employees' compliance with the Standard.

The *Standard 2: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 2.

PSC15 Proposed Revised Standard 3 Requirement to Include Plan Review

STANDARD 3

INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

This standard applies to the utilization of HACCP principles to control risk factors in a retail food inspection program.

Requirement Summary

An inspection program that focuses on the status of risk factors, determines and documents compliance, and targets immediate- and long-term correction of out-of-control risk factors through active managerial control.

Description of Requirement

Program management:

1. Implements the use of an inspection form that is designed for:
   a) The identification of risk factors and interventions.
   b) Documentation of the compliance status of each risk factor and intervention (i.e. a form with notations indicating IN compliance, OUT of compliance, Not Observed, or Not Applicable for risk factors)
   c) Documentation of all compliance and enforcement activities and
   d) Requires the selection of IN, OUT, NO, or NA for each risk factor.
2. Develops and uses a process that groups food establishments into at least three categories based on potential and inherent food safety risks.
3. Assigns the inspection frequency based on the risk categories to focus program resources on food operations with the greatest food safety risk
4. Develops and implements a program policy ***that requires:
   a) On-site corrective actions* as appropriate to the type of violation.
   b) Discussion of long-term control** of risk factor options, and
   c) Follow-up activities.
5. Establishes and implements written policies addressing code variance requests related to risk factors and interventions.
6. Establishes written policies regarding the verification and validation of HACCP plans when a plan is required by the code.
7. <u>Develops and implements a program policy to require the REGULATORY AUTHORITY to have a review and approval process for the construction plans*****, equipment specifications, and other information submitted by the PERMIT applicant or PERMIT HOLDER for the FOOD ESTABLISHMENT that is consistent with the requirements of the FDA Food Code. The policy should include a requirement that the REGULATORY AUTORITY discusses the establishments food safety management system**** as part of the plan review process. Contents of the PERMIT applicant's or PERMIT HOLDER's submission must include at least the following information:
   a) Intended menu
   b) Anticipated volume of FOOD to be stored, prepared, and sold or served
   c) Proposed layout, mechanical schematics, construction</u>

d) Proposed EQUIPMENT types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications
e) Standard operating procedures and HACCP plan if applicable, and
f) Other information that may be required by the REGULATORY AUTHORITY for the proper review of the proposed construction, conversion or modification, and procedures for operating a FOOD ESTABLISHMENT and
g) Documentation of all plan reviews conducted (approval, conditional, denial) or if the regulatory program does not conduct plan review or shares responsibility for the plan review with other entities or agencies, there are agreements in place and the process is documented.

Outcome

The desired outcome of this standard is a regulatory inspection system that uses HACCP principles to identify risk factors and to obtain immediate- and long-term corrective action for recurring risk factors.

Documentation

The quality records needed for this standard include:
1. Inspection form that requires the selection of IN, OUT, NO, or NA,
2. Written process used for grouping establishments based on food safety risk and the inspection frequency assigned to each category
3. Policy for on-site correction and follow-up activities,
4. Policy for addressing code variance requests related to risk factors and interventions,
5. Policy for verification and validation of HACCP plans required by code, and
6. Policy requiring the discussion of food safety control systems with management when out of control risk factors are recorded on subsequent inspections,
7. Documentation of the review and approval process for submission of a food safety management system plan, construction plans, equipment specifications, and other information that is consistent with the requirements of the FDA Food Code or if the plan review is conducted externally, documentation of the process (policy, contract, MOU). The review and approval should include at minimum:
a) Food safety management system plan discussion
b) Intended menu
c) Anticipated volume of FOOD to be stored, prepared, and sold or served
d) Proposed layout, mechanical schematics, construction
e) Proposed EQUIPMENT types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications
f) Standard operating procedures and HACCP plan if applicable, and
g) Documentation of all plan reviews conducted (approval, conditional, denial)

*Note: On-site corrective action as appropriate to the violation would include such things as:
a. Destruction of foods that have experienced extreme temperature abuse,
b. Embargo or destruction of foods from unapproved sources,
c. Accelerated cooling of foods when cooling time limits can still be met,
d. Reheating when small deviations from hot holding have occurred,
e. Continued cooking when proper cooking temperatures have not been met.

PSC15 Proposed Revised Standard 3 Requirement to Include Plan Review

f. Initiated use of gloves, tongs, or utensils to prevent hand contact with ready-to-eat foods, or
g. Required hand washing when potential contamination is observed.

Note: **Long-term control of risk factors requires a commitment by managers of food establishments to develop effective monitoring and control measures or system changes to address those risk factors most often responsible for foodborne illness. Risk control plans, standard operating procedures, buyer specifications, menu modification, HACCP plans and equipment or facility modification may be discussed as options to achieve the long-term control of risk factors.

***Note: Consideration of the elements outlined in Standard 4 will ensure a strong foundation for a quality and uniform inspection program.

*****Note 1: Through their committee process, the Conference for Food Protection has developed Plan Review for Food Establishment guidance on the CFP web site: www.foodprotect.org located under the icon titled, "Conference Developed Guides and Documents" and can be downloaded at http://www.foodprotect.org/guides-documents/plan-review-for-food-establishments-2016/.

**** Note 2: Food Safety Management System
refers to a specific set of actions (e.g., procedures, training, and monitoring) to help achieve active managerial control.

- **Procedures:** A defined set of actions adopted by food service management for accomplishing a task in a way that minimizes food safety risks. Procedures may be oral or written and include who, what, where, when, and how a task should be performed. The goal is to move toward complete, consistent, and primarily written procedures and may include topics such as when to wash your hands, how to set up a 3-compartment sink, how food temperatures are achieved and maintained/monitoring food temperatures.
- **Training:** The process of management's informing employees of the food safety procedures within the food service establishment and teaching employees how to carry them out. Information may be presented in formats such as a set of instructions/illustrations, recipe cards with process instructions, wall charts, wallet cards, or live demonstration. The goal is to provide and document training for all food safety tasks in a format and frequency adequate to ensure employees have the knowledge to carry out the procedures consistently and effectively.
- **Monitoring:** Routine observations and measurements conducted to determine if food safety procedures are being followed. Monitoring systems should include who, what, where, when, and how monitoring is to be performed and may be conducted visually or documented in writing. The goal is to move toward a well-documented system that can be verified and may include use of automated systems, digital thermometers, logs, charts, checklists, and other job aids and tools.

INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

STANDARD 3 – INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

Program Self-Assessment & Verification Audit Form

The *Standard 3: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 3. The form is included at the end of these instructions. Whether one is performing a program self-assessment or conducting a verification audit, it is recommended that the form be available as a reference to the Standards 3 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self Assessment

Jurisdictions conducting a self-assessment of Standard 3 must indicate on the form if each of the listed criteria is met. These responses are recorded under the column "Jurisdiction's Self Assessment."

Jurisdictions are not obligated to use this form. An equivalent form or process is acceptable provided that the results of the jurisdiction's self-assessment for the specific Standard 3 criteria listed on this form are available for review.

The *Standard 3: Program Self-Assessment and Verification Audit Form* is the only form a jurisdiction needs to use to record the results of their self-assessment. Standard 3 requires inspection policies to be established, written, and implemented. A policy without documentation of implementation does not meet the Standard 3 criteria.

The *Standard 3: Program Self-Assessment and Verification Audit Form* divides the Standard 3 criteria into seven steps:

1. Inspection Form Design
    a. The jurisdiction's inspection form identifies foodborne illness risk factors and *Food Code interventions*.
    b. The jurisdiction's inspection form documents actual observations using the convention IN, OUT, NA, and NO.
    c. The jurisdiction's inspection form documents compliance and enforcement activities.
2. Risk Assessment Categories
    a. A risk assessment is used to group food establishments into at least 3 categories based on their potential and inherent food safety risks.
3. Inspection Frequency
    a. The jurisdiction's inspection frequency is based on assigned risk categories.

4. Corrective Action Policy
    a. The jurisdiction has a written and implemented policy that requires on-site corrective action for foodborne illness risk factors observed to be out of compliance.
    b. The jurisdiction has a written and implemented policy that requires discussion for long-term control of foodborne illness risk factors.
    c. The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations.

5. Variance Request Policy
    a. The jurisdiction has a written and implemented policy on variance requests related to foodborne illness risk factors and *Food Code* interventions.
6. Verification and Validation of HACCP Plan Policy
    a. The jurisdiction has a written and implemented policy for the verification and validation of HACCP plans, when a HACCP plan is required by the *Food Code*.
7. Plan Review
    a. The jurisdiction develops and implements a program policy to require the submission and review of food establishment construction plans, and equipment specifications that is consistent with the FDA Food Code, or the program maintains a written agreement with another entity that is responsible for the plan review process. The policy should include a requirement that the REGULATORY AUTHORTY discusses the establishments food safety management system as part of the plan review process.

        Specifically, plan review criteria for self-assessment and verification language:
        a) The jurisdiction develops and implements a program policy to require the discussion of the establishment food safety management system plan.
        b) The jurisdiction develops and implements a program policy to require the submission, review and approval of establishment construction plans consistent with the FDA Food Code.
        c) The jurisdiction develops and implements a program policy to require the submission, review and approval of equipment specifications consistent with the FDA Food Code.
        d) Or, the program maintains a written agreement with another entity that is responsible for the plan review process.

The self-assessor must review each Standard 3 criterion and determine if the jurisdiction's source documents confirm that the Standard criteria are met. If the criteria are met, the self-assessor must place an "X" in the "YES" box under the "Jurisdiction's Self-Assessment" column of the *Standard 3: Program Self-Assessment and Verification Audit Form*.

If a review of the jurisdiction's source documents does not confirm that the Standard 3 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdict*ion's Self-Assessment" column of the* Standard 3: Program Self-Assessment and Verification Audit Form. The self-assessor may specify why the criteria are not met in the box provided.

The self-assessor should review the findings on the *Standard 3: Program Self-Assessment and*

Verification Form to ensure accuracy. The jurisdiction will be required to provide the auditor with their completed *Standard 3: Program Self-Assessment and Verification Audit Form* and any documents used to support and demonstrate that the Standard 3 criteria have been met.

Once all the criteria have been reviewed and documented on the form, the self-assessor must complete the Program Self-Assessment Summary section on page one of the *Standard 3: Program Self-Assessment and Verification Audit Form*. The self-assessor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 3 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 3 criteria.

Documenting the Findings from the Verification Audit

The jurisdiction requesting the verification audit must provide their completed *Standard 3: Program Self-Assessment and Verification Audit Form* to the auditor for review. The auditor must indicate on the *Standard 3: Program Self-Assessment and Verification Audit Form* if the criteria were met.

If a review of the jurisdiction's source documents confirms the self-assessment conclusion that the Standard criteria are met, the verification auditor places an "X" in the "YES" box under the "Auditor's Verification" column of the form.

If a review of the jurisdiction's source documents does not confirm the self-assessment conclusion that the Standard criteria are met, the verification auditor places and "X" in the "NO" box under the "Auditor's Verification" column of the form. The verification auditor must specify why the criterion is not met in the box provided. Supplemental pages may be used to explain findings. The

jurisdiction must meet all six program performance criteria outlined in Standard 3.

The verification auditor must discuss their findings with the program manager or their appointed representative and provide constructive feedback at the conclusion of the verification audit. In particular, any Standard 3 criteria for which the auditor cannot confirm through a review of the self-assessment should be thoroughly discussed. Ample time should be allotted to ensure that there is a clear understanding of the reasons for the "non-conforming" finding. The auditor should be prepared to identify the elements required for the jurisdiction to meet the Standard.

Once the close out interview has been conducted, the auditor must complete the Verification Audit Summary section located on the first page of the *Standard 3: Program Self-Assessment and Verification Audit Form*. The auditor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 3 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 3 criteria if the auditor does not confirm the self-assessment findings.

Standard 3: Inspection Program Based On HACCP Principles
Program Self-Assessment and Verification Audit Form

PROGRAM SELF-ASSESSMENT SUMMARY

Printed Name of the Person who conducted the Self-Assessment:		
Self-Assessor's Title:		
Jurisdiction Name:		
Jurisdiction Address:		
Phone:	**FAX:**	**E-Mail:**
Date the Standard 3 Self-Assessment was Completed:		
Self-Assessment indicates that the Jurisdiction MEETS the Standard 3 criteria: YES ☐ NO ☐		
I affirm that the information represented in the Self-Assessment of Standard 3 is true and correct.		
Signature of the Self-Assessor:		

VERIFICATION AUDIT SUMMARY

Printed Name of the Person who conducted the Verification Audit:		
Verification Auditor's Title:		
Auditor's Jurisdiction Name:		
Auditor's Jurisdiction Address:		
Phone:	**FAX:**	**E-Mail:**
Date the Verification Audit of Standard 3 was Completed:		
Verification Audit indicates that the Jurisdiction MEETS the Standard 3 criteria: YES ☐ NO ☐		
I affirm that the information represented in the Verification Audit of Standard 3 is true and correct.		
Signature of the Verification Auditor:		

Standard 3: Inspection Program Based On HACCP Principles
Program Self-Assessment and Verification Audit Form

Jurisdiction Name:

Criteria	Jurisdiction's Self-Assessment			Auditor's Verification		
	YES	NO	Self-Assessor's General Comments	YES	NO	If NO, Auditor is to specify why criterion is not met
1. Inspection Form Design						
a) The jurisdiction's inspection form identifies foodborne illness risk factors and Food Code interventions.	☐	☐		☐	☐	
b) The jurisdiction's inspection form documents actual observations using the convention IN, OUT, NA, and NO.	☐	☐		☐	☐	
c) The jurisdiction's inspection form documents compliance and enforcement activities.	☐	☐		☐	☐	
2. Risk Assessment Categories						
a) A risk assessment is used to group food establishments into at least 3 categories based on their potential and inherent food safety risks.	☐	☐		☐	☐	
3. Inspection Frequency						
a) The jurisdiction's inspection frequency is based on the assigned risk categories.	☐	☐		☐	☐	
4. Written and Implemented Corrective Action Policy						
a) The jurisdiction has a written and implemented policy that requires on-site corrective action for foodborne illness risk factors observed to be out of compliance.	☐	☐		☐	☐	
b) The jurisdiction has a written and implemented policy that requires discussion for long-term control of foodborne illness risk factors.	☐	☐		☐	☐	

Criteria	Jurisdiction's Self-Assessment			Auditor's Verification		
	YES	NO	Self-Assessor's General Comments	YES	NO	If NO, Auditor is to specify why criterion is not met
c) The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations.	☐	☐		☐	☐	
5. Variance Requests						
a) The jurisdiction has a written and implemented policy on variance requests related to foodborne illness risk factors and *Food Code* interventions.	☐	☐		☐	☐	
6. Verification and Validation of HACCP Plans						
a) The jurisdiction has a written and implemented policy for the verification and validation of HACCP plans, when a HACCP plan is required by the Code.	☐	☐		☐	☐	
7. Plan Review						
a) The jurisdiction develops and implements a program policy to require a food safety management system plan discussion as part of the plan review process. b) The jurisdiction develops and implements a program policy to require the submission, review, and approval of establishment construction plans consistent with the FDA Food Code. c) The jurisdiction develops and implements a program policy to require the submission, review, and approval of equipment specifications consistent with the FDA Food Code d) Or, the program maintains a written agreement with another entity that is responsible for the plan review process.	☐	☐		☐	☐	

Standard 3: Inspection Program Based On HACCP Principles
Program Self-Assessment and Verification Audit Form

GENERAL NOTES PERTAINING TO THE PROGRAM SELF-ASSESSMENT OR THE VERIFICATION AUDIT

PSC16 Standard 5 Data Collection Template

Note: This document is a PDF document of a Excel spreadsheet with tabs for Instructions, Data_Entry, Summary and Lookup.

Instructions:

This workbook is designed to help a food regulatory program maintain the data needed for compliance with FDA Voluntary National Retail Food Regulatory Program Standards #5.	
For each outbreak complete a new row on the Data_Entry tab - Row 2 contains an example	
OutbreakID	Enter the local health department identifier for the outbreak - this could also be the NEARS or NORS outbreak reporting ID - If multiple facilities are implicated use the same outbreakID for all implicated facilities
Facility	Enter the name of the facility that was implicated, you can have multiple facilities per outbreak (e.g., a contaminated ingredient was distributed to multiple restaurants)
LicenseID	Enter the license/permit id for the implicated restaurant
Establishment Type	Enter the establishment type
Single Location	Indicate if a single location was implicated
Outbreak Status	For the outbreak identify if the agent was confirmed, suspected, unknown, or if the outbreak is still ongoing.
Date Notified	Enter the date that the food program was made aware of the potential outbreak
Date of First Contact	Enter the date that the food program first made contact with the implicated establishment

Date Completed	Enter the date that the food program completed their investigation
Implicated Food	Enter the name of the implicated food (please use the same spelling for the same food))
Food Process	Indicate the basic food preparation process for the implicated food (No cook - food is not cooked, Cook-Serve - Food is cooked and then served, Complex - Food is cooked then cooled and reheated)
Contributing Factors Identified	Enter the contributing factors (what went wrong) for the implicated food - this only needs to be entered for one establishment per outbreak. If you choose Other - include the specifics in the Notes column
Agent	Select the implicated agent
Agent Other	If you select Other for Agent then enter the name here
Intentional Contamination	Indicate if intentional contamination was suspected for this outbreak
NOTES	Record any notes about the outbreak that will be helpful for understanding what occurred
On the Summary tab, you can change the year to get a summary for the year.	

Data_Entry

OutbreakID	Facility	LicenseID	Establishment Type	Single Location	Outbreak Status	Date Notified	Date of First Contact	Date Completed	Implicated Food	Food Process
2022-02	John's Doe	ABC123	Restaurant	YES	Confirmed	1/23/1976	1/24/1976	1/31/1976	Venison	Complex

Contributing Factors Identified	Agent	Agent Other	Intentional Contamination	NOTES
C1, C2	Other	Brucella	No	

Summary

XYZ County Health Department - Summary of Foodborne Illness Outbreaks									
Number of foodborne outbreaks			**Number of outbreaks by establishment type**						
Single Facility				Confirmed	Suspected	Ongoing	Unknown	Multifacility	
Confirmed	0		Restaurant	0	0	0	0	0	
Suspected	0								
Ongoing	0								
Unknown	0								

	TOTAL	**0**							
	MultiFacility								
	Confirmed	0							
	Suspected	0							
	Ongoing	0							
	Unknown	0							
	TOTAL	**0**							
TOTAL OUTBREAKS									
	Confirmed	0							
	Suspected	0							
	Ongoing	0							

	Unknown	0							
	TOTAL	**0**							
Intentional Food Contamination									
	0								

Number of outbreaks by food type						**Number of outbreaks by food process**				
	Confirmed	Suspected	Ongoing	Unknown			Confirmed	Suspected	Ongoing	Unknown
Venison	0	0	0	0		No Cook	0	0	0	0
						Cook-Serve	0	0	0	0
						Complex	0	0	0	0

Frequency of Contributing Factors			**Frequency of Agent**	
		# times marked		# times identified
C1	Toxin or chemical agent naturally part of the tissue	0	Norovirus	0

C2	Poisonous substance or infectious agent intentionally added to food cause illness (does not include injury)	0	Hepatitis A virus	0
C3	Poisonous substance accidentally/inadvertently added to food	0	Salmonella	0
			Campylobacter	0
C4	Ingredient's toxic in large amounts accidentally added to food	0	Clostridium	0
C5	Container or equipment used to hold or convey food was made with toxic substances	0	STEC O157	0
C6	Food contaminated by animal or environmental source at point of final preparation/sale	0	Other STEC	0
C7	Food contaminated by animal or environmental source before arriving at point of final preparation (pre- or post-harvest)	0	Listeria	0
C8	Cross-contamination of foods, excluding infectious food workers/handlers	0	Shigella	0
C9	Contamination from infectious food worker/handler through bare hand contact with food	0	Yersinia	0
			Other	0
C10	Contamination from infectious food worker/handler through glove-hand contact with food	0	Unknown	0
C11	Contamination from infectious food worker/handler through unknown type of hand contact with food or indirect contact with food	0		
C12	Contamination from infectious non-food worker/handler through direct or indirect contact with food	0		

C13	Other sources of contamination (specify)	0		
P1	Allowing foods to remain out of temperature control for a prolonged period during preparation	0		
P2	Allowing foods to remain out of temperature control for a prolonged period during food service or display	0		
P3	Inadequate cold holding temperature due to malfunctioning refrigeration equipment	0		
P4	Inadequate cold holding temperature due to an improper practice	0		
P5	Inadequate hot holding temperature due to malfunctioning equipment	0		
P6	Inadequate hot holding temperature due to an improper practice	0		
P7	Improper cooling of food	0		
P8	Extended refrigeration of food for an unsafe amount of time, relative to the food product and pathogen	0		
P9	Inadequate reduced oxygen packaging (ROP) of food	0		
P10	Inadequate non-temperature dependent processes (e.g., acidification, water activity, fermentation) applied to a food to prevent pathogens from multiplying	0		
P11	Other situations that promoted or allowed microbial growth or toxic production (specify)	0		
S1	Inadequate time and temperature control during initial cooking/thermal processing of food	0		
S2	Inadequate time and temperature control during reheating of food	0		

S3	Inadequate time and temperature control during freezing of food designed for pathogen destruction	0		
S4	Inadequate non-temperature dependent processes (e.g., acidification, water activity, fermentation) applied to a food to prevent pathogens from surviving	0		
S5	No attempt was made to inactivate the contaminant through initial cooking/thermal processing, freezing, or chemical processes	0		
S6	Other process failures that permit pathogen survival (specify)	0		

Lookup

YES	Suspected	No Cook	C1	Norovirus
NO	Confirmed	Cook-Serve	C2	Hepatitis A virus
	Ongoing	Complex	C3	Salmonella
	Unknown		C4	Campylobacter
			C5	Clostridium
			C6	STEC O157
			C7	Other STEC
			C8	Listeria
			C9	Shigella
			C10	Yersinia
			C11	Other
			C12	Unknown
			C13	
			P1	

			P2	
			P3	
			P4	
			P5	
			P6	
			P7	
			P8	
			P9	
			P10	
			P11	
			S1	
			S2	
			S3	
			S4	
			S5	
			S6	

A sample roadmap for Retail Food Program Standard 5 Foodborne Illness and Food Defense Preparedness and Response

Establishing an FBI program from Start to Finish

The intent of this document is to assist with the development of a Foodborne Illness and Food Defense Program. Often time when a jurisdiction starts to develop their FBI/FD Program in conformance with Standard 5, the task can seem complicated and at times overwhelming. This document is intended to be used as a job aide to assist with the crafting and implementation of your own FBI/FD program by walking through the minimum requirements step by step. Some smaller jurisdictions may find that answering the step-by-step questions may provide sufficient details for development of their FBI/FD Program. Whereas, some larger jurisdictions may need expand beyond the minimum requirements to meet their needs for a functional FBI/FD Program. Each jurisdiction has unique challenges and opportunities that cannot be entirely addressed by a single document. Therefore, this document is not intended to be a blueprint or blank template to the development of your program but to assist with your FBI/FD Program development.

To conform to the requirements of Standard 5, your FBI/FD Program needs to contain 7 elements, which include the following:

1. Investigative Procedures
2. Reporting Procedures
3. Laboratory Support Documentations
4. Trace-Back Procedures
5. Recall Procedures
6. Media Management
7. Data Review and Analysis

These 7 elements can be completed in any sequence, and often times you may find some elements more challenging than others. It is recommended that the easier or most straightforward elements be addressed first. The more challenging elements usually take longer and may seem insurmountable to some jurisdictions trying to meet Standard 5, particularly smaller jurisdictions. Also, you may find that by addressing the easier elements, you will find answering the more complicated questions less challenging, since there are frequent overlapping components. It is important to remember any progress in developing an FBI/FD Program improves the security and safety of the people that we serve, as well as highlights gaps in our programs that can be addressed.

One of the essential lessons of this job aide is to understand that the role or roles that your jurisdiction plays in Foodborne Illness and Food Defense is part of a broader network of Programs and jurisdictions. In fact one of the easiest steps that a jurisdiction can start with is the development of a contact list of mission critical personnel in the event of a Foodborne Illness or Food Defense event.

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The trip begins:

1. **Investigative Procedures**
   a. **The program has written operating procedures for responding to and/or conducting investigations of foodborne illness and food-related injury that clearly identify the roles, duties, and responsibilities of program staff and how the program interacts with other relevant departments and agencies.**

   (The procedures may be contained in a single source document or in multiple documents.)

It is critical that prior to an FBI/FD event that the role and roles that a jurisdiction may play in an event be determined and procedures developed. So, it is important to understand what role or roles your program may play. There are simple questions that can assist with this determination. These include the following:

- Who will receive the complaint(s)?
- Who conducts the illness interviews?
- Who will conduct the field inspections/ investigations?
- Who will liaise with federal agencies?
- Who will collect samples? Environmental, clinical, etc.
- Who will analyze collected samples?
- Who will coordinate the activities?
- Who will handle follow-up activities if needed?
- Who will write the final report?
- Who will determine when an FBI event has stopped?

is only investigations, decide how these inspections will be covered in general and by

Answering these questions can assist a jurisdiction to start understanding your role in investigating FBI/FD events. Some jurisdictions/ EHS units play a reduced role in these events, and others play a significant role or multiple roles in these events. Understand the scope of your activities and responsibilities in FBI/ FD events will help determine what procedures are needed to be developed and standardized. If a role(s) is outside your scope, then determine whose role is it. For example, if your role is limited to field inspections/ investigations, then you may not need to develop procedures for conducting illness interviews.

a. Next identify essential roles that are played in an FBI event.
b. Next if you do not perform all of the above roles, began to find out who does perform the role. Gather their contact information.
c. If no one is conducting an essential role, then this is a gap that should be worked on to be filled. Remember you do not necessarily need to fill the gap yourself, but recognizing a gap is a very good thing!
d. By now, you have a better understanding of your role(s) in an FBI event. Now start putting pen to paper and building your system. Remember that being general is ok. The key is developing a program that covers all of your responsibilities. If your role is

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only investigations, decide how these inspections will be covered in general and by which staff but not specifically who.

e. Next decide how information will be shared. Teleconferences, individual phone calls, emails, etc.
f. Next decide who will lead the information sharing. Having a coordinator or a point person can make the process go smoother.

b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illnesses, food-related injuries, or contamination of food.

1. Knowing who to contact in an emergency is one of the first steps in navigating an emergency.
2. Maintain a list of State, local, Federal contacts. (can include law enforcement contacts needed in step h) Remember that list from above in section c?
    i. Note: in general, a contact list has already been established by someone else in your State. Your do not need to reinvent the wheel.
        1. Do you have a State Rapid Response Team (RRT)?
        2. Does your State have a Manufactured Food Regulatory Program Standards (MFRPS) program?
        3. State Public Health often maintains lists of emergency contacts.
        4. Are you a small jurisdiction or program? Reach out to other jurisdictions in your State?

c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program / department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties, and responsibilities of each party.

How complex or formal you wish to establish roles is up to you.

i. If you feel a formal MOU with everyone's roles, is your process, then feel free to go that route.
ii. If you prefer a less formal approach, then as long as each role is identified, particularly your specific role(s), you have met the expectation.

Remember all the hard work in section 1a? Now it we pay off again. Summarize the roles of each group in the essential roles list, particularly your group's role. Be specific when it comes to your role(s). Now you can take the contact information from section b and publish this summary.

Provide examples/templates

d. The program maintains logs or databases for all complaint or referral reports from other sources alleging food-related illness, food-related injury, or unintentional

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food contamination. The final disposition for each complaint is recorded in the database or log and is filed in, or linked to, the establishment record for retrieval purposes.

This could be the Template that Adam Kramer developed.
Washtenaw County Template

e. **Program procedures describe the disposition, action, or follow-up and reporting required for each type of complaint or referral report.** What does this mean? Have a plan/procedure for each type of complaint you get. Lindy can ask Julie. Clinical, outbreak, suspect. Step by step instructions on what you would do based on the complaint type

f. **Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.**

This is where many smaller jurisdictions cannot meet the Standard.
Need to flesh out to provide some flexibility. What is the minimum to meet this. Depends on what the complaint reveals. (single complaint with only symptoms vs. confirmed lab illness, large numbers of ill. Define "initiate". Have at a minimum the "follow-up" step. Could be a simple as referring to the food person (text/email/phone call). Need to do some sort of follow-up. Need to figure out how to meet it. On call person without compensation may be a big challenge.

g. **The program has established procedures and guidance for collecting information on the suspect foods' preparation, storage or handling during on-site illness, food-injury, or outbreak investigations.**

The environmental investigation could involve another agency separate from the local jurisdiction. This should be included in the roles defined above.

This is a written procedure that could include a data collection form to document the collected information.
- Preparation
- Storage/handling

Develop flowchart for a small jurisdiction

h. **Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.**

Need to determine position within law enforcement to contact and include in the procedures. Written into the procedures include contact information for local/state/federal law enforcement agencies. Can be included in B-b.
Provide a template

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i. **Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.**

Contact FDA Customer Complaint Line
USDA
State Departments of Agriculture/Health

2. Reporting Procedures

a**. Possible contributing factors to the food-related illness, food-related injury or intentional food contamination are identified in each on-site investigation report.**

CDC 5213 NORs report (all states are participating in NOR's)
https://www.cdc.gov/nors/downloads/form-52-13.pdf

Investigation Collection form to have section to record this information.

Usually determine this after the investigation, during briefing meetings/teleconferences

Provide an example and a link to the CDC CF's
https://www.cdc.gov/nceh/ehs/nears/what-are-contributing-factors.htm

b**. The program shares final reports of investigations with the state epidemiologist and reports of confirmed foodborne disease outbreaks with CDC.**

Write this in your procedures. If above process is followed, State Epi and CDC will more than likely already be involved.

3. Laboratory Support Documentation

a. **The program has a letter of understanding, written procedures contract or MOU acknowledging that a laboratory is willing and able to provide analytical support to the jurisdiction's food program. The document describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.**

Smaller jurisdictions may not have the role to sample.

Labs that meet certain certifications then they will be capable of these tests.

Determine the capacity of your local or state labs. If they cannot provide the testing include the closest FDA lab. (Could provide a list/link of the FDA labs)

b. **The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental**

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laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).

This can be included contact list in Part 1

4. **Trace-Back Procedures**

a. **Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak or intentional food contamination. The trace-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.**

a. Is there anything already written for this?

5. **Recalls**
   a. **Program management has an established procedure to address the recall of foods implicated in an illness, outbreak or intentional food contamination.**

Is there anything already written for this?

b. **When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed**

c. **Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.**

Is there existing documents for this

6. **Media Management**
   a. **The program has a written policy or procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak for food safety emergency. The policy/procedure should address the coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.**

7. **Data Review and Analysis**

a. **At least once per year, the program conducts a review of the data in the complaint log or database and the foodborne illness and food-related injury investigations to identify trends and possible contributing factors that are most likely to cause foodborne illness or food related injury. These periodic reviews of foodborne illness may suggest a need for further investigation and may suggest steps for illness prevention.**

NOTE: This data collection tool could be stated as a Pre-Requisite at the beginning of the Standard. Everything is built on having this data.

The data has been collected so an annual review of the data that is documented will suffice.

Example of how to do data review may be found in your existing inspection/complaint database (Excel data collection tool as an example)

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b. **The review is conducted with prevention in mind and focuses on, but is not limited to the Food Borne Disease Outbreaks, Suspect Foodborne Outbreaks and Confirmed Foodborne Disease Outbreaks in the following:**
   - **Single establishment**
   - **Same establishment type**
   - **Implicating the same food**
   - **Associated with similar food preparation processes**

   Also determine:
   - **Number of confirmed foodborne disease outbreaks**
   - **Number of foodborne disease outbreaks (this seems the same as above??)**
   - **Number of suspect foodborne disease outbreaks**
   - **Contributing factors most often identified**
   - **Number of complaints involving real and alleged threats of international food contamination.**
   - **Number of complaints involving the same agent**
   - **Number of complaints involving unusual agents when identified.**

   This section can seem overwhelming especially for jurisdictions that rarely have outbreaks, suspected outbreaks or confirmed outbreaks and all the other things mentioned above. As long as you have a data collection tool with these fields to show that if it ever happens you would have the data to review.

Many jurisdictions will not have enough complaints to collect this data. Data collection tool will need to have these fields in the event the data is there.

c. **In the event that there have been no food-related illness or food-related injury outbreak investigations conducted during the twelve months prior to the data review and analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate response to an actual confirmed foodborne illness disease outbreak and include on-site inspection, sample collection and analysis. A mock investigation must be completed once per year when no foodborne disease outbreak investigation occur.** (this last sentence is redundant to me)

   Is the on-site piece required? The on-site requirement seems onerous

Outcome

Documentation

The quality records required to meet this standard include:

1. Logs or databases of alleged food-related illness and food-related injury* complaints maintained and current.
2. Collection forms specified in the operating procedures.
3. Investigation reports of alleged food-related illness, food-related injury*, or incidents. Reports are retrievable by implicated establishment name.
4. The written procedures, contracts or MOU's with the supporting laboratories.

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5. The procedure addressing the trace-back of food products implicated in an illness, outbreak, or contamination event.
6. 21 CFR, Part 7, or written procedures equivalent to 21 CFR, Part 7 for recalls.
7. Completed copies of the annual review and analysis (after 12 months of data).
8. Current written media policy/procedure and contact person.
9. The contact list for communicating with all relevant agencies.
10. Portions of any emergency response relevant to food safety and security.

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STANDARD 2 TRAINED REGULATORY STAFF

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STANDARD 2 TRAINED REGULATORY STAFF

This Standard applies to the essential elements of a training program for regulatory staff.

Requirement Summary

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have the knowledge, skills, and ability to adequately perform their required duties. The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

STEP 1
Completion of curriculum courses designated as "Pre" in Appendix B-1 prior to conducting and independent routine inspections.

STEP 2
Completion of the following:

- A minimum of 25 joint field training inspections (or a sufficient number of joint inspections determined by the trainer and verified through written documentation that the FSIO has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments); and
- Successful completion of the jurisdiction's FSIO Field Training Plan similar to the process outlined in *Appendix B-2: Conference for Food Protection (CFP) Field Training Manual*.

STEP 3
Completion of the following:

- A minimum of 25 independent inspections; and
- Remaining course curriculum (designated as "post" courses) outlined in *Appendix B-1: Curriculum for Retail Food Safety Inspection Officers*.

STEP 4
Completion of a standardization process similar to the FDA standardization procedures.

STEP 5
Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

Description of Requirement

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have successfully completed the required elements of the 5-step training and standardization process:

- Steps 1 through 4 within 24 months of hire or assignment to the retail food regulatory program.
- Step 5 every 36 months after the initial 24 months of training.

Step 1: Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in pre-requisite courses designated with a "Pre" in Appendix B-1, for the following curriculum areas:

1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
2. Public Health Principles;
3. Food Microbiology; and
4. Communication Skills.

There are two options for demonstrating successful completion of the pre-inspection curriculum.

OPTION 1: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- FDA ORA U pre-requisite courses identified as "Pre" in Appendix B-1; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances.

Note: *The estimated contact time for completion of the FDA ORA U pre-requisite ("Pre") courses is 42 hours.*

OPTION 2: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- Successful completion of courses deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the FDA ORA U pre- requisite (Pre") courses; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances; and
- Successful passing of one of the four written examination options (described later in this Standard) for determining if a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the listed ORA U courses are available from the web site link at: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

> **Note:** *While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:*
>
> - *Logs/records that are completed based on sign-in sheets; or*
> - *Information validated from the certificate at the time-of-issuance; or*
> - *A college transcript with a passing grade or other indication of successful completion of the course; or*
> - *Automated attendance records, such as those currently kept by some professional associations and state agencies, or*
> - *Other accurate verification of actual attendance.*

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORAU courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the four written examination categories specified herein.

1. The Certified Food Safety Professional examination offered by the National Environmental Health Association; or

2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable; or

3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or

4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

Note: *Written examinations are part of a training process, not a standardization/certification process. The examinations listed are not to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.*

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer who has successfully completed all training elements (Steps 1 – 3) of this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "training" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

If the trainer determines that the FSIO has successfully demonstrated the required performance elements and competencies, a lower minimum number of joint field training inspections can be established for that FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan in Appendix B-2, to support the exception.

Note: *The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."*

Demonstration inspections are those in which the jurisdiction's trainer takes the lead and the candidate observes the inspection process. Training inspections are those in which the candidate takes the lead, and their inspection performance is assessed and critiqued by the trainer. The jurisdiction's trainer is

responsible for determining the appropriate combination of demonstration and training inspections based on the candidate's food safety knowledge and performance during the joint field inspections.

The joint field inspections must be conducted using a field training process and forms similar to ones presented in the *CFP Field Training Manual* included as Appendix B-2. The *CFP Field Training Manual* consists of a training plan and log, trainer's worksheets, and procedures that may be incorporated into any jurisdiction's retail food training program. It is a national model upon which jurisdictions can design basic field training and provides a method for FSIOs to demonstrate competencies needed to conduct independent inspections of retail food, restaurant, and institutional foodservice establishments.

Jurisdictions are not required to use the forms or worksheets provided in the *CFP Field Training Manual*. Equivalent forms or training processes can be developed. To meet the intent of the Standard, documentation must be maintained that confirms FSIOs are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments.

> **Note:** *The CFP Field Training Manual is designed as a training approach providing a structure for continuous feedback between the FSIO and trainer on specific knowledge, skills, and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.*
>
> - *The CFP Field Training Manual is NOT intended to be used for certification or licensure purposes.*
> - *The CFP Field Training Manual is NOT intended to be used by regulatory jurisdictions for administrative purposes such as job classifications, promotions, or disciplinary actions.*

FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2013 *FDA Food Code*). The jurisdiction's trainer/food program manager can determine if the FSIO is ready to conduct independent inspections of risk category 1 establishments (as defined in Appendix B-3) at any time during the training process.

> **Note:** *The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can in lieu of the 25 joint field inspections:*
>
> - *Include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement; and*
> - *The supervisor/training officer must observe experienced FSIOs conduct inspections to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.*

Step 3: Independent Inspections and Completion of ALL Curriculum Elements

Within 24 months of hire or assignment to the regulatory retail food program, Food Safety Inspection Officers must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1, for the following eight curricula areas, must be completed within this 24-month time frame.

1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
2. Public health principles (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
3. Communication skills (Step 1);
4. Food microbiology (some of the courses for this element are part of the pre-requisite curriculum outlined in Step 1);
5. Epidemiology;
6. Hazard Analysis Critical Control Points (HACCP);
7. Allergen Management
8. Emergency Management

All courses for each of the curriculum areas must be successfully completed within 24 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

> **Note:** *The estimated contact time for completion of the FDA ORA U "post" courses is 26 hours. The term "post" refers to those courses in Appendix B-1 that were not included as part of the pre-requisite coursework. This includes all the courses in Appendix B-1 that do not have the designation "Pre" associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.*

As with the pre-requisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses listed under each curriculum area OR by completing courses, deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the listed ORA U courses are available from the FDA website: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners.

Step 4: Food Safety Inspection Officer – Field Standardization

Within 24 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the "FDA Standardization Procedures." The jurisdiction's "training standard" must have met all the requirements for conducting field standardizations as presented in the definition section of these Standards. The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years.

Note: *The field standardization and continuing standardization (re-standardization) criteria described in Step 4 is intended to provide a jurisdiction the flexibility to use their own regulation or ordinance. In addition, the reference to using standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers, is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written standardization protocol must include the five performance areas outlined above in Step 4.*

It is highly beneficial to use the FDA Food Code, standardization forms and procedures even when a jurisdiction has adopted modifications to the Food Code. Usually, regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge, and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA's standardization procedures are based on a minimum of 8 inspections. However, to meet Standard 2, a minimum of 4 standardization inspections must be conducted.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel versed in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate

consistent evaluation of all candidates.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors and communicates vital information about the inspection in a way that can be received, understood, and acted upon by retail food management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to both the regulatory agency and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard 2 criteria within the 24- month time frame, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5: Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (24 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer.

Training on any changes in the regulatory agency's prevailing statutes, laws and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine ten activities that are related specifically to food safety or food inspectional work:

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local);
4. Food safety related conferences and workshops; and
5. Distance learning opportunities that pertain to food safety, such as:
   - Web based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and
   - Satellite Broadcasts.
6. Foodborne illness training referenced in the Crosswalk Requirements for Foodborne Illness Training Programs - Standard 5.

A maximum of ten (10) contact hours may be accrued from the following activities:

1. Delivering presentations at professional conferences;
2. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
3. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period[1].

Note: *Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.*

A maximum of four (4) contact hours may be accrued for:

1. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- transcripts from a college or university;
- a letter from the administrator of the continuing education program attended;
- a copy of the peer-reviewed article or presentation made at a professional conference; or
- documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

Note: *The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of employee's continuing education activities, maintains the training records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses.*

Outcome

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);

2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process similar to that presented in Appendix B-2. **NOTE:** The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."
4. Certificates or other records showing proof of satisfactory standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successful completed the training and education steps outlined in this Standard.
7. Date of hire records or assignment to the retail food program; and
8. Summary record of employees' compliance with the Standard.

The *Standard 2: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 2.

STANDARD 5
FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

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STANDARD 5
FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

This standard applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies, either unintentional or deliberate, which results in illness, injury, and outbreaks.

Requirement Summary

The program has an established system to detect, collect, investigate, and respond to complaints and emergencies that involve foodborne illness, injury, and intentional and unintentional food contamination.

Description of Requirement

1. Investigative Procedures

a. The program has written operating procedures for responding to and /or conducting investigations of foodborne illness and food-related injury*. The procedures clearly identify the roles, duties, and responsibilities of program staff and how the program interacts with other relevant departments and agencies. The procedures may be contained in a single source document or in multiple documents.

b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, food-related injury* or contamination of food.

c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties, and responsibilities of each party.

d. The program maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, food-related injury* or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in or linked to the establishment record for retrieval purposes.

e. Program procedures describe the disposition, action or follow-up and reporting required for each type of complaint or referral report.

f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.

g. The program has established procedures and guidance for collecting information on the suspect food's preparation, storage or handling during on-site investigations of food-related illness, food-related injury*, or outbreak investigations.

h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.

i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.

2. Reporting Procedures

a. Possible contributing factors to the food-related illness, food-related injury* or intentional food contamination are identified in each on-site investigation report.

b. The program shares final reports of investigations with the state epidemiologist and reports of confirmed foodborne disease outbreaks* with CDC.

3. Laboratory Support Documentation

a. The program has a letter of understanding, written procedures, contract, or MOU acknowledging, that a laboratory(s) is willing and able to provide analytical support to the jurisdiction's food program. The documentation describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.

b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).

4. Trace-back Procedures

a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak, or intentional food contamination. The trace-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.

5. Recalls

a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak, or intentional food contamination.

b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed.

c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.

6. Media Management

a. The program has a written policy or procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.

7. Data Review and Analysis

a. At least once per year, the program conducts a review of the data in the complaint log or database and the foodborne illness and food-related injury* investigations to identify trends and possible contributing factors that are most likely to cause foodborne illness or food-related injury*. These periodic reviews of foodborne illnesses may suggest a need for further investigations and may suggest steps for illness prevention.

b. The review is conducted with prevention in mind and focuses on, but is not limited to, the following:

1) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* in a single establishment;
2) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Disease Outbreaks* in the same establishment type;
3) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* implicating the same food;
4) Foodborne Disease outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* associated with similar food preparation processes;
5) Number of confirmed foodborne disease outbreaks*;
6) Number of foodborne disease outbreaks* and suspect foodborne disease outbreaks*;
7) Contributing factors most often identified;
8) Number of complaints involving real and alleged threats of intentional food contamination; and
9) Number of complaints involving the same agent and any complaints involving unusual agents when agents are identified.

c. In the event that there have been no food-related illness or food-related injury* outbreak investigations conducted during the twelve months prior to the data review and analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate response to an actual confirmed foodborne disease outbreak* and include on-site inspection, sample collection and analysis. A mock investigation must be completed at least once per year when no foodborne disease outbreak* investigations occur.

Note: *Regulatory Programs are encouraged to refer to the Crosswalk - Requirements for Foodborne Illness Training Programs located on the CFP website at www.foodprotect.org under the Conference-Developed Guides and Documents tab and to also participate in the CDC National*

Environmental Assessment Reporting System (NEARS). The Crosswalk is a table that identifies training resources that correlate to the requirements listed in Standard 5. NEARS is designed to provide a more comprehensive approach to foodborne disease outbreak investigation and response and will provide a data source to measure the impact of food safety programs to further research and understand foodborne illness causes and prevention. (The following link provides additional information regarding NEARS: http://www.cdc.gov/nceh/ehs/nears/index.htm)

Outcome

A food regulatory program has a systematic approach for the detection, investigation, response, documentation, and analysis of alleged food-related incidents that involve illness, injury, unintentional or deliberate food contamination.

Documentation

The quality records required to meet this standard include:

1. Logs or databases of alleged food-related illness and food-related injury* complaints maintained and current.
2. Collection forms specified in the operating procedures.
3. Investigation reports of alleged food-related illness, food-related injury*, or incidents. Reports are retrievable by implicated establishment name.
4. The written procedures, contracts, or MOUs with the supporting laboratories.
5. The procedure addressing the trace-back of food products implicated in an illness, outbreak, or contamination event.
6. 21 CFR, Part 7, or written procedures equivalent to 21 CFR, Part 7 for recalls.
7. Completed copies of the annual review and analysis (after 12 months of data).
8. Current written media policy/procedure and contact person.
9. The contact list for communicating with all relevant agencies.
10. Portions of any emergency response relevant to food safety and security.

*[*Note: See the Standards Definitions for the meaning of these defined terms.]*

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COMMITTEE NAME: Program Standards (PSC), Subcommittee 1

DATE OF REPORT: ☐ ***Initial fall progress report*** ☐***Spring progress report*** ☒ ***Second fall progress report***
Date submitted: 10/31/2022 **Date amended (if applicable):** *Click here to enter a date.* **Date accepted by Executive Board:** *Click here to enter a date.*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: *Kenesha Williamson and Michael Touhey*

COMMITTEE CHARGE(S):

***Issue* # 2020 -II-017 Charges 1 & 2**

1. Identify inconsistencies in language between all Standards in the Retail Program Standards.
2. Continue review of initiatives (existing, new or under development) involving the training, evaluation and/or certification of food safety inspection officers to ensure the sharing of information and eliminate unnecessary redundancy in the creation of work products or assignments of tasks/responsibilities.

COMMITTEE WORK PLAN AND TIMELINE:

An introductory meeting in January 2022 followed by bi-weekly meetings January - February 2022 then monthly meetings through September 2022. Workgroup documents will be shared via CFP Microsoft Teams and attached to calendar invitations. Microsoft Teams will be used for presenting workgroup material and reviewing documents, during monthly meetings. The committee's members will be assigned individual Standards to evaluate for discussion within the group. Polls will be forwarded via email, as needed, to voting members to finalize recommendations. Periodic reports will be prepared and submitted in March 2022, July 2022, and October 2022, in accordance with the CFP master calendar.

COMMITTEE ACTIVITIES:

1. ***Dates of committee meetings or conference calls:*** January 13, 2022, February 3, 2022, February 17, 2022, March 15, 2022, April 19, 2022, May 31, 2022, June 28, 2022, August 24, 2022, September 8, 2022.

2. ***Overview of committee activities:***

    a. The conference call on January 13, 2022 was used to review the committee charges, determine the timeline for addressing the charges, and it was decided that Microsoft Teams will be used for document sharing. There was preliminary discussion of the Standards and review of poll responses regarding initial feedback on any known gaps within the Standards. The conference call on February 3 addressed charge 2, and a list of training, evaluation and/or certification courses available to food safety inspection officers was reviewed based on the draft created during the last biennium. The conference call on February 17, 2022 addressed charges 1 and 2, and the committee started work on edits to the list of training, evaluation and/or certification courses. The addition and removal of entries to list of courses were completed through screen sharing during the meeting. Committee members provided feedback on their review assignments. Changes to the assignments were made from the feedback and overall experience with the Standards.

    b. At the request of our FDA consultants, a special meeting was held on March 15, 2022 for Standard 6 to discuss the Standardized Key Crosswalk to the 2017 FDA Food Code and the Compliance and Enforcement worksheet. For this discussion, we hosted issue submitter Dan Joseph from State of Colorado. The conference call on April 19, 2022 was another special session which focused on Standard 8. Issue submitter Jo Ann Monroy presented at the meeting to review their staffing model pilot study on Standard 8 – Program Resources. On May 31, 2022 we began discussing the updates from the workgroups to review their assigned Standards. As each workgroup presented, the group screenshared the notes and discussions within the CFP Microsoft Teams folder. On June 28, 2022, the workgroups screenshared notes within the CFP Microsoft Teams folders and discussed possible Issues to be drafted for Standard 2 and 3 in the coming months.

    c. The full committee met on August 18, 2022 to discuss updates from each subcommittee. During the full committee meeting, subcommittee 5 gave us feedback on a Standard 1 Issue from the previous biennium, 2020 II-031. Regarding that Issue, consensus was reached on drafting a new Issue that would assign 2020 II-031 to Program Standards Committee. Program Standards can then continue working on the Issue given that it was originally submitted by AFDO and needs further review within the committee process. During the conference call on August 24, 2022 with the subcommittee, we discussed updates from the workgroups on reviewing Standards 1 through 9 to address Charge 1. The group also discussed the list of training, evaluation, and certification resources for Charge 2. Discussion continued on the proposed CFP Issues and selecting Issue submitters and presenters. We reached consensus on all of the proposed Issues after voting not to proceed with recommending Appendix B-1

be removed from Standard 2. During our final meeting on September 8th, we identified three Standards which still needed to be reviewed for issue recommendations, Standards 1, 7, and 9. To complete charge 1, we reviewed created a table of proposed Issues and discussed public health significance for Issues drafted thus far. The group decided to continue communications via email or phone going forward to finalize their Issues. Individual workgroups would meet again as needed to assist completion of their Issues.

3. ***Charges COMPLETED and the rationale for each specific recommendation:***
    a. Charge 1: We identified gaps and inconsistencies in language between all the Standards in the Retail Program Standards.
        i. Reassign Issue 2020 II-031 to the PSC Committee (see attachment 2.j). Missing Priority and Priority Foundation items will lead to a significant increase of out-of-control foodborne illness risk factors in those jurisdictions that do not fully meet all the provisions in the FDA Food Code.
        ii. Tracking versions of Standard 2 Appendix B-1: Adding a version number and/or revision date to Appendix B-1, will clarify which required courses should appear in FSIO training records. Attachment 2.k shows that Appendix B-1 does not include a version number or revision date.
        iii. Changing Re-Standardization Frequency: Changing the frequency of re-standardization from three years to five years for inspection staff who do not standardize others and maintaining that standardization officers continue to be re-standardized every three years. Agencies are struggling with resources and need to focus on standardizing newer staff instead of the more experienced staff. Staff turnover also has a major impact on meeting Standard 2. For standardization officers, the existing re-standardization frequency of every three years should be maintained.
        iv. Add FD218 to Standard 2 "post" curriculum. Inspectors need proper training to conduct risk-based inspections. Risk-based inspection methodology is not currently included in the key learning objectives of the general education courses in Standard 2. Risk-Based Inspection Methods, FD218, is being considered as an advanced course. But it is foundational (see attachment 2.l). Attachment 2.m shows the key learning objectives for FDA 38 and 39 Basics of Inspection.
        v. Adding language to Program Standard 2 that references the FDA's National Curriculum Standard (NCS) as a blueprint for Food Safety Inspection Officer (FSIO) training. The National Curriculum Standard (NCS) as part of the Integrated Food Safety System (IFSS) identifies the competencies (knowledge, skills, and abilities) needed by regulatory food protection professionals to successfully perform their job functions, whether they are inspecting retail food, manufactured food, animal food, or unprocessed food facilities. See attachment 2.o. The NCS also provides behavioral anchors (performance indicators) that serve to clarify the competencies and can be used for assessment purposes. Attachment 1.b.i shows drafted language about the current NCS within Standard 2.
        vi. Correcting the order of the terms "Validation" and "Verification" in the Standard 3 – Self Assessment and Verification Audit form. The HACCP concepts of "Validation" and "Verification" can be confusing concepts. In addition, the reuse of the terms for a regulatory approval of a submitted HACCP plan adds additional confusion. In both cases, the term "Validation" comes before "Verification". By reversing the terminology (Verification and Validation) in the Standard 3 documents, unnecessary additional confusion can be caused.
        vii. Create Standard 4 Uniform Inspection Program verification audit instructions. Verification auditors do not have standardized instructions on how to conduct a verification audit on Standard 4 which may result in audits not being assessed equally. There is no guidance on:
            - How many retail food inspection staff may fall short of having three field reviews during the five-year self-assessment period and the jurisdiction still meet the Standard (90% of staff for field standardization in Standard 2).
            - How many employee quality assurance records to review.
            - When additional employee quality assurance records may need to be reviewed.
            - The rate of agreement between the verification auditor and the self-assessment to meet the Standard.
        viii. Edits to the primary Standard 5 document and the standards definitions document to correct errors and achieve consistency with the other Standards. Attachments 1.b.ii and 1.b.iii demonstrate suggested changes to Standard 5 and Program Standards Definitions. The following summarizes the proposed edits:
            1. Add the word "foodborne" in the Standard 5 Data Review and Analysis section. The term was unintentionally omitted.
            2. Remove the footnote from Standard 5 page 5-5 and all corresponding asterisks.
            3. Reformat all defined terms in Standard 5 to small caps as shown in Standard 9.
            4. Expand the definition of "Foodborne Disease Outbreak" to establish that both suspect and confirmed outbreaks fit under this term, on page iv of the Program Standards Definitions document.
            5. Expand the definition of "Suspect Foodborne Outbreak", on page vi of the Program Standards Definitions document, to differentiate it from "Foodborne Disease Outbreak" and to establish that it is a foodborne illness outbreak that is not confirmed.
        ix. Establishment file worksheet based on FDA Food Code Form 3-A: Standard 6 requires that the program must demonstrate credible follow-up for each violation noted during an inspection, with particular emphasis being placed on risk factors that most often contribute to foodborne illness and public health interventions intended to prevent foodborne illness. Standard 6 includes a Compliance and Enforcement Establishment File Worksheet based on the risk factors and interventions. Many jurisdictions use regulations based on the FDA Model Food Code and an inspection

report based on the model FDA inspection form found in Annex 7 of the FDA Food Code (Food Inspection Report Form 3-A). Items 1 – 29 on inspection report Form 3-A are based on the risk factors and interventions. An additional Compliance and Enforcement Establishment File Worksheet based on Form 3-A would help jurisdictions more easily assess the required provisions of Standard 6. Attachment 1.b.iv demonstrates suggested changes for an additional Compliance and Enforcement Establishment File Worksheet.

x. Update Standard 6 – Standardized Key Crosswalk to the 2017 FDA Food Code with the attached version and replacing "Quick Reference Applicable Food Code Risk Factor Provisions" with "Standard 6 – Standardized Key Crosswalk to the 2017 FDA Food Code". Attachment 1.b.v demonstrates suggested changes to the Standard 6 – Standardized Key Crosswalk to the 2017 FDA Food Code. This document having a file name and website link title which differ from the document's title is confusing. The crosswalk lists risk factors and public health interventions as identified on the model FDA inspection form found in Annex 7 of the 2017 FDA Food Code (Food Inspection Report Form 3-A) with corresponding Food Code references. It serves as a resource for jurisdictions conducting a self-assessment of Standard 6 in making comparisons with their code against the 2017 FDA Food Code. The current version of this document has some errors including:
    - The formatting references for PIC,
    - The references for adequate handwashing sinks, and
    - A typo in Consumer Advisory provided for raw/undercooked foods.

xi. Define Standard 8 Verification Audit parameters. Updated language in Standard 8 for "Section 1: Staffing Levels" was much needed. There are now three choices/options within the Standard for ways to ensure that there is adequate staff to ensure inspectional and surveillance system needs are met to reduce risk factors. Two of the choices have clearly defined metrics and parameters around conformance or non-conformance. The third option is vague.

b. Charge 2: We continued review of initiatives (existing, new or under development) involving the training, evaluation and/or certification of food safety inspection officers to ensure the sharing of information and eliminate unnecessary redundancy in the creation of work products or assignments of tasks/responsibilities. See Attachment 2.n.

4. ***Status of charges still PENDING and activities yet to be completed:***

N/A

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***Board Action is NOT required and therefore the report can be placed on the consent calendar for Board review and acceptance.***
☐ ***Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.***

ATTACHMENTS:

1. ***Content Documents:***
    a. ***Committee Member Roster:*** ☐ ***See changes noted above under "requested action"*** ☒ ***No changes to previously approved roster***
    "Committee Members Template" (Excel) available at: www.foodprotect.org/work/ Committee roster to be submitted as a PDF attachment to this report.
    b. ***Committee Generated Content Documents (OPTIONAL):*** ☐ ***No draft content documents submitted at this time***
        i. Issue 5 Attachment Draft Program Standard 2 - NCS Added
        ii. Issue 8 Attachment Program Standards 2022 Standard 5 Edits
        iii. Issue 8 Attachment Program Standards 2022 Definitions Edits
        iv. Issue 9 Attachment Draft Standard 6 Establishment File Worksheet - Food Code Form 3A Based
        v. Issue 10 Attachment Draft Standard 6 – Standardized Key Crosswalk to the 2017 FDA Food Code
2. ***Supporting Attachments (OPTIONAL):*** ☐ ***Not applicable***
    a. Meeting #1 Minutes 01/13/2022
    b. Meeting #2 Minutes 02/03/2022
    c. Meeting #3 Minutes 02/17/2022
    d. Meeting #4 Minutes 03/15/2022
    e. Meeting #5 Minutes 04/19/2022
    f. Meeting #6 Minutes 05/31/2022
    g. Meeting #7 Minutes 06/28/2022
    h. Meeting #8 Minutes 08/24/2022
    i. Meeting #9 Minutes 09/08/2022
    j. Issue 1 Attachment CFP Issue 2020 II-031

k. Issue 2 Attachment 2022 Program Standard 2 Appendix B-1
l. Issue 4 Attachment AFDO - Risk-Based Inspection Methods in Retail FD218
m. Issue 4 Attachment Course Descriptions and Objectives - FDA 38 and 39
n. Charge 2 Training Evaluation and Certification Initiatives
o. Issue 5 Attachment IFSS Framework Basic Advanced Feb 2021

Template approved: 7/13/2021

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COMMITTEE NAME ***Program Standards (PSC), Subcommittee 2***

DATE OF FINAL REPORT: *10/29/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: DeBrena Hilton and Jennifer Hutson, Co-chairs

COMMITTEE CHARGE(S):

Issue # Issue # 2020 II-017

3. Maintain the "Crosswalk – Requirements for Foodborne Illness Training Programs" document as a resource for content baseline for foodborne illness training.

Issue # Issue # 2020 II-033

5. Review the Center for Disease Control and Prevention's National Environmental Assessment Reporting System (NEARS), Environmental Assessment Training Series (EATS), and Council to Improve Foodborne Outbreak Response (CIFOR) to consider inclusion of specific components.

COMMITTEE WORK PLAN AND TIMELINE: Committee members initially began reviewing documents outlined in Issues #2020 II-017 and #2020 II-033 by splitting out sections amongst our workgroup. We initially planned to meet monthly to report any updates that were needed to the documents selected. During our second meeting, we decided to review of certain documents individually and then report back in July with any needed updates.

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

1. ***Overview of committee activities:***

   Sub-committee 2 met via conference call on April 19, 2022; July 19, 2022.

   The subcommittee found that there weren't any changes needed to be made to the Crosswalk or NEARS, EATS, and CIFOR that would necessitate changes at this time. Forwarded the following recommendations to PSC Subcommittee 4:

   - *Recommend that the Crosswalk be referenced as a resource document in VNRFRPS - Standard 2 & Standard to bring more awareness to the document.*
   - *Committee recommended that the reiterations of the Crosswalk posted on CFP website be updated so that only the most current version be posted to alleviate any confusion.*
   - *Recommend that NEHA IFITT-RR (directed to food industry), Epi-Ready course, and all other documents/resources be easier to find for review.*

2. ***Charges COMPLETED and the rationale for each specific recommendation:***
   a.

3. ***Charges INCOMPLETE and to be continued to next biennium:***
   a. Issue 2020 II-033 Charge 5 has been submitted for continuation in the next biennium.
   b. Committee recommendation is that charges be continued to next biennium.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

1.
2.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. ***Issue #1: Report – Committee Name:*** **List of content documents submitted with this Issue:** ***Committee Member Roster:***

☐ ***See attached revised roster PDF*** ☐ ***No changes to previously approved roster***

"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) ***Other content documents:***

b. List of supporting attachments: ☐ ***Not applicable***

(1)

a. ***Committee Issue #2***:

b. ***Committee Issue #3***:

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COMMITTEE NAME PSC Subcommittee 3 Final Report

DATE OF FINAL REPORT: *11/1/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: **Catherine Feeney and Amanda Anderson (Co-chairs)**

COMMITTEE CHARGE(S):

Issue # *2020 II-023*

1. *The Program Standards committee and FDA staff continue to explore the feasibility of incorporation of plan review functions into the standards either as a stand-alone standard or inserted into the existing standards in the Voluntary National Retail Food Regulatory Program Standards.*
2. *Acknowledgement of the Preliminary Plan Review Proposal document to be utilized as a starting point for the 2020-2022 Program Standards Committee work on this issue.*

COMMITTEE WORK PLAN AND TIMELINE:

COMMITTEE ACTIVITIES: **Dates of committee meetings or conference calls:**

1. ***Overview of committee activities:***

   1/25, 2/8, 2/28, 3/21, 4/11, 4/25, 10/25

   Reviewed previous committee's work. Utilized Preliminary Plan Review Proposal as a starting point to the discussion.

   Discussed options for adding Plan Review as a separate standard or incorporating it into one or more existing Standards.

   Unanimously agreed to include plan review into Standard 3- Inspection Program based on HACCP Principles.

   Worked on wording for the Standard Requirement, Documentation, and accompanying Self-Assessment and Verification Audit.

   Discussed options for agencies that do not do plan review independently or at all so that Standard 3 could still be met.

   Deliberated expanding the scope of plan review to include food safety plans as well as construction, equipment, and HACCP plans.

   Met with Food Safety Management Committee to align Plan Review subcommittee's work.

   Plan Review subcommittee met to decide on incorporating the FSMS terminology and concept into the plan review element being proposed for Standard 3.

   Two issues that been drafted:

   1- a. Request that Plan Review Committee be reformed to work on updating the CFP 2016 Plan Review for Food Establishments document, b. Align work with the Food Safety Management System Committee

   2- a. Add plan review to Standard 3. Revise the SA/VA to reflect the addition.

2. ***Charges COMPLETED and the rationale for each specific recommendation:***
   - **a.** *Acknowledged Preliminary Plan Review Proposal document to be utilized as a starting point. This approach was taken to leverage work of previous plan review committee.*
   - **b.** *Recommendation to include Plan Review as an element of Standard 3. Language was added to the Standard and also the Self-Assessment and Verification Audit to reflect the addition for Council II's consideration. Plan review is a critical step in ensuring that an establishment is set up to ensure safe food. Submission, review, and approval of a food safety*

management system, construction plan, equipment specifications and location are key to a food businesses success in operating a safe food establishment.

c.

3. ***Charges INCOMPLETE and to be continued to next biennium:***

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

1.

2.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. ***Issue #1: Report – Committee Name:*** **List of content documents submitted with this Issue:** ***Committee Member Roster:***

☐ ***See attached revised roster PDF*** ☐ ***No changes to previously approved roster***

"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) ***Other content documents:***

b. **List of supporting attachments:** ☐ ***Not applicable***

(1)

Committee Issue #2*:*

Request that Plan Review Committee be reformed to work on updating the CFP 2016 Plan Review for Food Establishments document, Align work with the Food Safety Management System Committee

Committee Issue #3:

Recommend including Plan Review as an element of Standard 3. Language was added to the Standard and also the Self-Assessment and Verification Audit to reflect the addition for Council II's consideration. Plan review is a critical step in ensuring that an establishment is set up to ensure safe food. Submission, review, and approval of a food safety management system, construction plan, equipment specifications and location are key to a food businesses success in operating a safe food establishment.

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COMMITTEE NAME PSC Subcommittee 4 Final Report

DATE OF FINAL REPORT: *11/1/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: **Elizabeth A Nutt Co-Chair, Jeff Lindholm, Co-Chair**

COMMITTEE CHARGE(S):

Issue # 2020-II-033

1. Conduct a thorough review of Standard 5 "Foodborne Illness and Food Defense Preparedness and Response of the FDA Voluntary National Retail Food Regulatory Program Standards (VNRFRPS);
2. The review should include comparing the Standard to other similar FDA standards in food;
3. Review the "Description of Requirements" to ensure the requirements provide program flexibility and include items generally part of a retail food program;
4. Review Standard 5 "Data Review and Analysis" from a sampling of jurisdictions to determine if certain data analysis requirements typically have no or such limited data to make the information not valuable;
5. ~~Review the Center for Disease Control and Prevention's National Environmental Assessment Reporting System (NEARS), Environmental Assessment Training Series (EATS), and Council to Improve Foodborne Outbreak Response (CIFOR) to consider inclusion of specific components.~~ This Charge was reassigned to Subcommittee #2.
6. Propose amendments to Standard 5 of the VNRFRPS;
7. Report back committee findings and recommendations to the next Biennial Meeting.

COMMITTEE WORK PLAN AND TIMELINE:

Reviewing Charges
Comparing VNRFRPS (Retail Standards) and MFRPS (Manufacturing Standards) to determine if they can be aligned and achieve desired outcomes
Soliciting input from enrolled jurisdictions about concerns with Program Standard 5 and possible guidance on solutions.

COMMITTEE ACTIVITIES: **Dates of committee meetings or conference calls:**

1. ***Overview of committee activities:***
   Determined that Standard 5 was aligned with achieving the best approach to response to foodborne illness outbreaks but a Road Map to assist jurisdictions on how to meet the standard would be a resource to be available as an addendum. Road Map would provide steps to develop written procedures, MOU's, set up relationships with other agencies involved with outbreak response and tools to collect and track data.
2. ***Charges COMPLETED and the rationale for each specific recommendation:***
   a. Charge 1- Review of Standard 5 done by committee; no action
   b. Charge 2-Compared Retail food Standard 5 to Manufactured Foods Standards; no action.
   c. Charges 3 & 4- After reviewing these charges the committee determined that the creation of a Road Map would be the approach to assist jurisdictions in assessing the Standard.
3. ***Charges INCOMPLETE and to be continued to next biennium:***
   a. The subcommittee was unable to complete the road map and recommends continuation of Issue 2020 II-023. Specifically, the committee identified that a roadmap outlining the requirements of Standard 5 would be beneficial to assist enrolled jurisdictions in conducting self-assessments. Templates and examples of required documentation would accompany the roadmap. A first draft of the roadmap has been drafted but was not able to be finalized during this biennium.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☐ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***
☒ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. ***Issue #1: Report – Committee Name:*** **List of content documents submitted with this Issue:** ***Subcommittee Member Roster:***

☐ ***See attached revised roster PDF*** ☐ ***No changes to previously approved roster***

Copy of Subcommittee 4 rost

(1) ***Other content documents: Subcommittee Minutes***

Copy Minutes 2.23.22.pdf

Minutes 4.18.22 (002).docx

Minutes 5.25.22.docx

Minutes 6.22.22.docx

Minutes 7-27-22.docx

Minutes 8_31_22.docx

Minutes 9_23_2022.docx

Minutes 10_20_22.docx

b. **List of supporting attachments:** ☐ ***Not applicable***

(1) **Draft Road Map:**

STD 5 RoadMap DRAFT 10_2022.docx

(2) **Draft Data Collection Template:**

Data Collection Template.xlsx

Issue 2020-II-017

Charge 2: Initiatives (existing, new, or under development) involving the training, evaluation and/or certification available to Food Safety Inspection Officers (FSIO):

Training – Existing

ORAU Pre

- Public Health Principles FDA 36
- Overview of Microbiology MIC01
- Food Microbiological Control 2A: Gram-Negative Rods MIC02
- Food Microbiological Control 2A: Gram-Positive Rods and Cocci MIC03
- Food Microbiological Control 2A: Foodborne Viruses MIC04
- Food Microbiological Control 4: Foodborne Parasites MIC05
- Food Microbiological Control: Mid-Series Exam MIC16
- Food Microbiological Control 5: Controlling Growth Factors MIC06
- Food Microbiological Control 6: Control by Refrigeration and Freezing MIC07
- Food Microbiological Control 7A: Control by Thermal Processing MIC08
- Food Microbiological Control 7B: Control by Pasteurization MIC09
- Food Microbiological Control 10: Aseptic Sampling MIC13
- Food Microbiological Control 10: Cleaning and Sanitizing MIC15
- Basic Food Law for State Regulators FDA35
- Basics of Inspections: Beginning an Inspection FDA38
- Basics of Inspections: Issues and Observations FDA39
- An Introduction to Food Security Awareness FD251 **(https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/introduction-food-security-awareness)** NOTE: Required Exam is available via **www.compliancewire.com**
- Communication Skills for Regulators

ORAU Post

- An Introduction to Food Security Awareness MIC10
- Food Microbiological Control 8: Technology-based Food Processes MIC11
- Food Microbiological Control 9: Natural Toxins MIC12
- Basics of HACCP: Overview of HACCP FDA16
- Basics of HACCP: Prerequisite Programs and Preliminary Steps FDA17
- Basics of HACCP: Prerequisite Programs and Preliminary Steps FDA18
- Foodborne Illness Investigations 1: Collecting Surveillance Data FI01
- Foodborne Illness Investigations 2: Beginning an Investigation FI02
- Foodborne Illness Investigations 3: Expanding the Investigation FI03
- Foodborne Illness Investigations 4: Conducting a Food Hazard Review FI04
- Foodborne Illness Investigations 5: Epidemiological Statistics FI05
- Foodborne Illness Investigations 6: Final Report FI06

- Food Allergens (CC8029W) Course must be accessed through FDA Pathlore at**:** **(https://orauportal.fda.gov/stc/ora/psciis.dll?linkid=436613&mainmenu=ORA&top_frame=1)**

FEMA courses can be accessed at: **http://training.fema.gov/IS/NIMS.asp**

- Introduction to Incident Command System IS-100.C
- ICS for Single Resources and Initial Action Incidents IS-200.C
- NIMS an Introduction IS-700.B

FDA ComplianceWire

- Food Code Chapter 7: Poisonous and Toxic Materials FD112 Food Code (FDAFC01)
- Food Code Chapter 1: Purpose and Definitions FD112 Food Code (FDAFC02)
- Food Code Chapter 3: Part I FD112 Food Code (FDAFC03)
- Food Code Chapter 5: Water, Plumbing, and Waste FD112 Food Code (FDAFC04)
- Food Code Chapter 3: Part II FD112 Food Code (FDAFC05)
- Food Code Chapter 3: Part III FD112 Food Code (FDAFC06)
- Food Code Chapter 2: Supervision FD112 Food Code (FDAFC07)
- Food Code Chapter 4: Part I FD112 Food Code (FDAFC08)
- Food Code Chapter 6 FD112 Food Code (FDAFC09)
- Food Code Chapter 4: Part II FD112 Food Code (FDAFC10)
- Food Code Chapter 8: Enforcement and Annex 1 FD112 Food Code (FDAFC11)
- HACCP (CC8033W)
- Employee Hygiene: Food Service (FOOD1)
- HACCP (FOOD5)
- Preventing Microbial Cross-Contamination (FOOD3)

IFPTI Courses on ComplianceWire

- Regulatory Program Foundations (CC8021W)
- Allergens (CC8029W)
- Biological Hazards (CC8028W)
- Biosecurity (CC8023W)
- Communication Skills (CC8030W) Course must be accessed through FDA Pathlore at**:** **(https:// orauportal.fda.gov/stc/ORA/psciis.dll?linkid=675280&mainmenu=ORA&top_frame=1)**
- Data & Information Systems (CC8017W)
- Emergency Response
- Environmental Hazards (CC8027W)
- HACCP (CC8033W)
- Imports (CC8034W)
- Integrated Food Safety System (CC8018W)
- Inspections, Compliance, & Enforcement (CC8019W)
- Investigation Principles (CC8020W)

- Jurisdiction (CC8037W)
- Labeling (CC8038W)
- Laws, Regulations, Policies, & Procedures (CC8039W)
- Personal Safety (CC8031W)
- Pest Control
- Plumbing
- Preventive Controls (CC8040W)
- Professionalism (CC8025W)
- Public Health Principles (CC8026W)
- Recalls (CC8041W)
- Sampling (CC8035W)
- Sanitation Practices (CC8032W)
- Traceability (CC8042W)
- Transportation (CC8036)

FDA Pathlore

- Fermentation at Retail (FD8009W)
- Curing, Smoking, Drying of Meat, Poultry and Fish and the Processing of Fermented Sausages (FD8005W)
- Reduced Oxygen Packaging at Retail (FD8004W)
- Juicing at Retail (FD8008W)
- Shellfish Tanks at Retail (FD8007W)
- Custom Processing of Meats at Retail (FD8006W)
- HACCP (CC8033W)
- Plumbing Controls for Commercial Food Establishments (CC8001W)
- Pest Control in Food Establishments (FD180W100)

Instructor Led Courses

- FD112 – Food Code
- FD218 - Risk-Based Inspection Methods in Retail
- FD204 - Temporary Food Establishments
- FD207 – Plan Review for Food Establishments
- FD312 - Special Processes at Retail
- FD215 - Managing Retail Food Safety
- ER310 - Food Safety Issues in the Event of Disasters
- EPI-Ready in person training through (NEHA/Centers of Excellence)
- AFDO – Environmental Sampling in Retail Food Facilities

In-house training provided by State/Local Health Departments:

- Report writing
- State-specific
- Software
- Compliance and enforcement

- Risk-based inspection methods
- HACCP (application)
- Plumbing/backflow
- Consistency training (marking under same number)
- Meat/poultry inspection
- Scenario/mock inspection/role playing
- Ethnic Food Book
- Temporary Food Establishment training
- Mobile Vending training
- NAU Back Country Excursions
- Food Service During Disasters

Training Resources

- AFDO Ethnic Food CD/App
- AFDO Salvage Food
- AFDO Dented Cans
- AFDO Incubator (Community/Shared) Kitchens
- AFDO Cottage Food
- Centers of Excellence (COE) food safety tools
- CDC EATS 101
- CDC EATS 102

Evaluation

- CFP Training manual forms for new hires
- Standard 4 - 20 Quality Elements
- Standardization

Certification

- NEHA Registered Environmental Health Specialist/Registered Sanitarian (REHS/RS)
- NEHA Certified Professional - Food Safety (CPFS)
- NEHA Certified in Comprehensive Food Safety (CCFS) Credential
- NEHA Certified Foodborne Outbreak Investigator (CFOI)
- HACCP Alliance – Certified HACCP Manager
- NSF – Certified HACCP Manager
- ASQ (American Society for Quality) Root Cause Analysis Training
- 40 Hour HAZWOPER
- ANSI Food Safety Manager

Post Event Data

Retail Program Standards Symposium

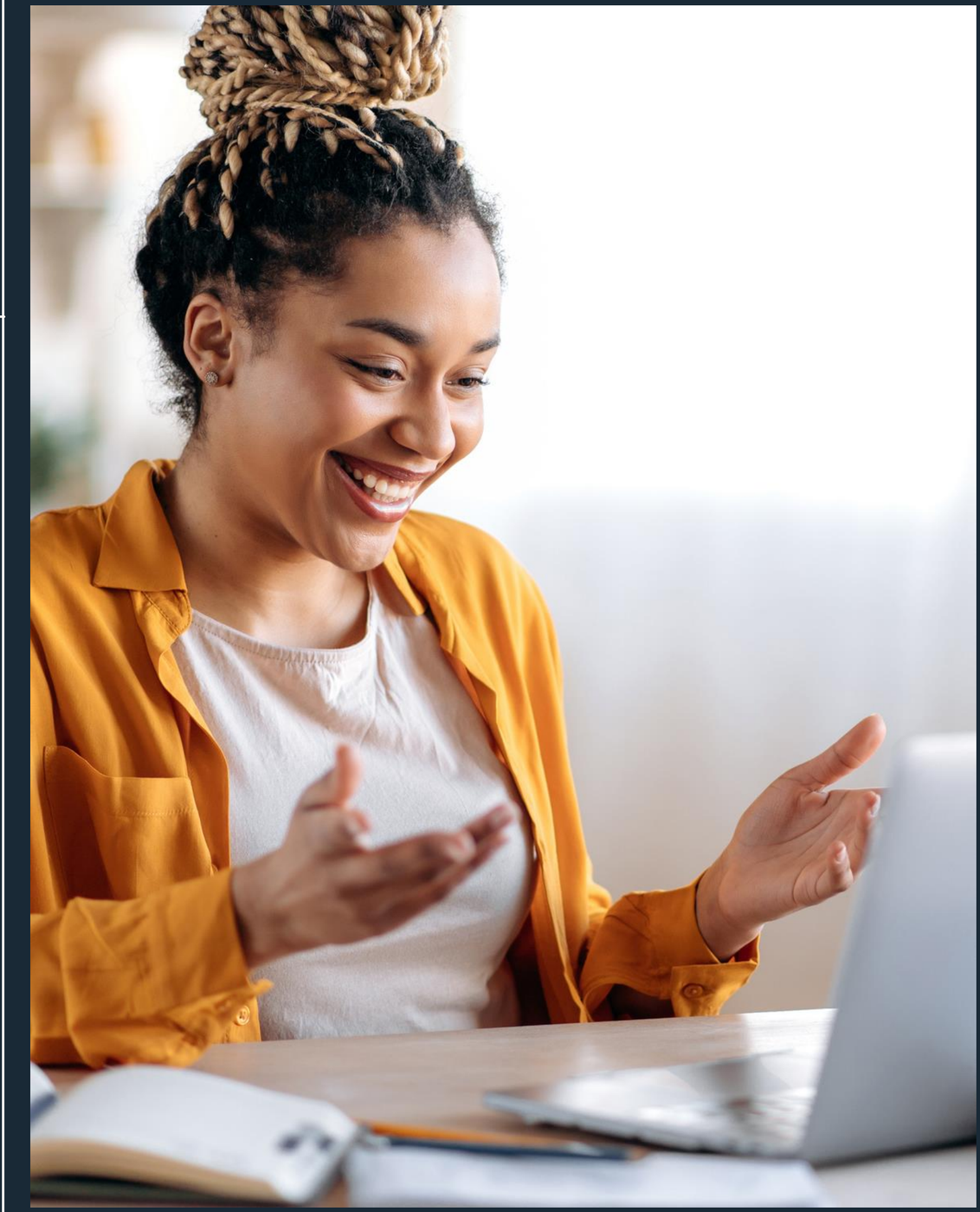
Presented by the NEHA-FDA RFFM Grant Program
in collaboration with the Conference for Food Protection

Contents

- Introduction
- Total Registrations
- Total Attendees
- Attendees by Session & Exhibit Hall Sessions
- RFFM Attendees
- Attendees by Agency
- Attendees by State
- Key Findings

Introduction

The following data was compiled from the 2022 Retail Program Standards Symposium (RPSS). This data includes total registrations for the RPSS and total attendees. Further detail is provided for attendees by session, to breakdown of attendees by agency classification, by region, and then by localities.



Registrations

958

Total RPSS Registrations

Includes all Registered Individuals
Does not include Speakers, Panelists, Moderators, or Staff

Attendees

755

Total RPSS Attendees

Includes all registered individuals that attended all or part of the RPSS
Does not include Speakers, Panelists, Moderators, or Staff

78.8% of Registrants

Day 1 Sessions

Session	Attendees
Welcome, Keynote Address & General Session	653
Track 1 Session: Roadmap for Success; Why Enroll in RPS?	227
Track 2 Session: Technology to Assist with Maintenance of RPS Records/ Supporting Docs	221
Track 3 Session: Sustaining RPS Activities/Having a Succession Plan	134
Day 1 Wrap Up Session	318

Day 2 Sessions

Session	Attendees
Welcome & General Session	586
Track 1 Session: What is Initial Self-Assessment; SA/VA Gap Analysis Tool; Continuous Strategic Improvement Plan (CSIP)	300
Track 2 Session: Self-Assessment & Verification Audit Resources; How to Find an Auditor	149
Track 3 Session: Mentorship Program	105
Day 2 Wrap Up Session	277

Day 3 Sessions

Session	Attendees
Welcome & General Session	524
Track 1 Session: Mentorship Programs (NACCHO)	127
Track 2 Session: What Does a Retail Program Standards Coordinator Do?	214
Track 3 Session: Retail Program Standards Networks/Champions	132
Day 3 Closing Session	264

Exhibit Hall Sessions

Session	Day 1	Day 2	Day 3
Retail Program Standard 1	117	45	27
Retail Program Standard 2	87	65	41
Retail Program Standard 3	37	52	30
Retail Program Standard 4	41	50	50
Retail Program Standard 5	44	59	49

*Exhibit Hall Session numbers are reflective of session page visits

Exhibit Hall Sessions

Session	Day 1	Day 2	Day 3
Retail Program Standard 6	21	46	36
Retail Program Standard 7	23	34	46
Retail Program Standard 8	13	25	27
Retail Program Standard 9	30	41	30

*Exhibit Hall Session numbers are reflective of session page visits

Exhibit Hall Sessions

Session	Day 1	Day 2	Day 3
Administrative Procedures	22	22	10
Comprehensive Strategic Improvement Plan (CSIP)	43	39	31
Mentorship	14	9	14
National Environmental Public Health Internship Program (NEPHIP)	12	4	7

*Exhibit Hall Session numbers are reflective of session page visits

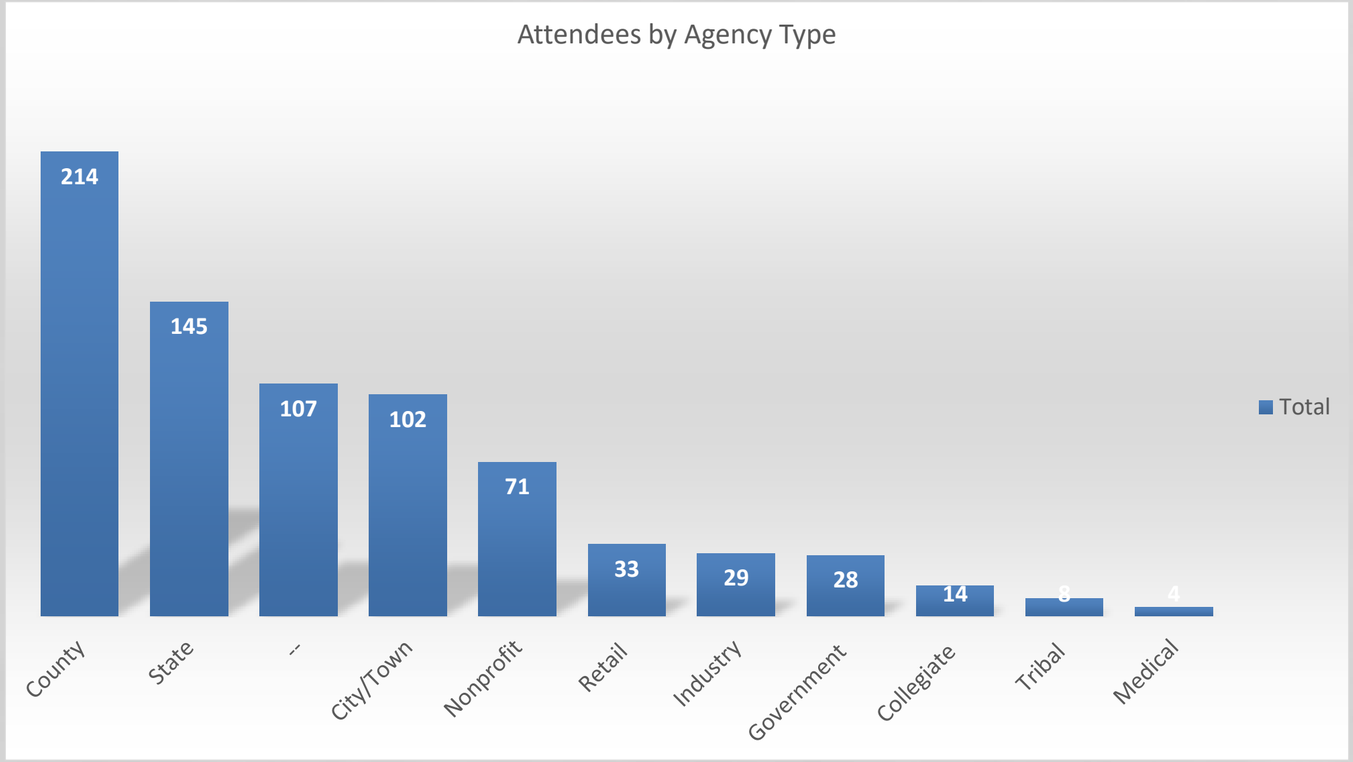
RFFM Attendees

Attendees	Registered & Attended RPSS
RFFM Subawardees	96
Registered in RFFM Portal (not Awarded)	17
TOTAL	113

Attendees by Agency

Includes Attendees counts by their respective agency type

Attendees from County agencies far exceeded the other categories, followed by State and City/Town agencies.

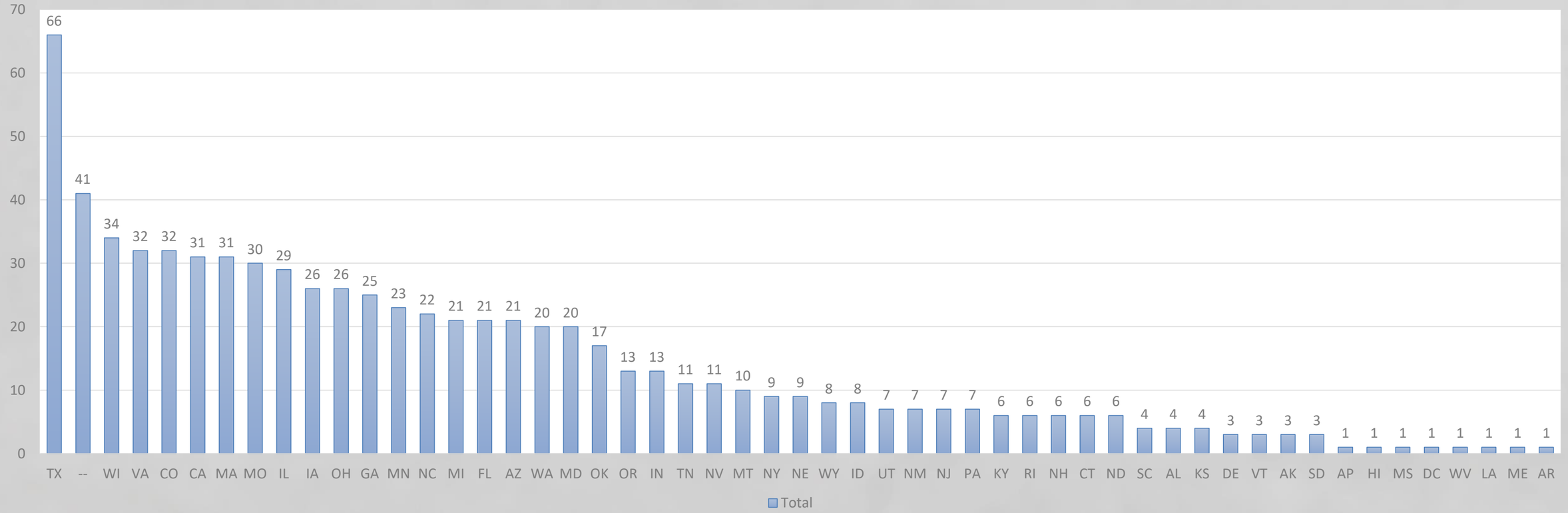


Attendees by State

Distribution of Attendees by State

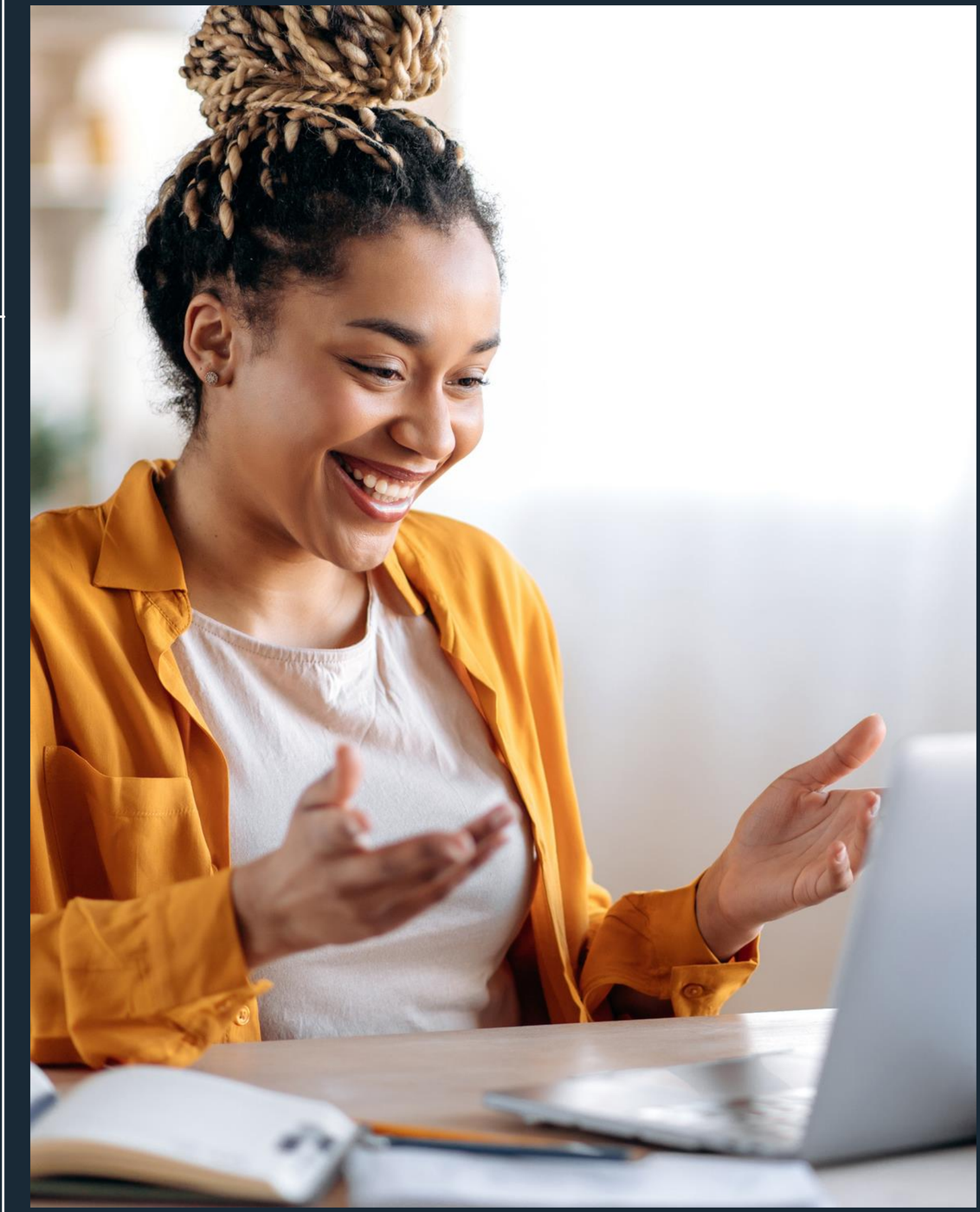
Includes all registered individuals that attended all or part of the RPSS

Most attendees came from the Texas, followed by Wisconsin, Virginia, and Colorado



Key Findings

The following data was compiled from the survey responses collected thus far. A Comprehensive Evaluation Report will be Distributed Separately.



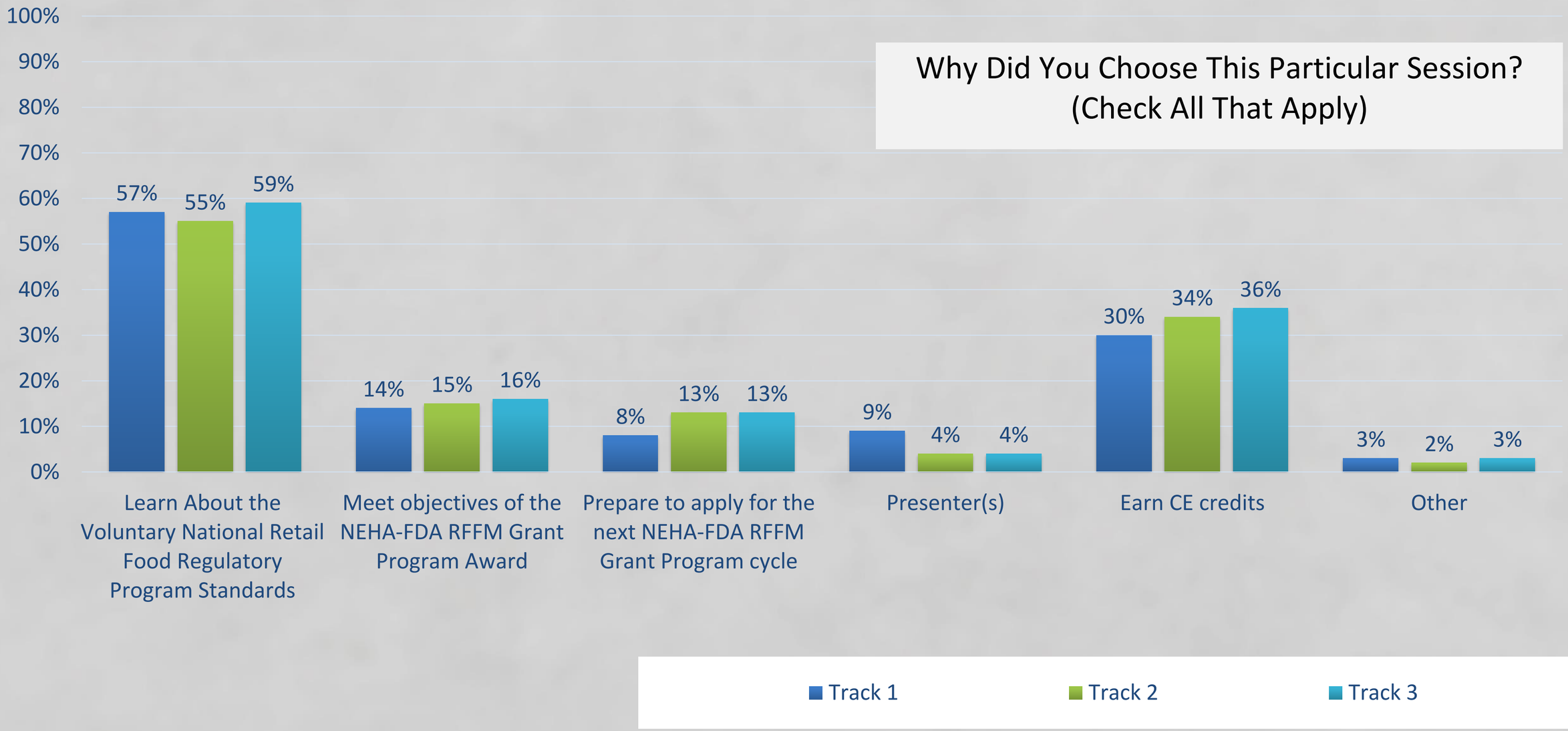
Response Rates

Sessions	June 7	June 8	June 9
Track 1 Survey	144 of 227 (63%)	147 of 300 (49%)	64 of 127 (50%)
Track 2 Survey	104 of 221 (47%)	81 of 149 (54%)	89 of 214 (42%)
Track 3 Survey	101 of 134 (75%)	59 of 105 (56%)	70 of 132 (53%)

Final Exit Questionnaire

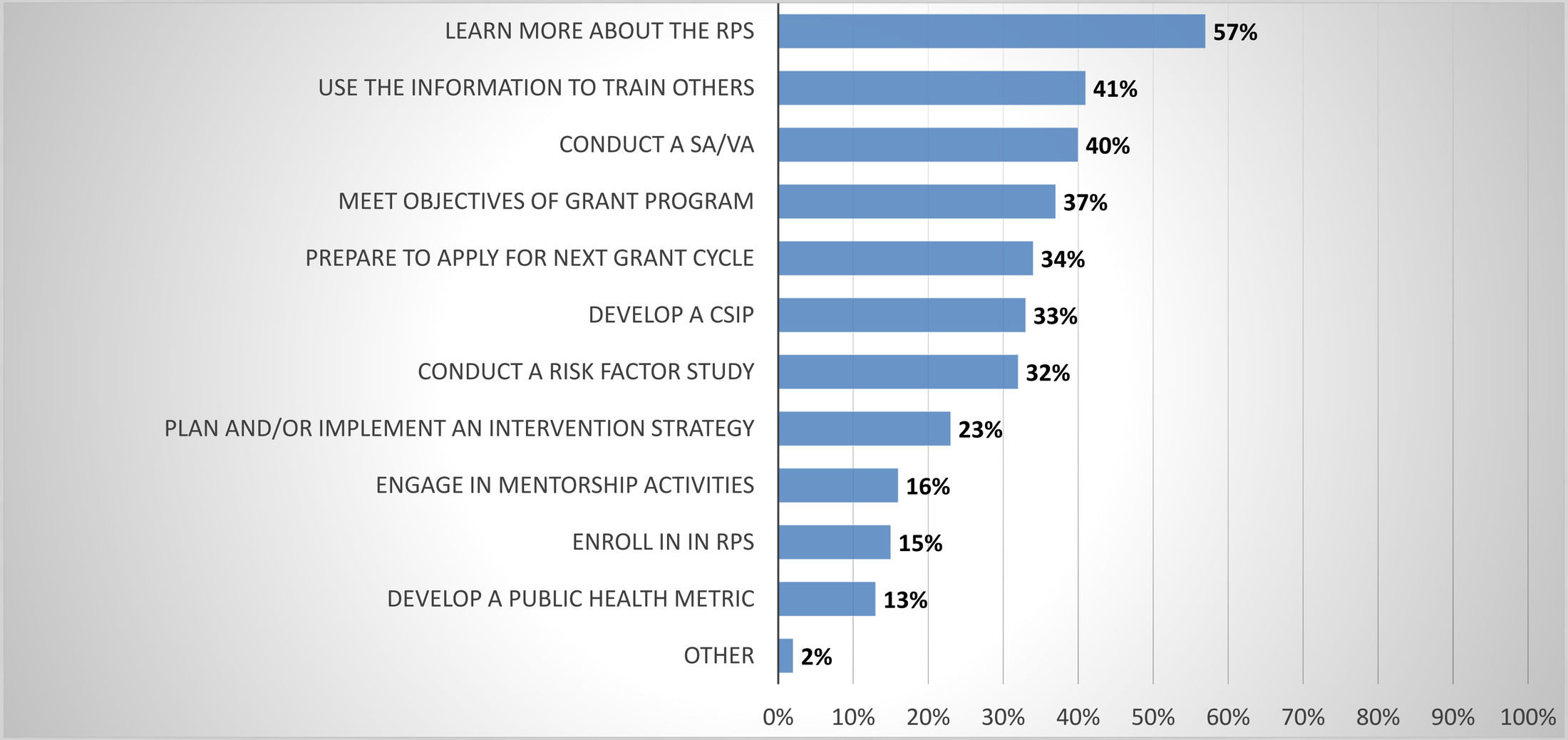
n=262 responses of 755 attendees
(35% response rate)

Reasons for Choosing Sessions- Tracks 1-3



Intention to Apply Information

How do you and/or your organization plan to apply some or all of the information learned from the RPSS? (Check All That Apply)

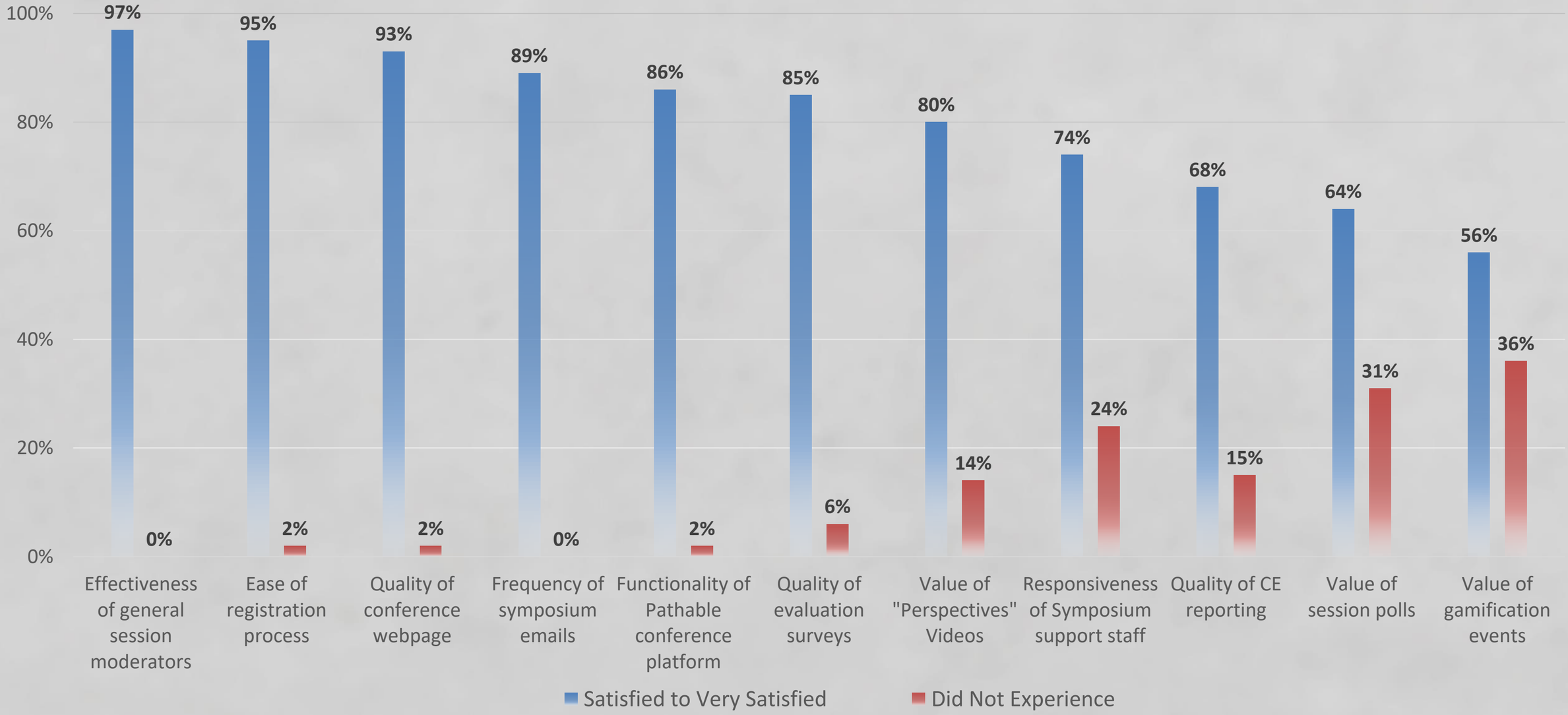


Note: From Final Exit Questionnaire

Satisfaction with Conference Features

Rate Your Satisfaction with the Following Conference Features

("Satisfied to Very Satisfied" Shown Below)



Note: From Final Exit Questionnaire

Conclusion

STANDARD 1 REGULATORY FOUNDATION

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STANDARD 1 REGULATORY FOUNDATION

This standard applies to the regulatory foundation used by a retail food program. Regulatory foundation includes any statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that governs the operation of a retail food establishment.

Requirement Summary

The regulatory foundation includes provisions for:

1. The public health interventions contained in the current published edition of the *Food Code* or one of the two most recent previous editions of the *Food Code;*
2. Control measures for the risk factors known to contribute to foodborne illness;
3. Good Retail Practices (GRP's) at least as stringent as the *Food Code* edition as specified in 1 above; and
4. Compliance and enforcement at least as stringent as the selected provisions from *Food Code* and Annex 1 of the *Food Code* edition as specified in 1 above.

Description of Requirement

A. *Food Code* Interventions and Risk Factor Control Measures

The regulatory foundation contains provisions that are at least as stringent as the public health interventions and the provisions that control risk factors known to contribute to foodborne illness contained in the current published edition of the *Food Code* or one of the two most recent previous editions of the *Food Code*. Jurisdictions that meet Standard 1 but who may become noncompliant due to the release of a new edition of the *Food Code* are considered to continue meeting the Standard for a period of two years from the release date of the new *Food Code* edition in order to complete the process of updating its regulations.

To meet this element of the Standard, regulations must have a corresponding requirement for the *Food Code* sections as listed and summarized in the *Standard 1: Self-Assessment Worksheet for Part I*, from #1 "Demonstration of Knowledge" through #11 "Highly Susceptible Populations." For initial listing, the regulatory foundation must contain at least 9 of the 11 interventions and risk factor controls. In order to meet fully the requirements of the Standard, the regulatory foundation must meet all 11 of the interventions and risk factor controls by the third audit.

B. Good Retail Practices

The regulations contain provisions that address Good Retail Practices that are at least as stringent as those described in the edition of the *Food Code* as specified in A. To meet this element of the Standard, regulations must have a corresponding requirement for 95 percent of the *Food Code* sections as listed and summarized in the *Standard 1: Self-Assessment Worksheet for Part II*, from #12 "Personnel" through #37 "Variance for Smoking."

C. Compliance and Enforcement

The regulations contain provisions that address Compliance and Enforcement requirements that are at least as stringent as those contained in the edition of the *Food Code* as specified in A. To meet this element of the Standard, regulations must have a corresponding requirement for each of the *Food Code* sections as listed in the *Standard 1: Self-Assessment Worksheet for Part III*, items 1 through 12; except item 12 pertaining to "Legal Remedies," where only one of the sections pertaining to criminal, injunctive, or civil penalties is required.

Outcome

The desired outcome of this standard is the adoption of a sound, science-based regulatory foundation for the public health program and the uniform regulation of industry.

Documentation

The quality records needed for this standard include:

1. The statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that govern the operation of a retail food establishment; and
2. The completed *Standard 1: Program Self-Assessment and Verification Audit Form*.
3. The completed *Standard 1: Self-Assessment Worksheet* for:
   - Part I – *Food Code* Intervention and Risk Factor Controls
   - Part II – Good Retail Practices
   - Part III – Compliance and Enforcement

Conference for Food Protection
2020 Issue Form

Issue: 2020 II-031

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Standard 1 Update to Require 80% of Certain Provisions

Issue you would like the Conference to consider:

Many times policy makers such as state legislatures and others outside the retail food program make decisions that impact the ability of the retail food program to meet all of the interventions and risk factors. This proposes changing the evaluation component to eighty percent adopting a percentage standard similar to the Good Retail Practices and not requiring a full-adoption of all invention and risk factors after the second self-assessment. For example, a legislature may choose to not ban barehand contact of ready-to-eat foods and all regulatory programs with the state automatically do not meet one of the of the 11 areas and after the second self-assessment would no-longer meet the Standard 1, because of an action completed un-related to the conduct of the regulatory program.

Public Health Significance:

This Standard currently is evaluating not only the regulatory program, but also decisions policy makers are making outside the regulatory programs control. The revisions allows programs to conform to the Standard if 80% of currently 9 to 11 of the Foodborne illness risk factors and public health interventions are adopted. While we absolutely support full adoption of the Code, the Standards already allow for this lower number for the first two self-assessments and the amendment seeks to eliminate the subsequent requirement for 100% adoption.

Recommended Solution: The Conference recommends...:

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), Standard 1 - Regulatory Foundation be amended as follows:

Many times policy makers such as state legislatures and others outside the retail food program make decisions that impact the ability of the retail food program to meet all of the interventions and risk factors. This proposes changing the evaluation component to eighty percent adopting a percentage standard similar to the Good Retail Practices and not requiring a full-adoption of all invention and risk factors after the second self-assessment. For example, a legislature may choose to not ban barehand contact of ready-to-eat foods and all regulatory programs with the state automatically do not meet one of the of the 11 areas and after the second self-assessment would no-longer meet the Standard 1, because of an action completed un-related to the conduct of the regulatory program.

1. Amend Standard 1, Description of Requirement, lettered paragraph "A" as follows (language to be deleted is in strikethrough format; language to be added is underlined):

A. *Food Code* Interventions and Risk Factor Control Measures
The regulatory foundation contains provisions that are at least as stringent as the public health interventions and the provisions that control risk factors known to contribute to foodborne illness contained in the current published edition of the *Food Code* or one of the two most recent previous editions of the *Food Code*. Jurisdictions that meet Standard 1 but who may become noncompliant due to the release of a new edition of the *Food Code* are considered to continue meeting the Standard for a period of two years from the release date of the new *Food Code* edition in order to complete the process of updating its regulations.

To meet this element of the Standard, regulations must have a corresponding requirement for the *Food Code* sections as listed and summarized in the *Standard 1: Self-Assessment Worksheet for Part I*, from #1 "Demonstration of Knowledge" through #11 "Highly Susceptible Populations." ~~For initial listing, the~~ The regulatory foundation must ~~contain~~ include at least 80% ~~9 of the 11~~ interventions and risk factor controls. ~~In order to meet fully the requirements of the Standard, the regulatory foundation must meet all 11 of the interventions and risk factor controls by the third audit.~~

1. Amend Standard 1 Instructions and Worksheet for Conducting a Self-Assessment as follows., Step 3, as follows (language to be deleted is in strikethrough format; language to be added is underlined):

STEP 3 - Document the Self-Assessment Results for Part I

A summary table is provided in Part I of the *Standard 1: Self-Assessment Worksheet* to document the results of the self-assessment for each of the 11 public health intervention and risk factor control measures. For80 each public health intervention and risk factor control measure, the self-assessor must record the findings from the self-assessment. If each *Food Code* section listed under an Intervention/ Risk Factor has a check in the "Full Intent is Met" column, the Standard criteria is met. Place an "X" in the Self-Assessment Results "YES" column.

If any of the *Food Code* sections are missing, or the jurisdiction's regulatory requirements only partially meet the intent of the language, place an "X" in the Self-Assessment Results "NO"
column for that intervention/risk factor control measure.

At the bottom of Part I of the *Standard 1: Self-Assessment Worksheet*, the self-assessor must record the jurisdiction's name and the number of interventions/risk factors that are

met. ~~For initial participation and listing purposes, the~~ The jurisdiction's self-assessment must indicate conformance with at least ~~9 of the 11~~ 80% of the intervention/risk factor categories. ~~By the third verification audit, the jurisdiction must meet 11 of the 11 intervention/risk factor control categories in order to meet the Standard 1 criteria.~~

Examples of documents that may be reviewed:
ØThe jurisdiction's statute, regulation, rule, ordinance or other prevailing set of regulatory requirements that govern the operation of its food establishments

ØVersion of the *Food Code* that was used for the self-assessment

ØCompleted *Standard 1: Self-Assessment Worksheet,* Part I - *Food Code* Interventions and Risk Factor Controls

ØIf applicable, documents discussing or comparing code provisions excepted if adoption was made by reference with exceptions.

1. Amend Standard 1 Instructions and Worksheet for Conducting a Verification Audit as follows Step 4, as follows (language to be deleted is in strikethrough format; language to be added is underlined):

STEP 4 - Document the Verification Audit Results for Part I

Part I of the *Standard 1: Self-Assessment Worksheet*, included at the end of these instructions, contains 11 public health interventions and risk factor controls:

1. Demonstration of Knowledge
2. Employee Health
3. Consumer Advisory
4. Approved Source
5. Time/Temperature
6. Protection from Contamination
7. Control of Hands as a Vehicle of Contamination
8. Good Hygienic Practices
9. Chemical
10. Conformance with Approved Procedures
11. Highly Susceptible Population

To meet any one of the 11 public health intervention and risk factor controls identified under the self-assessment process, the self-assessment must indicate that the jurisdiction's regulatory requirements address all *Food Code* sections listed for that area. ~~For initial listing, the~~ The jurisdiction's regulatory foundation must ~~contain~~ include at least ~~9 of the 11~~ 80% of public health interventions and risk factor controls. ~~In order to fully meet the requirement of the Standard, the regulatory foundation must meet all 11 of the interventions and risk factor controls by the third verification audit cycle.~~

If four or more of the 15 selected code sections reviewed during the audit process do not meet the stringency of language criteria, the Standard 1, Part I element fails to meet the criteria, and no further sampling is necessary. If one, two or three of the 15 selected code sections do not meet the stringency of the language criteria but the jurisdiction continues to meet the required number of interventions and risk factor controls to meet the Standard, then randomly select an additional 15 *Food Code* sections. No more than three total disagreements are acceptable in the thirty (30) Code sections drawn for comparison in

order for the audit to confirm the Part I element of Standard 1 as met. In addition, at least 9 out of the 11 (80%) interventions and risk factor controls must still be met at the end of the first audit after the disagreements are taken into account~~, and the jurisdiction must meet 11 out of the 11 interventions and risk factor controls by the third regular audit in order to meet the Standard 1 criteria~~.

Examples of documents that may be reviewed:

ØThe jurisdiction's statute, regulation, rule, ordinance or other prevailing set of regulatory requirements that govern the operation of its food establishments

ØVersion of the *FDA Food Code* that was used for the self-assessment Ø? Completed *Standard 1: Self-Assessment Worksheet*, Part I - *Food Code* Interventions and Risk Factor Controls
ØIf applicable, documents discussing or comparing code provisions excepted if adoption was made by reference with exceptions.

d) Amend any forms and instructions as needed to conform with the above changes.

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It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

Standard 2: Trained Regulatory Staff
APPENDIX B-1: Curriculum for Retail Food Safety Inspection Officers

NOTE about course information: The courses listed below are updated and moved across different learning management systems over time. The latest information will be posted on the FDA Program Standards Landing Page at https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019

For state, local, tribal, & territorial (SLTT) regulators to register on-line for free access to web courses, go to: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

Pre-requisite ("Pre") Curriculum Courses

(To be completed during the 25 joint inspection period AND prior to conducting any independent inspections)

PUBLIC HEALTH PRINCIPLES

Courses	Course Number
1-Public Health Principles	FDA36 (90)

MICROBIOLOGY

Courses	Course Number
1-Overview of Microbiology	MIC01 (60)
2A-Gram Negative Rods	MIC02 (60)
2B-Gram-Positive Rods & Cocci	MIC03 (90)
3- Foodborne Viruses	MIC04 (60)
4- Foodborne Parasites	MIC05 (90)
Mid-Series Exam	MIC16 (30)
5- Controlling Growth Factors	MIC06 (90)
6-Control by Refrigeration & Freezing	MIC07 (60)
7A-Control by Thermal Processing	MIC08 (90)
7B- Control by Pasteurization	MIC09 (90)
10- Aseptic Sampling	MIC13 (90)
12-Cleaning & Sanitizing	MIC15 (90)

PREVAILING STATUTES, REGULATIONS, ORDINANCES

Courses	Course Number
1. Basic Food Law for State Regulators	FDA35 (60)
2. Basics of Inspection: Beginning an Inspection	FDA38 (90)
3. Basics of Inspection: Issues & Observations	FDA39 (90)
4. An Introduction to Food Security Awareness	FD251 (60) A PDF/READABLE VERSION at (https://www.fda.gov/training-and- continuing-education/office-training-education-and-development-oted/introduction-food-security-awareness) Note: Required exam is available via www.compliancewire.com.

5. FDA Food Code: Specific SLTT laws and regulations to be addressed by each jurisdiction.	**Note:** Some jurisdictions may require the FDA Food Code Course in addition to SLTT food code training.

COMMUNICATION SKILLS

Courses	Course Number
1. Communication Skills	CC8030W **NOTE**: Course must be accessed through FDA Pathlore at: (https:// orauportal.fda.gov/stc/ORA/psciis.dll?linkid=675280&mainmenu=ORA &top_frame=1)

Curriculum ("Post") Courses

(To be completed any time prior to Food Code Standardization AND within 24 months of hire or assignment to the regulatory retail food program)

MICROBIOLOGY

Courses	Course Number
7C-Control by Retorting	MIC10 (90)
8-Technology-Based Food Processes	MIC11 (120)
9-Natural Toxins	MIC12 (90)

HACCP

Courses	Course Number
1. Overview of HACCP	FDA16 (60)
2. Prerequisite Programs & Preliminary Steps	FDA17 (60)
3. The Principles	FDA18 (60)

ALLERGEN MANAGEMENT

Courses	Course Number
1. Allergens	CC8029W on PATHLORE https://orauportal.fda.gov/stc/ora/psciis.dll?linkid=436613&mainmenu=ORA&top_frame=1

EPIDEMIOLOGY

Courses	Course Number
1. Collecting Surveillance Data	FI01 (90)
2. Beginning the Investigation	FI02 (90)
3. Expanding the Investigation	FI03 (90)
4. Conducting a Food Hazard Review	FI04 (90)
5. Epidemiological Statistics	FI05 (90)
6. Final Report	FI06 (30)

EMERGENCY MANAGEMENT – FEMA

Incident Command System and National Incident Management System: Course available from FEMA web link http://training.fema.gov/IS/NIMS.asp

Courses	Course Number
1. Introduction to Incident Command System	IS-100.C, Introduction to the Incident Command System, (180) ICS-100 for FDA
2. Basic Incident Command System for Initial Response	IS-200.C, Basic Incident Command System for Initial Response (180)
3. An Introduction to NIMS	IS 700.B, An Introduction to NIMS, (180) ICS-700

( ) Average time in minutes required to take the course, 60 minutes equals .1 CEU, 90-120 minutes equals .2 CEUs

Estimated total hours for "Pre" courses are 42 hours.

Estimated total hours for "Post" courses are 26 hours.

Estimated total hours for completion of all Program Standard #2 coursework are 68 hours

STANDARD 2 TRAINED REGULATORY STAFF

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STANDARD 2 TRAINED REGULATORY STAFF

This Standard applies to the essential elements of a training program for regulatory staff.

Requirement Summary

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have the knowledge, skills, and ability to adequately perform their required duties. The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

STEP 1
Completion of curriculum courses designated as "Pre" in Appendix B-1 prior to conducting and independent routine inspections.

STEP 2
Completion of the following:

- A minimum of 25 joint field training inspections (or a sufficient number of joint inspections determined by the trainer and verified through written documentation that the FSIO has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments); and
- Successful completion of the jurisdiction's FSIO Field Training Plan similar to the process outlined in *Appendix B-2: Conference for Food Protection (CFP) Field Training Manual*.

STEP 3
Completion of the following:

- A minimum of 25 independent inspections; and
- Remaining course curriculum (designated as "post" courses) outlined in *Appendix B-1: Curriculum for Retail Food Safety Inspection Officers*.

STEP 4
Completion of a standardization process similar to the FDA standardization procedures.

STEP 5
Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

Description of Requirement

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have successfully completed the required elements of the 5-step training and standardization process:

- Steps 1 through 4 within 24 months of hire or assignment to the retail food regulatory program.
- Step 5 every 36 months after the initial 24 months of training.

Step 1: Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in pre-requisite courses designated with a "Pre" in Appendix B-1, for the following curriculum areas:

1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
2. Public Health Principles;
3. Food Microbiology; and
4. Communication Skills.

There are two options for demonstrating successful completion of the pre-inspection curriculum.

OPTION 1: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- FDA ORA U pre-requisite courses identified as "Pre" in Appendix B-1; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances.

Note: *The estimated contact time for completion of the FDA ORA U pre-requisite ("Pre") courses is 42 hours.*

OPTION 2: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- Successful completion of courses deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the FDA ORA U pre- requisite (Pre") courses; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances; and
- Successful passing of one of the four written examination options (described later in this Standard) for determining if a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the listed ORA U courses are available from the web site link at: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

> **Note:** *While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:*
>
> - *Logs/records that are completed based on sign-in sheets; or*
> - *Information validated from the certificate at the time-of-issuance; or*
> - *A college transcript with a passing grade or other indication of successful completion of the course; or*
> - *Automated attendance records, such as those currently kept by some professional associations and state agencies, or*
> - *Other accurate verification of actual attendance.*

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORAU courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the four written examination categories specified herein.

1. The Certified Food Safety Professional examination offered by the National Environmental Health Association; or

2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable; or

3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or

4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

Note: *Written examinations are part of a training process, not a standardization/certification process. The examinations listed are not to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.*

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer who has successfully completed all training elements (Steps 1 – 3) of this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "training" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

If the trainer determines that the FSIO has successfully demonstrated the required performance elements and competencies, a lower minimum number of joint field training inspections can be established for that FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan in Appendix B-2, to support the exception.

Note: *The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."*

Demonstration inspections are those in which the jurisdiction's trainer takes the lead and the candidate observes the inspection process. Training inspections are those in which the candidate takes the lead, and their inspection performance is assessed and critiqued by the trainer. The jurisdiction's trainer is

responsible for determining the appropriate combination of demonstration and training inspections based on the candidate's food safety knowledge and performance during the joint field inspections.

The joint field inspections must be conducted using a field training process and forms similar to ones presented in the *CFP Field Training Manual* included as Appendix B-2. The *CFP Field Training Manual* consists of a training plan and log, trainer's worksheets, and procedures that may be incorporated into any jurisdiction's retail food training program. It is a national model upon which jurisdictions can design basic field training and provides a method for FSIOs to demonstrate competencies needed to conduct independent inspections of retail food, restaurant, and institutional foodservice establishments.

Jurisdictions are not required to use the forms or worksheets provided in the *CFP Field Training Manual*. Equivalent forms or training processes can be developed. To meet the intent of the Standard, documentation must be maintained that confirms FSIOs are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments.

> **Note:** *The CFP Field Training Manual is designed as a training approach providing a structure for continuous feedback between the FSIO and trainer on specific knowledge, skills, and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.*
>
> - *The CFP Field Training Manual is NOT intended to be used for certification or licensure purposes.*
> - *The CFP Field Training Manual is NOT intended to be used by regulatory jurisdictions for administrative purposes such as job classifications, promotions, or disciplinary actions.*

FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2013 *FDA Food Code*). The jurisdiction's trainer/food program manager can determine if the FSIO is ready to conduct independent inspections of risk category 1 establishments (as defined in Appendix B-3) at any time during the training process.

> **Note:** *The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can in lieu of the 25 joint field inspections:*
>
> - *Include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement; and*
> - *The supervisor/training officer must observe experienced FSIOs conduct inspections to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.*

Step 3: Independent Inspections and Completion of ALL Curriculum Elements

Within 24 months of hire or assignment to the regulatory retail food program, Food Safety Inspection Officers must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1, for the following eight curricula areas, must be completed within this 24-month time frame.

1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
2. Public health principles (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
3. Communication skills (Step 1);
4. Food microbiology (some of the courses for this element are part of the pre-requisite curriculum outlined in Step 1);
5. Epidemiology;
6. Hazard Analysis Critical Control Points (HACCP);
7. Allergen Management
8. Emergency Management

All courses for each of the curriculum areas must be successfully completed within 24 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

> **Note:** *The estimated contact time for completion of the FDA ORA U "post" courses is 26 hours. The term "post" refers to those courses in Appendix B-1 that were not included as part of the pre-requisite coursework. This includes all the courses in Appendix B-1 that do not have the designation "Pre" associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.*

As with the pre-requisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses listed under each curriculum area OR by completing courses, deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the listed ORA U courses are available from the FDA website: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners.

Step 4: Food Safety Inspection Officer – Field Standardization

Within 24 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the "FDA Standardization Procedures." The jurisdiction's "training standard" must have met all the requirements for conducting field standardizations as presented in the definition section of these Standards. The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years.

Note: *The field standardization and continuing standardization (re-standardization) criteria described in Step 4 is intended to provide a jurisdiction the flexibility to use their own regulation or ordinance. In addition, the reference to using standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers, is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written standardization protocol must include the five performance areas outlined above in Step 4.*

It is highly beneficial to use the FDA Food Code, standardization forms and procedures even when a jurisdiction has adopted modifications to the Food Code. Usually, regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge, and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA's standardization procedures are based on a minimum of 8 inspections. However, to meet Standard 2, a minimum of 4 standardization inspections must be conducted.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel versed in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate

consistent evaluation of all candidates.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors and communicates vital information about the inspection in a way that can be received, understood, and acted upon by retail food management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to both the regulatory agency and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard 2 criteria within the 24- month time frame, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5: Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (24 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer.

Training on any changes in the regulatory agency's prevailing statutes, laws and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine activities that are related specifically to food safety or food inspectional work:

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local);
4. Food safety related conferences and workshops; and
5. Distance learning opportunities that pertain to food safety, such as:
    - Web based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and
    - Satellite Broadcasts.

A maximum of ten (10) contact hours may be accrued from the following activities:

1. Delivering presentations at professional conferences;
2. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
3. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period[1].

Note: *Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.*

A maximum of four (4) contact hours may be accrued for:

1. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- transcripts from a college or university;
- a letter from the administrator of the continuing education program attended;
- a copy of the peer-reviewed article or presentation made at a professional conference; or
- documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

Note: *The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of employee's continuing education activities, maintains the training records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses.*

Outcome

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);

2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process similar to that presented in Appendix B-2. **NOTE:** The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."
4. Certificates or other records showing proof of satisfactory standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successful completed the training and education steps outlined in this Standard.
7. Date of hire records or assignment to the retail food program; and
8. Summary record of employees' compliance with the Standard.

The *Standard 2: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 2.

- Identify the activities that occur during an inspection
- Identify the types of evidence that may be collected during an inspection
- Recognize the importance of taking good notes during an inspection
- Identify the remedies that are available if the establishment repeatedly fails to comply with the law
- Identify the behaviors that you should demonstrate when testifying in court
- Identify the role of hearsay in a trial

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FDA38 – Basics of Inspection: Beginning an Inspection
After completing this course, you will be able to identify how to prepare for an inspection. You will also recognize how to properly deal with management and recognize initial observations you should make at the start of an inspection. In addition, you will identify the purpose of a Hazard Analysis Critical Control Point (HACCP) plan. You will also recognize what to look for when searching for potential food contaminants, and you will identify examples of chemical and physical hazards. Finally, you will recognize the purpose of corrective actions.
Length: 90 mins
CEUs: 0.2
Available at http://www.eduneering.com/Partners/fdaora (http://www.eduneering.com/Partners/fdaora) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Objectives:

- Recognize what to look for when reviewing the history of the facility to be inspected.
- Identify recommended equipment and supplies needed during an inspection.
- Recognize the proper attire for an inspection.
- Recognize how to best deal with management when beginning an inspection.
- Identify initial observations during an inspection.
- Identify the definition of HACCP.
- Recognize observations for food flow cycles.
- Recognize observations for time/temperature controls.
- Recognize how to identify if a food is potentially hazardous.
- Recognize where and what to look for when searching for product cross-contamination.
- Identify the definition of a chemical hazard.

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- Recognize examples of chemical hazards.
- Identify the definition of a physical hazard.
- Recognize examples of physical hazards.
- Recognize why corrective actions are needed.
- Recognize the importance of a recall/traceback program.

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FDA39 – Basics of Inspections: Issues and Observations
After completing this course, you will be able to identify the unsatisfactory practices that lead to contaminated food, including: processing equipment issues; employee practices; food storage/display issues; contamination; and water supply and plumbing concerns. You will also be able to recognize proper sampling procedures. In addition, you will be able to identify what to include in an inspection report and how to conduct a closing conference at the conclusion of an inspection.
Length: 90 mins
CEUs: 0.2
Available at http://www.eduneering.com/Partners/fdaora (http://www.eduneering.com/Partners/fdaora) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Objectives:

- Recognize poor hygienic practices.
- Recognize what constitutes bare-hand contact with ready-to-eat foods.
- Recognize proper handwashing procedures.
- Recognize the potential contamination that may come from ill employees.
- Recognize the importance of food safety training programs.
- Recognize cleaning and sanitation issues to look for while inspecting processing equipment.
- Recognize how to identify equipment condition issues.
- Recognize what constitutes improper use of equipment.
- Recognize the need for equipment to perform as desired.
- Recognize approved source requirements.
- Recognize typical observations of conditions that may indicate a problem with foods offered for sale.
- Recognize proper label compliance procedures.

Top ()

- Recognize examples of poor practices that result in cross-contamination.
- Recognize proper storage and disposal of objectionable products.
- Recognize conditions that indicate the presence of pests.
- Recognize how to determine if a water source is approved.
- Recognize proper water temperatures for various activities that use water.
- Recognize proper plumbing systems for food facilities.
- Recognize proper warewashing procedures.
- Recognize the purpose of a sample.
- Identify the steps in sampling and the properties of each step.
- Recognize information that should be included in the inspection report.
- Identify the purpose of evidence documentation in the inspection report.
- Recognize the usefulness of photographs in the inspection report.
- Recognize how to handle corrections to the inspection report.
- Identify supporting documents that should be reviewed.
- Recognize the critical elements of the closing conference.
- Identify the individual(s) that should be present during the closing conference.
- Recognize how to handle disputes.

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FDA16 – Basics of HACCP: Overview of HACCP
Hazard Analysis and Critical Control Point (HACCP) is a food safety management system designed for use in all segments of the food industry. This course provides an introduction to HACCP and is the first in the three-part Basics of HACCP series. Basics of HACCP is intended for individuals involved with the control of food safety at any point in the food industry. There are no prerequisites.
Length: 60 mins
CEUs: 0.1
Available at http://www.eduneering.com/Partners/fdaora (http://www.eduneering.com/Partners/fdaora) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Objectives:

- Recall characteristics of HACCP and CCP.
- Recall characteristics of a HACCP plan and a HACCP system.

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- Recall key developments involved in the origin of HACCP.
- Identify factors that make HACCP important to the U.S. and global food supply.
- Identify the benefits gained from using HACCP.
- Recall specific U.S. and foreign government organizations that utilize HACCP.

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FDA17– Basics of HACCP: Prerequisite Programs and Preliminary Steps
After completing this course, you will be able to recognize important prerequisite programs for a HACCP system, including basic sanitation, good facility design, and proper personal hygiene practices, and recognize how these prerequisite programs help make a HACCP system successful. You will also be able to identify the five preliminary steps to developing a HACCP plan and recognize how those steps benefit HACCP plan development. Finally, you will recognize other practices that must be in place before you implement a HACCP plan.
Length: 60 mins
CEUs: 0.1
Available at http://www.eduneering.com/Partners/fdaora (http://www.eduneering.com/Partners/fdaora) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Objectives:

- Recall specific prerequisite programs.
- Identify characteristics of prerequisite programs.
- Recognize the benefits of prerequisite programs.
- Recognize how prerequisite programs provide a foundation for a successful HACCP system.
- Recognize the five preliminary steps to developing a HACCP plan.
- Identify appropriate members of the HACCP team.
- Recognize the benefit of assembling a HACCP team.
- Recognize how to describe the food and its distribution.
- Recognize the benefit of describing the food and its distribution.
- Recognize how to describe the intended use and consumers of the product.
- Recognize the benefit of describing the intended use and consumers of the product.
- Recognize how to develop a flow diagram describing the process under consideration.
- Recognize the benefit of developing and verifying the flow diagram.

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Risk-Based Inspection Methods in Retail (FD218)

Upcoming Courses

Registration Process

Questions about FD218

This workshop builds upon concepts learned in FD215 Managing Retail Food Safety and is designed to further enhance the knowledge, skills, and abilities of food safety inspection officers in conducting risk-based inspections.

Topics include:

- Key terms, applicable laws/policies, and necessary equipment
- Food microbiology
- Three common food preparation processes and their associated hazards and control measures
- Communication techniques related to risk-based inspections including establishing rapport, active listening, asking strategic questions, and oral versus print culture communication styles
- Strategies used to focus the inspection, set priorities, and determine inspection flow
- Differences between assessing code compliance and active managerial control (AMC) of foodborne illness risk factors during inspections and the reasons why assessing AMC is essential to public health
- Techniques for determining code compliance and AMC of foodborne illness risk factors
- Determining the most appropriate immediate corrective actions for out-of-control foodborne illness risk factors
- Determining the most appropriate long-term intervention strategies for out-of-control risk factors

AFDO is a regulatory organization that connects food and medical-products safety stakeholders and impacts the regulatory environment by shaping sound, science-based rules, law, regulations, and sharing best practices that protect public health. Or simply put: connect, share, impact, and protect.

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Contact

National Curriculum Standard

Through a Cooperative Agreement* with the US Food and Drug Administration (FDA), IFPTI is leading the development and build-out of the National Curriculum Standard (NCS). The NCS is a key element of the ***Integrated Food Safety System*** (IFSS), a seamless partnership and collaboration among human and animal food regulatory jurisdictions: Federal, State, Local, Tribal, and Territorial.

The NCS represents a ***national competency standard*** for human and animal food regulatory professionals, across their entire careers. The NCS depicts the ***knowledge, skills, and abilities*** needed by these regulators in

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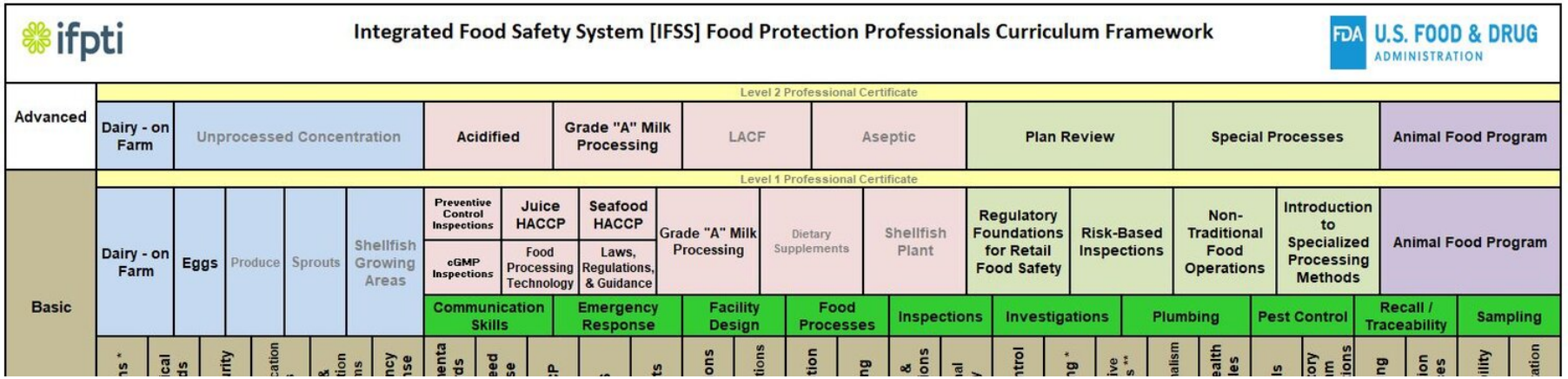
order to successfully perform their jobs, thereby assuring a ***competent regulatory workforce doing comparable work*** across all jurisdictions.

A key component of the NCS is the IFSS Curriculum Framework, shown below. The IFSS Framework is a color-coded schematic of the human and animal food regulatory profession, demonstrating the interrelationship between and among professional career levels, program areas, and content or topic areas. The Framework is a living, breathing document, and is consistently being revised and updated as buildout of the Framework continues.



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The NCS, along with the IFSS Framework, serve three primary purposes: 1. Creating “blueprints” for training development, 2. Acting as a cataloging system, and 3. Helping with assessment.

Blueprint for course development

One of the foundational processes used by training developers in the instructional systems design (ISD) field is the ADDIE model, which outlines the five steps for developing effective training. The chronological steps in the model are: Analysis, Design, Development, Implementation, and Evaluation.

When we build out a particular content or topic area within the IFSS Framework, we are essentially creating a “blueprint” for training

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Taken together, the competencies and behavioral anchors provide all the details concerning what should be covered in a training course.

ISD professionals, therefore, can use these content or topic area “blueprints” and, in close collaboration with appropriate subject matter experts, can create course learning objectives (which are often modified versions of the competencies), build course content, course activities, learner interactions, and knowledge checks, all of which are recommended components of any learning event.

Looking back at the ADDIE model, then, we can see that these “blueprints” represent the Analysis and Design phases of the process. The Analysis involves identifying what the regulator needs to know or be able to do, and the Design relates to arranging the competencies and behavioral anchors into a sequenced, organized blueprint that can be utilized during the next step of the ADDIE process, the Development phase.

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Cataloging system and gap analysis/inventory

The IFSS Framework is a carefully organized schematic, arranged by professional levels (Basic, Advanced, etc.), specific program areas or concentrations such as Retail Food, Manufactured Food, Unprocessed Food, and Animal Food, and focused content or topic areas tailored to each professional level.

As such, the Framework can serve as a unique, open-source system to be

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training developers to arrange existing materials into their appropriate slot, much like a book is placed on a particular shelf in a library.

This cataloging system can be used to organize any existing training courses, guidance documents, and reference materials. Additionally, the system can help identify gaps in existing training across the US, and can help identify learning events in need of development.

Assessment against competencies

The content area “blueprints” aid in the assessment process.
Remember, the blueprints comprise a set of:

1. competencies (knowledge, skills,

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regulatory professionals to successfully perform their job functions; and

2. behavioral anchors tailored to each competency, which are indicators that an individual can actually demonstrate the particular knowledge, skills, or ability.

Taken together, the competencies and behavioral anchors can be used by an *assessor* to help measures an individual's level of competency and help identify any competency gaps that can be addressed through training, mentoring, job shadowing, or field experience. For example, an individual can conduct a self-assessment to determine if he or she possesses competencies necessary at a particular career level, and can use the results of the self-assessment to determine their progress within a particular career path.

Additionally, a supervisor or manager can assess an entire staff against a set of competencies, to help determine if any new or refresher training is

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Basic Level Courses

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STANDARD 3
INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

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STANDARD 3
INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

This standard applies to the utilization of HACCP principles to control risk factors in a retail food inspection program.

Requirement Summary

An inspection program that focuses on the status of risk factors, determines, and documents compliance, and targets immediate- and long-term correction of out-of-control risk factors through active managerial control.

Description of Requirement

Program management:

1. Implements the use of an inspection form that is designed for:
    a) The identification of risk factors and interventions.
    b) Documentation of the compliance status of each risk factor and intervention (i.e., a form with notations indicating IN compliance, OUT of compliance, Not Observed, or Not Applicable for risk factors)
    c) Documentation of all compliance and enforcement activities and
    d) Requires the selection of IN, OUT, NO, or NA for each risk factor.
2. Develops and uses a process that groups food establishments into at least three categories based on potential and inherent food safety risks.
3. Assigns the inspection frequency based on the risk categories to focus program resources on food operations with the greatest food safety risk.
4. Develops and implements a program policy ***that requires:
    a) On-site corrective actions* as appropriate to the type of violation.
    b) Discussion of long-term control** of risk factor options, and
    c) Follow-up activities.
5. Establishes and implements written policies addressing code variance requests related to risk factors and interventions.
6. Establishes written policies regarding the verification and validation of HACCP plans when a plan is required by the code.

Outcome

The desired outcome of this standard is a regulatory inspection system that uses HACCP principles to identify risk factors and to obtain immediate- and long-term corrective action for recurring risk factors.

Documentation

The quality records needed for this standard include:

1. Inspection form that requires the selection of IN, OUT, NO, or NA,
2. Written process used for grouping establishments based on food safety risk and the inspection frequency assigned to each category,

3. Policy for on-site correction and follow-up activities,
4. Policy for addressing code variance requests related to risk factors and interventions,
5. Policy for verification and validation of HACCP plans required by code, and
6. Policy requiring the discussion of food safety control systems with management when out of control risk factors are recorded on subsequent inspections.

*Note: **On-site** corrective action as appropriate to the violation would include such things as:

a. Destruction of foods that have experienced extreme temperature abuse,
b. Embargo or destruction of foods from unapproved sources,
c. Accelerated cooling of foods when cooling time limits can still be met,
d. Reheating when small deviations from hot holding have occurred,
e. Continued cooking when proper cooking temperatures have not been met.
f. Initiated use of gloves, tongs, or utensils to prevent hand contact with ready-to-eat foods, or
g. Required hand washing when potential contamination is observed.

Note: **Long-term control of risk factors requires a commitment by managers of food establishments to develop effective monitoring and control measures or system changes to address those risk factors most often responsible for foodborne illness. Risk control plans, standard operating procedures, buyer specifications, menu modification, HACCP plans and equipment or facility modification may be discussed as options to achieve the long-term control of risk factors.

***Note: Consideration of the elements outlined in Standard 4 will ensure a strong foundation for a quality and uniform inspection program.

STANDARD 3 – INSPECTION PROGRAM BASED ON HACCP PRINCIPLES INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

Program Self-Assessment & Verification Audit Form

The *Standard 3: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 3. The form is included at the end of these instructions. Whether one is performing a program self-assessment or conducting a verification audit, it is recommended that the form be available as a reference to the Standards 3 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self-Assessment

Jurisdictions conducting a self-assessment of Standard 3 must indicate on the form if each of the listed criteria is met. These responses are recorded under the column "Jurisdiction's Self-Assessment."

Jurisdictions are not obligated to use this form. An equivalent form or process is acceptable provided that the results of the jurisdiction's self-assessment for the specific Standard 3 criteria listed on this form are available for review.

The *Standard 3: Program Self-Assessment and Verification Audit Form* is the only form a jurisdiction needs to use to record the results of their self-assessment. Standard 3 requires inspection policies to be established, written, and implemented. A policy without documentation of implementation does not meet the Standard 3 criteria.

The *Standard 3: Program Self-Assessment and Verification Audit Form* divides the Standard 3 criteria into six steps:

1. Inspection Form Design
    a. The jurisdiction's inspection form identifies foodborne illness risk factors and *Food Code interventions*.
    b. The jurisdiction's inspection form documents actual observations using the convention IN, OUT, NA, and NO.
    c. The jurisdiction's inspection form documents compliance and enforcement activities.
2. Risk Assessment Categories
    a. A risk assessment is used to group food establishments into at least 3 categories based on their potential and inherent food safety risks.
3. Inspection Frequency
    a. The jurisdiction's inspection frequency is based on assigned risk categories.
4. Corrective Action Policy
    a. The jurisdiction has a written and implemented policy that requires on-site corrective action for foodborne illness risk factors observed to be out of compliance.
    b. The jurisdiction has a written and implemented policy that requires discussion for long- term control of foodborne illness risk factors.
    c. The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations.
5. Variance Request Policy
    a. The jurisdiction has a written and implemented policy on variance requests related to foodborne illness risk factors and *Food Code* interventions.

6. Verification and Validation of HACCP Plan Policy
    a. The jurisdiction has a written and implemented policy for the verification and validation of HACCP plans, when a HACCP plan is required by the *Food Code*.

The self-assessor must review each Standard 3 criterion and determine if the jurisdiction's source documents confirm that the Standard criteria are met. If the criteria are met, the self-assessor must place an "X" in the "YES" box under the "Jurisdiction's Self-Assessment" column of the *Standard 3: Program Self-Assessment and Verification Audit Form*.

If a review of the jurisdiction's source documents does not confirm that the Standard 3 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdict*ion's Self-Assessment" column of the* Standard 3: Program Self-Assessment and Verification Audit Form. The self-assessor may specify why the criteria are not met in the box provided.

The self-assessor should review the findings on the *Standard 3: Program Self-Assessment and Verification Form* to ensure accuracy. The jurisdiction will be required to provide the auditor with their completed *Standard 3: Program Self-Assessment and Verification Audit Form* and any documents used to support and demonstrate that the Standard 3 criteria have been met.

Once all the criteria have been reviewed and documented on the form, the self-assessor must complete the Program Self-Assessment Summary section on page one of the *Standard 3: Program Self-Assessment and Verification Audit Form*. The self-assessor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 3 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 3 criteria.

Documenting the Findings from the Verification Audit
The jurisdiction requesting the verification audit must provide their completed *Standard 3: Program Self-Assessment and Verification Audit Form* to the auditor for review. The auditor must indicate on the *Standard 3: Program Self-Assessment and Verification Audit Form* if the criteria were met.

If a review of the jurisdiction's source documents confirms the self-assessment conclusion that the Standard criteria are met, the verification auditor places an "X" in the "YES" box under the "Auditor's Verification" column of the form.

If a review of the jurisdiction's source documents does not confirm the self-assessment conclusion that the Standard criteria are met, the verification auditor places and "X" in the "NO" box under the "Auditor's Verification" column of the form. The verification auditor must specify why the criterion is not met in the box provided. Supplemental pages may be used to explain findings.

The jurisdiction must meet all six program performance criteria outlined in Standard 3.

The verification auditor must discuss their findings with the program manager or their appointed representative and provide constructive feedback at the conclusion of the on-site visit. In particular, any

Standard 3 criteria for which the auditor cannot confirm through a review of the self-assessment should be thoroughly discussed. Ample time should be allotted to ensure that there is a clear understanding of the reasons for the "non-conforming" finding. The auditor should be prepared to identify the elements required for the jurisdiction to meet the Standard.

Once the close out interview has been conducted, the auditor must complete the Verification Audit Summary section located on the first page of the *Standard 3: Program Self-Assessment and Verification Audit Form*. The auditor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 3 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 3 criteria if the auditor does not confirm the self-assessment findings.

Standard 3: Inspection Program based on HACCP Principles
Program Self-Assessment and Verification Audit Form

PROGRAM SELF-ASSESSMENT SUMMARY

Printed Name of the Person who conducted the Self-Assessment:	
Self-Assessor's Title:	
Jurisdiction Name:	
Jurisdiction Address:	
Phone:	
Fax:	
E-mail:	
Date the Standard 3 Self-Assessment was Completed:	
Self-Assessment indicates that the Jurisdiction MEETS the Standard 3 criteria (indicate YES/NO):	
I affirm that the information represented in the Self-Assessment of Standard 3 is true and correct. **Signature of the Self-Assessor:**	

VERIFICATION AUDIT SUMMARY

Printed Name of the Person who conducted the Verification Audit:	
Verification Auditor's Title:	
Auditor's Jurisdiction Name:	
Auditor's Jurisdiction Address:	
Phone:	
Fax:	
E-mail:	
Date the Verification Audit of Standard 3 was Completed:	
Verification Audit indicates that the Jurisdiction MEETS the Standard 3 criteria (indicate YES/NO):	
I affirm that the information represented in the Verification Audit of Standard 3 is true and correct. **Signature of the Verification Auditor:**	

Standard 3: Inspection Program based on HACCP Principles
Program Self-Assessment and Verification Audit Form

Jurisdiction Name: _____

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
1. Inspection Form Design	a) The jurisdiction's inspection form identifies foodborne illness risk factors and Food Code interventions						
1. Inspection Form Design	b) The jurisdiction's inspection form documents actual observations using the convention (IN, OUT, NO, and NA).						
1. Inspection Form Design	c) The jurisdiction's inspection form documents compliance and enforcement activities.						
2. Risk Assignment Categories	a) A risk assessment is used to group food establishments into at least 3 categories based on their potential and inherent food safety risks.						
3. Inspection Frequency	a) The jurisdiction's inspection frequency is based on the assigned risk categories.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
4. Written and Implemented Corrective Action Policy	a) The jurisdiction has a written and implemented policy that requires on-site corrective actions for foodborne illness risk factors observed to be out of compliance.						
4. Written and Implemented Corrective Action Policy	b) The jurisdiction has a written and implemented policy that requires discussion for long-term control of foodborne illness risk factors.						
4.Written and Implemented Corrective Action Policy	c) The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations.						
5. Variance Requests	a) The jurisdiction has a written and implemented policy on variance requests related to foodborne illness risk factors and Food Code interventions.						
6. Verification and Validation of HACCP Plans	a) The jurisdiction has a written and implemented policy for the verification and validation of HACCP plans, when a HACCP plan is required by the Code.						

GENERAL NOTES PERTAINING TO THE PROGRAM SELF-ASSESSMENT OR THE VERIFICATION AUDIT

STANDARD 2-TRAINED REGULATORY STAFF

INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

STEP 1 – Verify Employees Training Records

The jurisdiction should document and retain a training record for each employee. The training record must include the date of hire or assignment to the retail food program. The Standard 2 Self-Assessment Worksheet may be used by the jurisdiction as a training record. The worksheet is included at the end of these instructions. In lieu of the Standard 2 Self-Assessment Worksheet, other manual forms or automated records may be used by the jurisdiction to retain training records related to the self- assessment as long as the information required in the Standard 2 criteria is documented in some manner.

STEP 2 – Verify Jurisdiction's Worksheet Percentage Calculation

Review the jurisdiction's Standard 2 Self-Assessment Worksheet, or equivalent documentation, to determine if the results of the jurisdiction's self-assessment indicate that ninety percent (90%) of the retail food program staff successfully completed all the Standard 2 training and standardization elements within the required time frames. If audit calculations result in a percentage that is less than 90%, the auditor can conclude that the jurisdiction does not meet the Standard 2 criteria. If this conclusion is reached, the audit process for Standard 2 is completed. There is no need to randomly select and review individual employee training records.

STEP 3 – Determine the Number of Employee Training Records to Review

If the jurisdiction used the Standard 2: Self-Assessment Worksheet, the employees will be listed in numerical order. The verification auditor must use a random selection method to determine which employees' training records will be reviewed. Employees should be substituted during the random selection process if they meet one of the following criteria:

1. The employee has been employed or worked in the retail food program for less than 24 months; or
2. The employee is no longer assigned to the retail food program; or
3. The self-assessor indicated on the Self-Assessment Worksheet that the employee did not meet each Standard 2 element.

The number of training records that must be randomly selected is based on the number of employees conducting retail food establishment inspections. Use the chart below to determine the number of employee training records to review.

Number of Employees	Number of Files to Select
5 or less	All
20 or less	5
21 or more	25 percent

STEP 4 – Obtain Random Numbers

A list of random numbers can be obtained from the following web site: www.randomizer.org
Record the random numbers generated from the web site (or from an alternate random number selection process) on the Standard 2 Verification Audit Worksheet. The worksheet is included at the end of these instructions.

STEP 5 – Select Employee Training Records to Review

Using the jurisdiction's Standard 2 Self-Assessment Worksheet, or equivalent documentation, the verification auditor must identify the employee training records that correspond to the randomly selected numbers recorded on the Standard 2 Verification Audit Worksheet. Record the employee's name adjacent to the corresponding random number on the Standard 2 Verification Audit Worksheet.

Only those employees' training records that the jurisdiction reports as meeting all the Standard 2 training and standardization elements are to be reviewed. If an employee is randomly selected but the jurisdiction indicated that employee does not meet the Standard 2 criteria, the verification auditor should randomly select a substitute employee training record to review.

STEP 6 – Verify Documentation of the Completion of the Standard Training Criteria

The verification auditor must review the training file for each of the randomly selected employees to confirm completion of the following items:

- coursework related to the Standard 2 Pre-requisite ("Pre") curriculum;
- a minimum of 25 joint field training inspection, including documentation that confirms Food Safety Inspection Officers (FSIOs) are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments;
- a minimum of 25 independent inspections and ALL the Standard 2 ("Post") curriculum requirements;
- field standardization within 18 months of hire or re-standardization every three years after initial standardization, and
- 20 hours of food safety related continuing education every three years

NOTE: For new hires or employees newly assigned to the retail food protection program, the date recorded in the "Completion of Field Standardization" column must be within 18 months of the date recorded in the "Date of Hire or Assignment to the Retail Food Protection Program."

For experienced employees, however, the completion date for standardization may be in excess of 18 months of their date of hire. This is because the jurisdiction may not have been standardizing their retail food protection program staff prior to enrollment in the Program Standards. Keep in mind that the Standard 2 language was written to establish a training and standardization process for new employees. As long as the experienced FSIO has successfully completed standardization at the time of the self-assessment the Standard 2 criteria is met.

STEP 7 – Making a Determination Based on the Results of the Audit

For each employee training file reviewed, the verification auditor must mark the appropriate box on the Standard 2 Verification Audit Worksheet. The auditor must indicate "YES –Standard 2 criteria are met" or "NO" – Standard 2 criteria is not met." If the verification auditor determines an employee training record did not meet the Standard 2 criteria, an explanation must be provided noting any deficiencies. A jurisdiction meets the Standard 2 criteria if ninety percent (90%) of the retail food program inspection staff fulfilled all the training and standardization requirements within the specified time frames.

Standard 2: Trained Regulatory Staff
Verification Audit Worksheet

No.	Randomly Selected Number	Employee Name	Yes Standard 2 Criteria are Met	No Standard 2 Criteria are Not Met	If NO, auditor is to specify why criterion is not met
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

NOTE:

1. All randomly selected employee training records must contain documentation that the Standard 2 training and standardization elements have been successfully completed.
2. Based on the documentation from this worksheet, record your determination for each of the items on the jurisdiction's *Standard 2: Program Self-Assessment and Verification Audit Form*.

ADDITIONAL STANDARD 2 VERIFICATION AUDIT WORKSHEET (if needed)

Standard 2: Trained Regulatory Staff
Verification Audit Worksheet

No.	Randomly Selected Number	Employee Name	Yes Standard 2 Criteria are Met	No Standard 2 Criteria are Not Met	If NO, auditor is to specify why criterion is not met
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

NOTE:

1. All randomly selected employee training records must contain documentation that the Standard 2 training and standardization elements have been successfully completed.
2. Based on the documentation from this worksheet, record your determination for each of the items on the jurisdiction's *Standard 2: Program Self-Assessment and Verification Audit Form*.

STANDARD 6 – COMPLIANCE AND ENFORCEMENT

INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

Using the Standard 6: Verification Audit Worksheet

The auditor should have the *Standard 6: Verification Audit Worksheets* available as a reference when reading through this guidance. The following worksheet is provided at the end of these instructions:

- *Standard 6: Verification Audit Worksheet*

The Standard 6: Verification Audit Worksheet is designed to provide a listing of the establishments randomly selected from the jurisdiction's inventory that were reviewed as part of the self-assessment process. This worksheet provides a summary as to whether or not the inspection file/records for each of the randomly selected establishments meet the Standard 6 criteria.

The Standard 6: Establishment File Worksheet provides a systematic way of collecting the compliance and enforcement history for each of the randomly selected establishments. Jurisdictions do not have to use this form. However, a jurisdiction must provide documentation of the review process. The documentation must indicate if appropriate compliance and enforcement actions were taken for out-of-control risk factors and *Food Code* interventions at each establishment randomly selected for the self-assessment.

STEP 1 – Verify the Elements in the Written Compliance & Enforcement Program

To meet the criteria of Standard 6, the jurisdiction must have written step-by-step procedures outlining its compliance and enforcement process. The verification auditor should review its compliance and enforcement policies and procedures to ensure that there is clear guidance for staff. The policies and procedures should provide steps and actions to be taken when various categories of violations occur. The policies and procedures should also provide a progression of steps to be taken when violations are not corrected within regulatory or administratively established time frames.

Standard 6 does not dictate a required compliance process. The jurisdiction is free to determine any actions to be taken for violations of its regulations and the progression of consequences for repeated violations. The time frames and triggers for additional actions are also left to the discretion of the jurisdiction.

In addition, to meet the requirements of Standard 6, the jurisdiction's inspection form must use the IN compliance, OUT of compliance, Not Applicable, and Not Observed conventions to record the compliance status of the foodborne illness risk factors and the public health interventions identified in the *Food Code*.

Jurisdictions that have not adopted all the recommended foodborne illness risk factors and *Food Code* interventions are not penalized under Standard 6 for these omissions.

STEP 2 – Verify the Effectiveness of the Compliance & Enforcement Program

Randomly selected establishment files must be reviewed to determine if documented violations were resolved satisfactorily. The results of the review will be used to assess the success of the compliance and enforcement program. This section of the self-assessment process has been broken down into the following four parts:

Part I Verify that the jurisdiction reviewed the appropriate number of files

Part II Randomly select establishment files from the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet*

Part III Verify Self-Assessment findings for each selected establishment file

Part IV Verify that 80% of selected establishment files adhere to the jurisdiction's written compliance and enforcement procedures

Part I - Verify that the jurisdiction reviewed the appropriate number of files

The number of establishment files a jurisdiction must review as part of the Standard 6 self-assessment process is based on the size of their establishment inventory. Jurisdictions with less than 800 total establishments must select at least 40 files for review. If a jurisdiction has less than 40 establishments in the inventory, then all files will be reviewed. Jurisdictions with 800 or more establishments must select a sample size equal to 5% of the total establishments up to a maximum of 70 files.

Establishment Inventory	Number of Files to Review for the Self-Assessment
Less than 800	40 establishment files
800 or more	5% of the total number of establishments (Up to a maximum of 70 files)

Some of the randomly selected establishment files listed on the *Standard 6: Self-Assessment Summary Worksheet* may not qualify for the self-assessment process. Deletion of an establishment from the sample of files to be reviewed as part of the self-assessment process is limited to those establishments where:

1. The selected establishment has not been in business long enough to have at least three regularly scheduled routine inspections; or
2. A review of inspection reports in the selected establishment file reveals that there were no risk factor or *Food Code* intervention violations documented on the "start-point" inspection

The jurisdiction's self-assessment process must include a listing of the substitute establishment files that were reviewed as replacements for those that did not qualify. When an establishment does not qualify for the self-assessment process, the substitute establishment must not be recorded on the *Standard 6: Self-Assessment Summary Worksheet*, but instead on the *Standard 6: Self-Assessment Summary Worksheet Substitute Establishment Files Worksheet*. The auditor should verify this.

Part II - Randomly select establishment files from the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet*

Using a table of random numbers or a random number generator is the preferred method of sample selection. The random selection will be made from the establishment files listed on the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet*. The number of establishment files that must be selected for review as part of the verification audit process is indicated in the chart below.

Establishment Inventory	Number of Files to Review for the Self-Assessment	Number of Files to Select for the Verification Audit
Less than 800	40 establishment files	5
800 or more	5% of the total number of establishments (Up to a maximum of 70 files)	10

Using the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet*, the verification auditor will identify the establishment files that correspond to the randomly selected number recorded on the *Standard 6: Verification Audit Worksheet*. The verification auditor must record the establishment name or identification number for each of the randomly selected numbers on the *Standard 6: Verification Audit Worksheet.*

The verification auditor must only review establishment files that the jurisdiction has indicated as meeting all the elements of their compliance and enforcement procedures. This will require the verification auditor to eliminate establishment files that are marked "NO" on the jurisdiction's Self-Assessment Summary Worksheet. (An "X" placed in the "NO" box indicates that the self-assessment review process determined that the inspection history documented in the establishment file did not meet, or only partially met, the Standard 6 criteria and all the elements in the jurisdiction's written compliance and enforcement procedures.)

In instances where the verification auditor has randomly selected an establishment file from the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet* that did not qualify (D.N.Q.) for the self-assessment review process, the substitute establishment that the jurisdiction selected for that disqualified establishment should be used.

Note: There are two types of substitutes for the audit process, which are treated differently:

1. If the auditor selects an establishment that was previously failed by the self-assessor, then use the auditor-generated substitute list of random numbers to select a substitute establishment.
2. If the auditor selects an establishment that "did not qualify" for the original self-assessment, then use the substituted establishment that was already assigned in the original self- assessment review.

Part III - Verify Self-Assessment findings for each selected establishment file

Using the jurisdiction's written compliance and enforcement procedures, the verification auditor will review the Establishment File Worksheet for each of the establishments randomly selected for the verification audit.

The *Standard 6: Establishment File Worksheet* provides a systematic way of documenting the compliance and enforcement history for each of the randomly selected establishments. Jurisdictions do not have to use this form but must provide documentation of the review process conducted to determine whether the appropriate compliance and enforcement actions for out-of-control risk factors and *Food Code* interventions were taken for each selected establishment.

Review the inspection history in each selected file beginning with the identified "start-point" inspection and moving forward through two additional inspections. Verify that either on-site corrective action, follow-up corrective action or enforcement action occurred by the end of the third inspection for each out-of-compliance risk factor or intervention marked on the start point inspections. In addition, verify that the actions taken on each violation documented on the "start-point" inspection followed the jurisdiction's written compliance policy and procedures.

In order for an establishment file to meet the Standard 6 criteria, each column marked with a violation at the "start-point" inspection must have a subsequent indication that at least one type of follow-up action was taken, and the jurisdiction's written procedures must have been followed. A single violation on the "start-point" inspection without a final resolution, either correction or compliance/enforcement activity, will result in a determination that the establishment file does not meet the Standard 6 criteria. In any instances where the auditor disagrees with the jurisdiction's self-assessment of a file, the auditor must meet with the jurisdiction's program manager or representative to gain a full understanding of the rationale used for the self-assessment determination.

The verification auditor will record his or her findings for each of the establishment files reviewed on the *Standard 6: Verification Audit Worksheet*. If the verification audit of the establishment file review indicates that the full intent of the Standard 6 criteria is met, place an "X" in the "YES" box. If full intent of the Standard 6 criteria is not met, place an "X" in the "NO" box. If the verification auditor disagrees with the jurisdiction's self-assessment decision, an explanation must be provided in the last column of the *Standard 6: Verification Audit Worksheet*. Additional sheets can be used to document the need for expanded explanations.

Part IV - Verify that 80% of selected establishment files adhere to the jurisdiction's written compliance and enforcement procedures

The criteria for Standard 6 requires that 80 percent of the files with an identified violation of a foodborne illness risk factor or a *Food Code* intervention on the "start-point" inspection adhere to the jurisdiction's written compliance and enforcement procedures. Files that "did not qualify" (D.N.Q.) for the self-assessment review are not used in the calculation of the percentage.

Legitimate differences of opinion regarding stringency of language may occur during the verification audit process. An approximate ten percent (10%) discrepancy allowance is made to accommodate potential differences in interpretations.

Jurisdictions with less than 800 Establishments - If two or more of the five audited establishment files rated as passing by the jurisdiction are not verified by the auditor as having met the Standard 6 criteria, the Part III element fails to meet the criteria, and no further sampling is necessary. Even if no additional disagreements are found by sampling an additional set of randomly drawn establishment files, the dilution of agreements to disagreements will be insufficient to meet the approximate ten percent (10%) disagreement allowance.

Determine the need for supplemental sampling. If only one establishment file from the initial sample is determined by auditor to have not met the Standard 6 criteria, then randomly select an additional 5 establishment files. Follow the same audit process used to review the first set of establishment files. The *Standard 6: Verification Audit Worksheet* for substitute establishment files, provided on a following page, can be used to record all the information related to the supplemental sampling of establishment files.

If no additional disagreements in the review of establishment files are noted, then the jurisdiction meets the Standard 6 criteria. If one or more additional establishment files fails the audit review, then the Standard 6 criteria are not met, since the dilution of agreements to disagreements will be insufficient to meet the approximate ten percent (10%) disagreement allowance.

Jurisdictions with more than 800 Establishments - If three or more of the ten audited establishment files rated as passing by the jurisdiction are not verified by the auditor as having met the Standard 6 criteria, then the jurisdiction fails to meet Standard 6. Even if no additional disagreements are found by sampling an additional set of randomly drawn establishment files, the dilution of agreements to disagreements will be insufficient to meet the approximate ten percent (10%) disagreement allowance.

Determine the need for supplemental sampling. If one or two establishment files from the initial sample are determined by auditor to have not met the Standard 6 criteria, then randomly select an additional 10 establishment files. Follow the same audit process used to review the first set of establishment files. The *Standard 6: Verification Audit Worksheet* for substitute establishment files, provided on a following page, can be used to record all the information related to the supplemental sampling of establishment files.

No more than a total of two of 20 establishment files drawn can be determined by the auditor as not meeting the Standard 6 criteria. If more than two establishment files fail the audit review, then the Standard 6 criteria are not met, since the dilution of agreements to disagreements will be insufficient to meet the approximate ten percent (10%) disagreement allowance.

Standard 6: Compliance and Enforcement
Verification Audit Worksheet
Establishment Files

Jurisdiction Name: _____

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	If NO, Auditor is to specify why the establishment file does not meet all the elements contained in the jurisdiction's written compliance and enforcement procedures
1						
2						
3						
4						
5						
6						
7						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	If NO, Auditor is to specify why the establishment file does not meet all the elements contained in the jurisdiction's written compliance and enforcement procedures
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	If NO, Auditor is to specify why the establishment file does not meet all the elements contained in the jurisdiction's written compliance and enforcement procedures
18						
19						
20						

STANDARD 5
FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

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STANDARD 5
FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

This standard applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies, either unintentional or deliberate, which results in illness, injury, and outbreaks.

Requirement Summary

The program has an established system to detect, collect, investigate, and respond to complaints and emergencies that involve foodborne illness, injury, and intentional and unintentional food contamination.

Description of Requirement

1. Investigative Procedures

a. The program has written operating procedures for responding to and /or conducting investigations of foodborne illness and food-related injury*. The procedures clearly identify the roles, duties, and responsibilities of program staff and how the program interacts with other relevant departments and agencies. The procedures may be contained in a single source document or in multiple documents.

b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, food-related injury* or contamination of food.

c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties, and responsibilities of each party.

d. The program maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, food-related injury* or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in or linked to the establishment record for retrieval purposes.

e. Program procedures describe the disposition, action or follow-up and reporting required for each type of complaint or referral report.

f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.

g. The program has established procedures and guidance for collecting information on the suspect food's preparation, storage or handling during on-site investigations of food-related illness, food-related injury*, or outbreak investigations.

h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.

i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.

2. Reporting Procedures

a. Possible contributing factors to the food-related illness, food-related injury* or intentional food contamination are identified in each on-site investigation report.

b. The program shares final reports of investigations with the state epidemiologist and reports of confirmed foodborne disease outbreaks* with CDC.

3. Laboratory Support Documentation

a. The program has a letter of understanding, written procedures, contract, or MOU acknowledging, that a laboratory(s) is willing and able to provide analytical support to the jurisdiction's food program. The documentation describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.

b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).

4. Trace-back Procedures

a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak, or intentional food contamination. The trace-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.

5. Recalls

a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak, or intentional food contamination.

b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed.

c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.

6. Media Management

a. The program has a written policy or procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.

7. Data Review and Analysis

a. At least once per year, the program conducts a review of the data in the complaint log or database and the foodborne illness and food-related injury* investigations to identify trends and possible contributing factors that are most likely to cause foodborne illness or food-related injury*. These periodic reviews of foodborne illnesses may suggest a need for further investigations and may suggest steps for illness prevention.

b. The review is conducted with prevention in mind and focuses on, but is not limited to, the following:

1) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* in a single establishment;
2) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Disease Outbreaks* in the same establishment type;
3) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* implicating the same food;
4) Foodborne Disease outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* associated with similar food preparation processes;
5) Number of confirmed foodborne disease outbreaks*;
6) Number of foodborne disease outbreaks* and suspect foodborne disease outbreaks*;
7) Contributing factors most often identified;
8) Number of complaints involving real and alleged threats of intentional food contamination; and
9) Number of complaints involving the same agent and any complaints involving unusual agents when agents are identified.

c. In the event that there have been no food-related illness or food-related injury* outbreak investigations conducted during the twelve months prior to the data review and analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate response to an actual confirmed foodborne disease outbreak* and include on-site inspection, sample collection and analysis. A mock investigation must be completed at least once per year when no foodborne disease outbreak* investigations occur.

Note: *Regulatory Programs are encouraged to also participate in the CDC National Environmental Assessment Reporting System (NEARS). NEARS is designed to provide a more*

comprehensive approach to foodborne disease outbreak investigation and response and will provide a data source to measure the impact of food safety programs to further research and understand foodborne illness causes and prevention. (The following link provides additional information regarding NEARS: http://www.cdc.gov/nceh/ehs/nears/index.htm)

Outcome

A food regulatory program has a systematic approach for the detection, investigation, response, documentation, and analysis of alleged food-related incidents that involve illness, injury, unintentional or deliberate food contamination.

Documentation

The quality records required to meet this standard include:

1. Logs or databases of alleged food-related illness and food-related injury* complaints maintained and current.
2. Collection forms specified in the operating procedures.
3. Investigation reports of alleged food-related illness, food-related injury*, or incidents. Reports are retrievable by implicated establishment name.
4. The written procedures, contracts, or MOUs with the supporting laboratories.
5. The procedure addressing the trace-back of food products implicated in an illness, outbreak, or contamination event.
6. 21 CFR, Part 7, or written procedures equivalent to 21 CFR, Part 7 for recalls.
7. Completed copies of the annual review and analysis (after 12 months of data).
8. Current written media policy/procedure and contact person.
9. The contact list for communicating with all relevant agencies.
10. Portions of any emergency response relevant to food safety and security.

*[*Note: See the Standards Definitions for the meaning of these defined terms.]*

Voluntary National Retail Food Regulatory Program Standards

DEFINITIONS

The following definitions apply in the interpretation and application of these Standards.

1) **Active Managerial Control** – The purposeful incorporation of specific actions or procedures by industry management into the operation of a business to attain control over foodborne illness risk factors.
2) **Auditor** – Any authorized city, county, district, state, federal, tribal, or other third-party person who has no responsibilities for the day-to-day operations of that jurisdiction and is charged with conducting a verification audit, which confirms the accuracy of the self-assessment.
3) **Baseline Survey** – See Risk Factor Study.
4) **Candidate** - A regulatory officer whose duties include the inspection of retail food establishments.
5) **Compliance and Enforcement** – Compliance includes all voluntary or involuntary conformity with provisions set forth by the regulatory authority to safeguard public health and ensure that food is safe. Enforcement includes any legal and/or administrative procedures taken by the regulatory authority to gain compliance.
6) **Confirmed Foodborne Disease Outbreak** – means a foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiologic analysis implicates the food as the source of the illness or epidemiological analysis alone implicates the food as the source of the illness.
7) **Direct Regulatory Authority (DRA) –** The organizational level of government that is immediately responsible for the management of the retail program. This may be at the city, county, district, state, federal, territorial, or tribal level.
8) **Enforcement Actions –** Actions taken by the regulatory authority such as, but not limited to, warning letters, revocation or suspension of permit, court actions, monetary fines, hold orders, destruction of food, etc., to correct a violation found during an inspection.
9) **Follow-up Inspection –** An inspection conducted after the initial routine inspection to confirm the correction of a violation(s).
10) **Food Code Interventions** – the preventive measures to protect consumer health stated below:
    1. management's demonstration of knowledge;
    2. employee health controls;
    3. controlling hands as a vehicle of contamination;
    4. time / temperature parameters for controlling pathogens; and
    5. consumer advisory.
11) **Food-Related Injury** – Means an injury from ingesting food containing a physical hazard such as bone, glass, or wood.
12) **Foodborne Disease Outbreak** – The occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.
13) **Good Retail Practices (GRP's)** – Preventive measures that include practices and procedures to effectively control the introduction of pathogens, chemicals, and physical objects into food, that are prerequisites to instituting a HACCP or Risk Control Plan and are not addressed by the *FDA Food Code* interventions or risk factors.
14) **Hazard** – A biological, chemical, or physical property that may cause food to be unsafe for human consumption.

15) **National Registry of Retail Food Protection Programs (National Registry) – A** listing of retail food safety programs that have voluntarily enrolled as participants in the *Voluntary National Retail Food Regulatory Program Standards*.
16) **Person in charge (PIC)** – The individual present at a food establishment who is responsible for the operation at the time of inspection.
17) **Program Element –** One of the program areas for which a National Standard has been established such as regulations, training, inspection system, quality assurance, foodborne illness investigation, compliance and enforcement, industry and consumer relations, and program resources.
18) **Program Manager** – The individual responsible for the oversight and management of a retail food regulatory program.
19) **Quality Records –** Documentation of specific elements of program compliance with the National Standards as specified in each Standard.
20) **Risk Control Plan (RCP)** – a concisely written management plan developed by the retail or food service operator with input from the health inspector that describes a management system for controlling specific out-of-control risk factors.
21) **Risk Factors** – the improper employee behaviors or improper practices or procedures in retail food and food service establishments stated below which are most frequently identified by epidemiological investigation as contributing to foodborne illness or injury:
    1. improper holding temperature;
    2. inadequate cooking;
    3. contaminated equipment;
    4. food from unsafe source; and
    5. poor personal hygiene.
22) **Risk Factor Study** (formerly Baseline Survey) – A study on the occurrence of foodborne illness risk factors within institutional, foodservice, restaurants, and retail food facility types under a jurisdiction's regulatory authority. Criteria for a Risk Factor Study are detailed in Standard 9, including at a minimum:
    1. Data Collection, analysis, and a written report;
    2. A collection instrument with data items pertaining to the five foodborne illness risk factors;
    3. A collection instrument that uses the convention of IN, OUT, NA and NO to document observations;
    4. All facility types identified by FDA's national study that are under the jurisdiction's regulatory authority; and
    5. Studies subsequent to the initial study repeated at 5-year intervals.
23) **Routine Inspection – A** full review and evaluation of a food establishment's operations and facilities to assess its compliance with Food Safety Law, at a planned frequency determined by the regulatory authority. This does not include re-inspections and other follow-up or special investigations.
24) **Self-Assessment** – An internal review by program management to determine whether the existing retail food safety program meets the *Voluntary National Retail Food Regulatory Program Standards*.
25) **Self-Assessment Update** – Comparison of one or more program elements against the *Voluntary National Retail Food Regulatory Program Standards* between the required 60-month periodic self-assessment.

26) **Standardization Inspection** – An inspection used to demonstrate a candidate's knowledge, communication skills, and ability to identify violations of all regulatory requirements and to develop a risk control plan for identified, uncontrolled risk factors.
27) **Suspect Foodborne Outbreak** – Means an incident in which two or more persons experience a similar illness after ingestion of a common food or eating at a common food establishment/gathering.
28) **Trainer** – An individual who has successfully completed the following training elements as outlined in Steps 1 – 3, Standard 2, and is recognized by the program manager as having the field experience and communication skills necessary to train new employees.
    1. Satisfactory completion of the prerequisite curriculum;
    2. Completion of a field training process similar to that contained in Appendix B-2; and
    3. Completion of a minimum of 25 independent inspections and satisfactory completion of the remaining course curriculum.
29) **Training Standard** – An individual who has successfully completed the following training elements AND standardization elements in Standard 2 and is recognized by the program manager as having the field experience and communication skills necessary to train new employees. The training and standardization elements include:
    1. Satisfactory completion of the prerequisite curriculum;
    2. Completion of a field training process similar to that contained in Appendix B-2;
    3. Completion of a minimum of 25 independent inspections and satisfactory completion of the remaining course curriculum;
    4. Successful completion of a standardization process based on a minimum of eight inspections that includes development of HACCP flow charts, completion of a risk control plan, and verification of a HACCP plan, similar to the FDA standardization procedures;
    5. Completion of a minimum of 20 contact hours of continuing education in food safety every 36 months after the initial training is completed as outlined in Standard 2; and
    6. Standardization maintained every three (3) years as outlined in Standard 2.
30) **Verification Audit** – A systematic, independent examination by an external party to confirm the accuracy of the Self-Assessment.

STANDARD 8 PROGRAM SUPPORT AND RESOURCES

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STANDARD 8 PROGRAM SUPPORT AND RESOURCES

This standard applies to the program resources (budget, staff, equipment, etc.) necessary to support an inspection and surveillance system that is designed to reduce risk factors and other factors known to contribute to foodborne illness.

Requirement Summary

The program provides funding, staff, and equipment necessary to accomplish compliance with the Voluntary National Retail Food Regulatory Program Standards.

Description of Requirement

The program budget provides the necessary resources to develop and maintain a retail food safety program that meets the following criteria:

1. Staffing Level

Note: Jurisdictions can achieve conformance using one of two methods. Both methods can be accessed for downloading from the Conference for Food Protection (CFP) web site: www.foodprotect.org and located under the icon titled, "Conference Developed Guides and Documents."

Option 1: Standard 8 Staffing Level Assessment

A staffing level of one full-time equivalent (FTE) devoted to food for every 280 – 320 inspections performed. Inspections for purposes of this calculation include routine inspections, re- inspections, complaint investigations, outbreak investigations, compliance follow-up inspections, risk assessment reviews, process reviews, variance process reviews and other direct establishment contact time such as on-site training.

A process should exist for the regulated food establishments to be grouped into at least three categories based on food safety risk (See Standard 3). The number of inspections assigned per FTE should be adjusted within the 280 – 320 range depending upon the composition of low- to high –risk establishments in the assigned inventory. When an FTE is divided between program areas, the total number of food inspections planned for that FTE should be adjusted to compensate for the additional training time required to maintain competency in multiple program areas. An adjustment of planned inspections per FTE should also occur when food establishments are geographically dispersed due to increased travel time. Through their committee process, the CFP has developed an assessment tool and instruction guide as resources that can be used by a jurisdiction to calculate the FTE to inspection ratio.

Option 2: Standard 8 Staffing Level Alternative Conformance Method

Jurisdictions may access an alternative model for achieving conformance with Standard 8 from the Conference for Food Protection (CFP) web site: www.foodprotect.org and located under the icon titled, "Conference Developed Guides and Documents."

2. Inspection Equipment

Inspection equipment of each inspector to include head covers, thermocouples, flashlights, sanitization test kits, heat sensitive tapes or maximum registering thermometers, necessary forms, and administrative materials. The following equipment must be available for use by inspectors when needed: computers, cameras, black lights, light meters, pH meters, foodborne illness investigation kits, sample collection kits, data loggers and cell phones.

3. Administrative Program Support

Equipment for administrative staff to include computers, software and/or items necessary to support the record keeping system utilized by the program. A system is in place to collect, analyze, retain, and report pertinent information.

4. Regulatory Foundation

Staff and resources to adopt a sound, science-based regulatory foundation for the public health program and the uniform regulation of industry required in Standard No. 1.

5. Trained Regulatory Staff

Training and training documentation for all regulatory staff to meet the level specified in Standard No. 2.

6. Inspection Program Based on HACCP Principles

Staff to meet all of the requirements in Standard No. 3, inspection based on HACCP principles.

7. Uniform Inspection Program

Administrative and supervisory staff to administer and monitor a uniform inspection program based on HACCP principles that meet Standards No. 3 and 4.

8. Foodborne Illness & Food Defense Preparedness & Response

Staff and resources to maintain a foodborne illness investigation and response system that meets Standard No. 5.

9. Compliance & Enforcement

A program that demonstrates follow-though on all compliance and enforcement actions initiated according to the written step-by-step procedures required in Standard No. 6.

10. Industry & Community Relations

An industry and consumer relations program as specified in Standard No. 7.

11. Program Assessment

Sufficient staff and resources to conduct regular program self-assessment and risk factor surveys as specified in Standard No. 9.

12. Accredited Laboratory

Funds to provide access to accredited laboratory resources in support of the program as specified under these nine Standards.

The essential program elements required to demonstrate compliance with this standard are:

A. Full-time equivalent (FTE) personnel to inspections accomplished ratio as described in section 1.
B. Inspection equipment assigned or available as described in section 2.
C. Equipment and/or supplies required for administering the program as described in Section 3.
D. A full and accurate completion of the *Standard 8: Self-Assessment Worksheet* or equivalent whether or not those standards are met.

Outcome

The desired outcome of this standard is that resources are available to support a risk-based retail food safety program designed to reduce the risk factors known to contribute to foodborne illness.

Documentation

The quality records needed for this standard include:

1. Documentation of FTE to inspections ratio,
2. Inventory of assigned and available inspection equipment,
3. Documentation and demonstration of records system and adequacy of support,
4. The completed Standard 8 Self-Assessment Worksheet

*[*NOTE: An average workload figure of 150 establishments per FTE with two inspections per year was originally recommended in the 1976 Food Service Sanitation Manual, the standard originating from a book entitled, "Administration of Community Health Services." Annex 4 of the Code since 1993 has included a recommendation that 8 to 10 hours be allocated for each establishment per year to include all the activities reflected here in the definition of an inspection. The range of 280 – 320 broadly defined inspections per FTE is consistent with these previous recommendations. A measure of resources defined as inspections per FTE rather than establishments per FTE allows for the same unit of measure to be used for any jurisdiction regardless of the frequency of routine inspections conducted among the various priority categories.]*

Standard 8 Staffing Level

Purpose of Standard 8 staffing level section:

Standard 8 Section 1. Staffing Level requires a health department (HD) to demonstrate that they have the staff "necessary to support an inspection and surveillance system that is designed to reduce risk factors and other factors know to contribute to foodborne illness"

Current criteria to pass Standard 8:

A HD currently meets this standard if they demonstrate an inspection to FTE ratio range of 280-320 inspections per FTE. The Conference for Food Protection (CFP) developed an assessment tool and instruction guide that can be used by a HD if desired. If not the HD has to calculate their inspection to FTE ratio through their own method and see if it falls within the required range.

Problem with inspection to FTE ratio range:

It has been agreed by upon by subcommittee that this range is problematic as it's based on the idea that every inspection should take 4 hours. The subcommittee has also agreed that a range is problematic as it allows for an adequately staffed health department to fail the standard as they could fall below the range.

Recommendations:

We are recommending removing the range and allowing HDs to demonstrate to independent auditors that they are adequately staffed in a more appropriate way. The following are the 3 options we think are reasonable that a HD can use to demonstrate staffing levels.

1. A HD can use their own method they feel is appropriate for them to demonstrate adequate staffing levels

2. A HD can use the current assessment tool (with inspection to FTE section removed) developed by CFP to assess if they're adequately staffed

3. A health department can use the updated CFP assessment tool that calculates staffing levels by risk category
    a. Using the updated vs. current assessment tool may make it easier for a HD to prove to their auditor that they are adequately staffed because:
        i. It has a section that calculates how many FTEs a HD *should* have based on risk categories (current assessment does not do this)
        ii. It then automatically compares how many FTEs a health department *currently* has with how many they *should* have (the current assessment only calculates *current* FTE, so it may be challenging to convince an auditor that a current calculated FTE # demonstrates a HD to be adequately staffed)

Updated CFP Assessment Tool

The following is an example of how to use the updated assessment tool to calculate if a health department is adequately staffed.

Discussion on Table 1. The risk category column is broken into three categories, the minimum required by Standard 8. The number of establishments will be unique to each health department. The rows in the remaining columns show values that are based off of survey data of 100 local and state health departments throughout the country (see footnotes for more details). A HD should feel free to use these values or input ones that more appropriately fit their organization.

Table 1.

Risk Category	Number of Establishments	Inspection Frequency[1]	Average Inspection Time (does not include travel)[2]	Reinspection frequency[3]	FBI Inspection Frequency[4]	Other Frequency[5]
Low	1,000	1	45 minutes	15%	1%	10%
Medium	2,000	2	75 minutes	15%	1%	10%
High	1,000	3	120 minutes	15%	1%	10%

Step 1. Calculate available annual inspection time per full time equivalent (FTE) using assessment tool. 1200 hours a year will be used for this example.

Step 2. Calculate number of FTE currently available at health department. This # is calculated in the current and updated assessment tools.

Step 3. Calculate total number of hours required to inspect each risk category. Formula for calculating # of inspection hours per risk type below (low risk type used for example):

(1000 establishments x 1 inspection a year = 1000 inspections) + (1000 establishments x 15 % reinspections a year = 150 inspections) + (1000 establishments x 1% FBI inspections a year = 10 inspections) + (1000 inspections x 10% other inspections a year = 100 inspections) = 1260 inspections a year x 45 minutes an inspection = 945 hours a year

Medium risk = 4520 inspections a year x 75 minutes = 5650 hours

High Risk = 3260 inspections a year x 120 minutes =6520 hours

Total inspection time = 945 + 5650 + 6520 = 13,115 inspection hours a year

Step 4. Calculate number of FTE's required

13,115 total inspection time hours /1200 inspection hours available per FTE = 10.93 FTEs

Step 5. Calculate if health department is adequately staffed

If FTEs currently available >= 10.93 FTEs that a HD should have then that HD is adequately staffed

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[1] Median inspection frequencies of 100 health departments from 2017 survey
[2] Median inspection times of 100 health departments from 2017 survey
[3] Median reinspection frequency %s of 60 health departments form 2017 survey2
[4] Median food borne illness inspection frequency %s of 60 health departments from 2017 survey2
[5] Final % value still being calculated, 10% being used for this demonstration

Appendix 8.2 Calculation for determining a required number of inspectors

This appendix is an example of how to calculate the number of field staff required to conduct inspections[21] of food plants. The data in the following table will vary significantly based on local or regional conditions. The State program may use the risk categories and inspection frequencies found in the statement of work for the food contract as a basis for determining the required number of inspectors.

Risk category	Number in inventory	Inspection frequency	Average inspection time (includes travel) [22]	Reinspection frequency
High	1,000	12 months	7.2 hours	10%
Medium	2,000	18 months	5.7 hours	10%
Low	1,000	24 months	4.2 hours	10%

1. Calculate available annual inspection time per full time equivalent (FTE).

For example, the State agency determines that after allowances for annual leave, sick leave, holidays, training, administrative time, and other activities each State program FTE has 1200 hours available for conducting inspections.

2. Calculate the number of hours required to inspect establishments in each risk category.

Formula for high risk establishment inspection time:
1000 firms x 100% coverage = 1000 inspections + 10% reinspection = 1100 total inspections per year x 7.2 hours = 7920 hours

Formula for medium risk establishment inspection time:
2000 firms x 66.6% coverage = 1333 inspections + 10% reinspection = 1466 total inspections per year x 5.7 hours = 8356 hours

Formula for low risk establishment inspection time:
1000 firms x 50% coverage = 500 inspections + 10% reinspection = 550 inspection total inspections x 4.2 hours = 2320 hours

3. Calculate the number of FTE's required.

Formula:
7920 hours for high risk + 8356 hours for medium risk + 2320 hours for low risk = 18596 inspection hours required / 1200 inspection hours available per FTE = **15.5 FTEs**

[19] Includes routine surveillance, reinspections, complaint or outbreak investigations, compliance follow-up investigations, risk assessment reviews, process reviews, and other direct establishment contact time such as on-site training.

[20] Inspection times based on calculations presented in "DHHS Office of Inspector General's FDA Oversight of State Food Firm Inspections" dated June 2000.

PSC13 IFSS Framework Basic Advanced Feb 2021 Color Chart

#	Color	Shade Level	R	G	B	Hex	Used For	Example
1	Yellow	1	255	255	167	FFFFA7	Certificate Rows	
2	Yellow	2	255	255	71	FFFF47	Leadership Skills PL Span	
3	Orange	1	255	216	93	FFD85D	IFSS PL Span	
4	Orange	2	250	191	143	FABF8F	Leadership Level	
5	Orange	3	252	205	166	FCCDA6	Vessel Sanitation Placeholder	
6	Blue	1	218	238	243	DAEEF3	Instructor Skills PL Span	
7	Blue	2	197	217	241	C5D9F1	NMFS Placeholder, Unprocessed Foundations	
8	Blue	4	184	204	228	B8CCE4	Professionalism PL Span	
9	Green	1	213	255	215	D5FFD7	Communication Skills Spanning	
10	Green	2	171	255	175	ABFFAF	ITP Placeholder	
11	Green	3	216	228	188	D8E4BC	Retail Food Program	
12	Green	4	196	215	155	C4D79B	Emerging Issues PL Span	
13	Green	5	111	207	116	8ED992	Food Foundations	
14	Pink	1	242	220	219	F2DCDB	Manufactured Foundations	
15	Pink	2	233	194	193	E9C2C1	Meat & Poulty Placeholder	
16	Gray	1	213	213	213	D5D5D5	Technical Specialist Electives	
17	Gray	2	191	191	191	BFBFBF	Technical Specialist (Expert) Level	
18	White	1	255	255	255	FFFFFF	Advanced Level	
19	Purple	1	212	202	224	D4CAE0	Emergency Response Spanning	
20	Purple	2	200	187	224	C8BBE0	Import Foundations	
21	Brown	1	237	213	181	EDD5B5	DOD Placeholder	
22	Brown	2	196	189	151	C4BD97	Entry (Basic) Level	

IFSS Curriculum Framework

Intended Audience: U.S. government human and animal food protection employees who conduct regulatory activities.

Basic Level	Human and animal food protection professionals who are newly hired in a local, state or federal feed/food protection program. These individuals have developed their investigational and communications knowledge and skills through formal education, training courses, and on-the-job-training activities, often working with more experienced inspectors.
Allergens	An overview of food allergens, including labeling requirements, preventive controls, and societal impact
Biological Hazards	Introductory knowledge, skills, and abilities related to biological hazards, focusing on sources of contamination, growth factors, and control methods.
Biosecurity	Introductory knowledge, skills, and abilities related to controlling disease transmission between people, animals and plants.
Communication Skills	Skills required for an effective communicator in the regulatory field.
Data & Information Systems	Introductory knowledge, skills, and abilities related to systems used by regulatory agencies to store, process, and manage data and information.
Emergency Response	Foundational knowledge related to reacting to emergency public health situations.

Environmental Hazards	Introductory knowledge, skills, and abilities related to environmental hazards focusing on sources of contamination and associated control methods.
Food/Feed Defense	Introductory knowledge, skills, and abilities related to the reduction of intentional contamination of the feed or food supply.
HACCP	Introductory knowledge, skills, and abilities related to the hazard analysis and critical control points (HACCP) system.
IFSS	Introductory knowledge, skills, and abilities related to the regulation of feed and food products grown, produced, or manufactured outsie of or returned to the U.S.
Imports	Introductory knowledge, skills, and abilities related to the concept of a national collaborative and cooperative network of federal, state, local, tribal, and territorial feed and food protection agencies working in concert to protect the U.S. feed and food supply.
Inspections, Compliance, and Enforcement	Introductory knowledge, skills, and abilities related to ensuring regulatory compliance through inspection and enforceent activities.
Investigations	Introductory knowledge, skills, and abilities related to conducting an investigation of a feed or food safety-related event.
Jurisdiction	Introductory knowledge, skills, and abilities related to various regulatory agencies and their authority over feed and food.
Labeling	Introductory knowledge, skills, and abilities related to labeling requirements, and the components of feed and food product labels.

Laws & Regulations	Inroductory knowledge, skills, and abilities related to the system of federal, state, and local laws that provide the authority to regulate feed and food, and associated policies and procedures.
Personal Safety	Introductory knowledge, skills, and abilities related to hazards encountered by regulators, and appropriate protective actions to mitigate hazards.
Pest control	The management of pests that can be perceived to be detrimental to the production of safe human food and food for animals.
Plumbing	Knowledge, skills, and abilities related to the deliver, distribution or storage of potable and non-potable water in a manufacturing food facility and retail food establishment.
Preventive Controls	Introductory knowledge, skills, and abilities related to measures implemented by feed and food manufacturing facilities to ensure feed and food safety.
Professionalism	Introductory knowledge, skills, and abilities related to ethics, integrity, and personal conduct during job-related activities.
Public Health Principles	Introductory knowledge, skills, and abilities related to how regulatory agencies promote health and prevent and control feed and food-related illness.
Recalls	Introductory knowledge, skills, and abilities related to the process of removing a product from commerce.
Regulatory Program Foundations	Introductory knowledge, skills, and abilities related to the elements of feed and food regulatory programs

Sampling	Introductory knowledge, skills, and abilities related to feed and food sample collection, and the role of the laboratory.
Sanitation Practices	Introductory knowledge, skills, and abilities related to cleaning, sanitizing, and disinfecting, and the importance of facility and euqipment sanitary design.
Traceability	Introductory knowledge, skills, and abilities related to tracking feed and food throughout the supply chain.
Transportation	Introductory knowledge, skills, and abilities realted to preventing contamination of feed and food during transport.
Dairy On-farm	Regulatory activities related to dairy on-farm operations.
Eggs	Regulator activities related to egg operations.
Produce	
Sprouts	
Shellfish Growing Areas	
Communication Skills	Knowledge, skill, and abilities to follow policies that guide communication practices across all commodities.
Emergency Response	Knowledge, skills, and abilities to prepare for, execute, and recover from events that affect public health.
Facility Design	Knowledge related to the design and construction of a faciity.
Food Processes	Knowledge of how food is porcessed.
Inspections, Compliance, and Enforcement	Knowledge, skills, and abilities to evaluate food safety.
Investigations	Knowledge, skills, and abilities to participate in an investigation.
Plumbing	Knowledge, skills, and abilities related to reviewing the water and wastewater systems.

Pest Control	Knowledge, skills and abilities realted to assessing pest management systems.
Recall/Traceability	Knowledge, skills, and abilities needed to trace product and remove products from commerce.
Sampling	Knowledge, skills, and abilities realted to sampling.
cGMP Inspections	Knowledge, skills, and abilities related to ensuring regulatory compliance through inspection.
Food Processing Technology	Knowledge, skills, and abilities related to the evaluation of food processes.
Laws, Regulations, and Guidance	Knowledge and application of regulations and guidance related to manufactured food.
Preventive Controls Inspections	Knowledge, skills, and abilities related to conducting a preventive controls inspection.
Juice HACCP	Control strategies and practices associated with juice products.
Seafood HACCP	Control strategies and practices associated with fish and fishery products.
Grade A Dairy Processing	Regulatory activities realted to milk plant operations.
Non-Grade A Dairy Processing	
Dietary Supplements	
Shellfish Plant	
Regulatory Foundations for Retail Food Safety	The public health rationale and science behind the guidance incorporated into the FDA Food Code that can be used by federal, state, local, tribal, and territorial agencies to regulate retail food operations.

Risk-based Inspections	An inspectional approach to assess the occurrence and daily control of foodborne illness risk factors. The methodology provides a structure for prioritizing time based on risk; evaluating code compliance and active managerial control; obtaining immediate, science-based corrective actions for out-of-control risk factors; and implementing intervention strategies for long-term compliance.
Non-traditional Food Operations	Food operations not fitting the model of a typical brick and mortar restaurant or supermarket.
Introduction to Specialized Food Processing Methods	Introduction to food processes at retail.
Animal Food & Ingredients	Product used in the production of animal food.
Animal Food Safety Plans and Preventive Controls	Regulatory requirements to mitigate hazards in animal food
Animal Nutrition	Basic knowledge of animal nutrition.
Animal Species and Classes	The different species, classes, and life stages of livestock, poultry, and pets.
BSE Inspections	Conducting Bovine Spongiform Encephalopathy inspections.
Current Good Manufacturing Practices	Regulatory requirements for producing safe feed.
Feed Mill Overview	Introductory knowledge related to feed mills.
Labeling	Required components of product labeling for animal food.
Laws and Regulations	Regulatory authority related to animal food.
Medicated Feed Overview	An introduction to feed that contains medication.
Sampling	Agency-approved procedures to collect, prepare, and transport animal food samples.

Advanced	Human and animal food protection professionals who are able to independently perform sanitary inspections at a variety of facilities in addition to performing more complex investigations than inspectors at the basic level. These professionals would normally comprise the bulk of the feed/food inspection workforce and perform most of the core feed/food protection activities for their program.
Communication Skills	Adapting content, style, tone, and medium of communication in order to convey feed/food safety-related information to a variety of stakeholders.
Emergency Response	Minimizing the impact of an adverse event related to feed/food safety, public health or animal health.
Enforcement	Regulatory actions taken to address non-compliance
Evidence	Legally defensible items and information used to support regulatory actions.
Food/Feed Defense	Assessing systems for the potential of intentional adulteration, determining if intentional adulteration has occurred and responding to intentional adulteration.
Imports	
IFSS	Advanced knowledge, skills, and abilities related to a collaborative and cooperative global feed/food safety network.
Inspections	Advanced knowledge, skills, and abilities to conduct integrated, multi-faceted inspections in a flexible manner.
Instructor Skills	

Investigative Techniques	Advanced knowledge, skills, and abilities related to conducting an investigation.
Leadership Skills	
Laboratories	Knowledge of the interface between laboratory and regulatory activities.
Outbreak Investigation	Using a systematic approach to identify the source of an outbreak and mitigate the impact on public health.
Product Disposition	Knowledge, skills, and abilities to address salvage, diversion, and disposal of feed/food.
Risk Analysis	Basic knowledge, skills, and abilities related to risk analysis in feed/food protection.
Sampling	Advanced knowledge, skills, and abilities related to feed/food sample collection.
Transportation	Advanced knowledge, skills, and abilities related to preventing contamination of feed and food during transport.
Dairy On-farm	Regulatory activities related to dairy-on farm operations.
Unprocessed Concentration	
Acidified	
LACF	
Aseptic	
Plan Review	A regulatory procedure intended to ensure that retail food facilities and proposed operational processes are properly designed and that sanitary practices are implemented in order to serve their intended purposes.
Special Processes	Knowledge, skills, and abilities related to the inspection of special food processes at retail as defined in the Food Code.
Animal Food & Ingredients	Products used in the production of animal feed, including complete feed, supplements, minerals, medication, and by-products.

Animal Food Safety Plans and Preventive Controls	Advanced resource for internal training and external education related to food safety plans and preventive controls.
Animal Nutrition	Advanced knowledge of animal nutrition, including complex rations, micro-ingredients, and uncommon feed ingredients.
Aseptic Sampling	Procedures to collect non-routine feed samples.
Complaints	Feed related issues reported by consumers and/or industry.
Compliance and Enforcement Actions	Activities to achieve compliance with relevant laws and regulations.
Labeling	
Medicated Feed Mill Overview	Inspections at FDA-licensed medicated feed manufacturing facilities.
Safety Issues	Hazards associated with production and distribution of feed.
Technical Specialist	Human and animal food protection professionals with knowledge in a specific technical area, and who may or may not have a great deal of field experience. These professionals are able to conduct complex, high risk inspections and investigations, coordinate or convene key stakeholders in process development/improvement activities and will be engaged in problem solving activities. These professionals are depended upon to provide assistance and advanced or specialized support to inspectors at the Basic and Advanced Levels.
Audit	
Communication Skills	
Critical Thinking	
Emergency Response	

Rood Defense Vulnerability Assessment	
IFSS	
Leadership Skills	
Legal Proceedings Preparation	
Management Skills	
Policy Development	
Professional Development Planning	
Program Evaluation	
Program Management	
Reference Materials	
Report Evaluation	
Risk Analysis	
Supervision Skills	
Researvh Design	
Statistical Analysis	
Dairy On-farm	
Unprocessed Concentration	
Manufactured Concentration	
FDA Retail Program Standards	
Special Processes	
Animal Food & Ingredients	Feed ingredient expertise to support agency personnel and industry.
Animal Food Safety Plans & Preventive Controls	Providing expertise to agency personnel and industry related to preventive controls.
Animal Nutrition	Animal nutrition expertise provided to agency personnel and industry.
Complex Feed Labeling	Expertise in all labeling issues to support agency personnel and industry.
Compliance & Enforcement Actions	Developing strategies to achieve compliance with relevant laws and regulatrions.
Investigation Management	Managing a multi-agency response during a large-scale feed incident.
Laboratory Services	Managing the coordination between laboratory services and feed regulatory programs.

Safety Issues	Expertise applied in response to complex food safety issues.
Leadership	Human and animal food protection professionals who design, improve, and prioritize program activities, and communicate these activities within the program and to external stakeholders. Human and animal food protection professionals at the Leadership Level are involved in strategic planning and policy making for their program, and often serve as mentors and role models for other feed/food protection professionals.
Advocacy	Providing information, conducting outreach and education, and justifying program resource needs to influence decisions within politiacl, economic, and social systems.
Communication Management	Crafting and controlling program messaging.
Communication Skills	
Compliance	Influencing industry to adhere to laws and regulations.
Emergency Response	
Human Resource Management	Overseeing the employee performance system to maximize efficiency based on program priorities, ensuring that the program meets its objectives, making decisions related to staffing, and addressing employee/employer concerns.
IFSS	Ensuring alignment with a shared feed and food safety vision.
Laws & Regulations	Managing the application and understanding the impact of legal authorities on program functions and activities.
Leadership Skills	

Legislative Affairs	Regulatory program interactions with the executive and lawmaking branches of government.
Mediation	Facilitating the process of finding solutions to disagreements, disputes, or conflicts.
Organizational Design	Creating and operationalizing organizational structures.
Program Resources	Planning and overseeing the personnel, physical, and financial assets necessary to carry out program activities.
Risk Management	Balancing program policies, strategies, and activities to address public health concerns.
Strategic Planning	The process of defining the mission, and assessing the current landscape, to determine the program's future direction.

Integrated Food Safety System [IFSS] Food Protection Professionals Curriculum Framework

ifpti

U.S. FOOD & DRUG ADMINISTRATION

Advanced

Level 2 Professional Certificate

Dairy - on Farm	Unprocessed Concentration	Acidified	Grade "A" Milk Processing	LACF	Aseptic	Plan Review	Special Processes	Animal Food Program

Basic

Level 1 Professional Certificate

Dairy - on Farm	Eggs	Produce	Sprouts	Shellfish Growing Areas	Preventive Control Inspections / cGMP Inspections	Juice HACCP / Food Processing Technology	Seafood HACCP / Laws, Regulations, & Guidance	Grade "A" Milk Processing	Dietary Supplements	Shellfish Plant	Regulatory Foundations for Retail Food Safety	Risk-Based Inspections	Non-Traditional Food Operations	Introduction to Specialized Processing Methods	Animal Food Program

Communication Skills	Emergency Response	Facility Design	Food Processes	Inspections	Investigations	Plumbing	Pest Control	Recall / Traceability	Sampling
Allergens *	Biological Hazards	Biosecurity	Communication Skills	Data & Information Systems	Emergency Response	Environmental Hazards	Food/Feed Defense	HACCP	IFSS	Imports	Inspections	Investigations	Jurisdiction	Labeling	Laws & Regulations	Personal Safety	Pest Control	Plumbing *	Preventive Controls **	Professionalism	Public Health Principles	Recalls	Regulatory Program Foundations	Sampling	Sanitation Practices	Traceability	Transportation

Food Establishment Plan Review Manual

2016 Version

As recommended by the Conference for Food Protection, Plan Review Committee

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PREFACE

The FOOD Establishment Plan Review Manual was developed to assist the REGULATORY AUTHORITY and architects, FOOD consultants and other interested professionals in the plan review process when proposing to build or remodel a FOOD ESTABLISHMENT. However, it does not establish regulatory requirements and the recommendations contained herein are not intended to supplant, or otherwise serve as, the rules and regulations applicable to FOOD ESTABLISHMENTs in a given Federal, State, local, or tribal jurisdiction.

- This Manual is intended as a training tool for individuals responsible for conducting plan reviews and can be used in Food and Drug Administration (FDA)-sponsored training courses on Plan Review.
- Is intended to be consistent with the recommendations of the FDA as contained in the FDA 2013 Food Code. The FDA Food Code contains requirements for safeguarding public health and ensuring FOOD is unadulterated and honestly presented when offered to the consumer. Terminology with respect to the word "shall" is based on the recommendations within the FDA Food Code.
- Was developed by the Conference for Food Protection's 2014-2016 Plan Review Committee to update the 2008 Plan Review for Food Establishments Document.

INTRODUCTION

The plan review process presents a unique opportunity to discuss and prepare a proper foundation that will enable a FOOD ESTABLISHMENT to be successful, remain in compliance over time, and protect public health. Quality plan review, process improvement and the dedication to providing excellent customer service are high priorities for this Manual. Plan review assists in providing greater uniformity, technical assistance, and is essential for customer success and avoiding future establishment problems. Poor design, repair, and maintenance will compromise the functionality of the PHYSICAL FACILITIES and its operations. Plan review is intended to ensure PHYSICAL FACILITIES and proposed operational processes are properly designed and sanitary practices implemented in order to serve their intended purposes.

The plan review process provides the REGULATORY AUTHORITY with the opportunity to complete an effective evaluation of a FOOD ESTABLISHMENT's ability to ensure the following:

- Minimum standards are met for the protection of environmental health and safety of the public.
- Prevention of environmental health related illness and promote public health.
- Minimum standards are met for the sanitary design, facility layout, operational and product flow, menus, construction, operation and maintenance of regulated establishments, PREMISES, and surroundings.
- Food Code violations are eliminated prior to construction or implementation.
- Conditions are corrected and prevented that may adversely affect persons utilizing regulated establishments.

- Technical assistance is provided to industry to establish organized and efficient operations.
- Meets consumer expectations for the safe operation of a permitted FOOD ESTABLISHMENT.

No establishment is to be constructed and no major alteration or addition is to be made until detailed plans and specifications for such construction, alteration or addition have been submitted to and APPROVED by the REGULATORY AUTHORITY.

The REGULATORY AUTHORITY may impose specific requirements and provisions in addition to the requirements contained in codes that are authorized by law that are necessary to protect against public health hazards or nuisances. The REGULATORY AUTHORITY shall document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale.

The function of plan review, construction inspections, pre-operational inspections, and the permit approval process is to provide a comprehensive overview of proposed operations with an emphasis on contents of plans, EQUIPMENT specifications, architectural design, and operational procedures. The end goal of the plan review process is to prevent foodborne illness resulting from poor sanitary facility design and/or floor plans, and, where applicable, when the process is based on menu, FOOD preparation, and FOOD product flow.

DEFINITIONS

The following definitions as used in this document are intended to assist in the understanding of this manual.

Definitions found within the FDA Food Code have been identified in CAPS within this document. A link to the FDA Food Code is included for your reference.
http://www.fda.gov/FOOD/GuidanceRegulation/RetailFOODProtection/FOODCode/ucm374275.htm

"Easily Disassembled Equipment" means EQUIPMENT that is accessible for cleaning and inspection by:

(1) Disassembling without the use of tools, or

(2) Disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and Allen wrenches.

"Flashing" means an impervious sheet of material placed in construction to prevent water penetration or direct flow of water.

"Service Sink" means a curbed cleaning facility or janitorial sink used for the disposal of mop water and similar liquid wastes.

CONTENTS AND FORMAT OF PLANS AND SPECIFICATIONS

Proper plan review submittal with EQUIPMENT listed and located on floor plans as well as specifications for finish and plumbing schedules will highlight potential problems on paper while allowing for modifications to be made before costly purchases, installations, and construction are performed.

All facilities, systems, processes, and menus, when applicable, will be evaluated to determine minimum operational requirements. Refer to Appendix A for a copy of the Plan Review Application.

The following is a summary of what should be included in the plan submittal:

- Legible plans at minimum of 11 x 14 inches in size drawn to scale (scale - ¼ inch = 1 foot)
- Proposed menu, seating capacity, and projected daily meal volume for the FOOD ESTABLISHMENT.
- Provisions for adequate rapid cooling, including ice baths and refrigeration, and for hot and cold-holding of TIME/TEMPERATURE CONTROL for SAFETY (TCS) FOOD.
- Location of all FOOD EQUIPMENT. Each piece of EQUIPMENT must be clearly labeled, marked, or identified. Provide EQUIPMENT schedule that identifies the make and model numbers and listing of EQUIPMENT that is certified or classified for sanitation by an ANSI accredited certification program (when applicable). Elevation drawings may be requested by the REGULATORY AUTHORITY.
- Location of all required sinks: HANDWASHING SINKS, WAREWASHING sinks, Utility Sink and FOOD preparation sinks (if required).
- Auxiliary areas such as storage rooms, garbage rooms, toilets, basements and/or cellars used for storage or FOOD preparation.
- Entrances, exits, loading/unloading areas and delivery docks.
- Complete finish schedules for each room including floors, walls, ceilings and coved juncture bases.
- Plumbing schedule including location of floor drains, floor sinks, water supply lines, overhead waste-water lines, hot water generating EQUIPMENT with capacity and recovery rate, backflow prevention, and wastewater line connections.
- Location of lighting fixtures.
- Source of water and method of SEWAGE disposal.
- A color coded flow chart may be requested by the REGULATORY AUTHORITY demonstrating flow patterns for:
  - FOOD (receiving, storage, preparation, service);
  - UTENSILS (clean, soiled, cleaning, storage); and
  - REFUSE (service area, holding, storage, and disposal).
- Storage of Employee Personal Items.
- Ventilation.

MENU REVIEW AND FOOD FLOW

The menu review and the flow of FOOD through the FOOD ESTABLISHMENT are integral parts of the plan review process. The menu or a listing of all of the FOOD and beverage items to be offered at the FOOD ESTABLISHMENT must be submitted as part of the plan review application to the REGULATORY AUTHORITY.

As with the inspection process, the plan review process should focus on the FOOD and its flow through receipt, storage, preparation and service. The source and quantity of FOOD to be served should be reviewed along with the preparation and post-preparation operations. It is imperative to have knowledge of this information so that a proper assessment of the PHYSICAL FACILITIES can be made.

The food that flows through retail FOOD ESTABLISHMENT operations can be placed into the 3 following processes:

- **FOOD PROCESSES WITH NO COOK STEP**
  - **Receive – Store - Prepare – Hold – Serve**

  (Other processes may occur, but there is **NO cooking step**)
  - Examples: Salads, deli meats, cheeses, sashimi, raw oysters

- **FOOD PREPARATION FOR SAME DAY SERVICE**
  - **Receive – Store - Prepare - Cook – Hold – Serve**

  (Other processes may occur, including thawing)
  - Examples: Hamburgers, fried chicken, hot dogs

- **COMPLEX PROCESSES**
  - **Receive – Store - Prepare – Cook – Cool – Reheat – Hot Hold – Serve** (Other processes may occur, but the key is repeated trips through the temperature danger zone)
  - Examples: Refried beans, leftovers

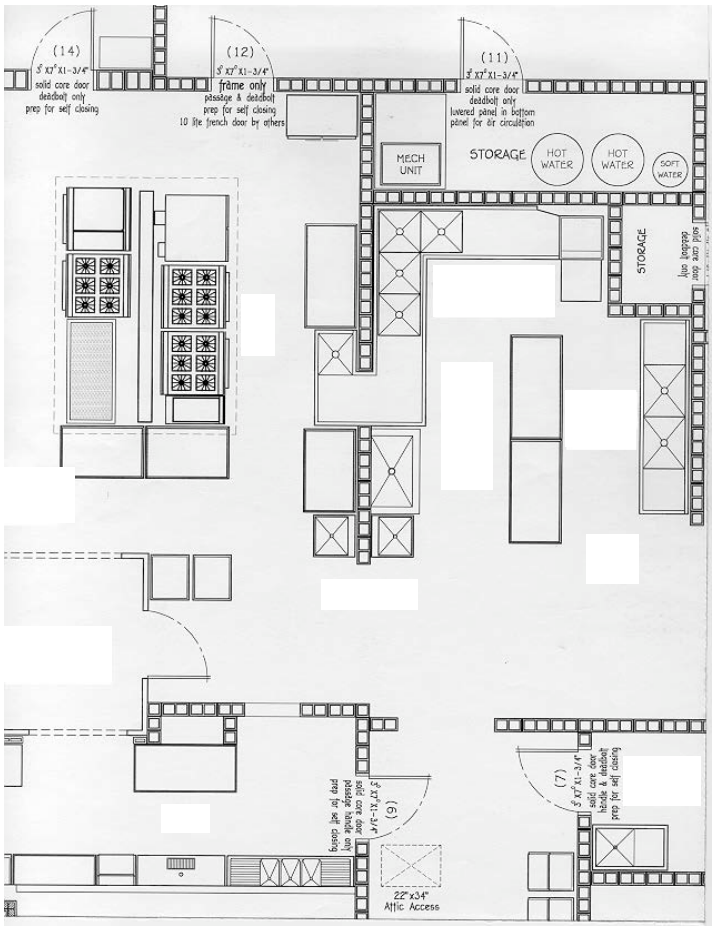
Knowledge of how the FOOD is intended to flow through the FOOD ESTABLISHMNET is very useful since the CRITICAL CONTROL POINTS for each process remain the same regardless of the individual menu ingredients.

Special attention should be given to the review of complex FOOD processes which involve:

- Multiple ingredients being assembled or mixed
- TIME/TEMPERATURE CONTROL FOR SAFETY(TCS) FOODs
- FOODs which will be prepared or held for several hours prior to service
- FOODs requiring cooling and reheating
- Multiple step processing (passing through the Time Temperature Danger Zone,

135˚F - 41˚F more than once)

The process approach can be described as dividing the many flows in a FOOD ESTABLISHMENT into broad categories, analyzing the risks, and placing manager controls on each grouping of FOOD processes. These groupings will also impact the facility design; FOOD flow; and the numbers, types, function and placement of EQUIPMENT.



The drawing above is an example of a fixture plan submitted for plan review. It is a handy tool when following the FOOD process as described by the FOOD ESTABLISHMENT operator or their representative.

Layout, flow and menu (including FOOD preparation processes) should be major considerations to help facilitate an operator's Active Managerial Control (AMC) of the risk factors for foodborne illness. Strategic layout and placing of facilities and EQUIPMENT will separate different FOOD preparation processes, a major step towards preventing contamination of FOOD that may result from poor personal hygiene, contaminated EQUIPMENT, and improper holding temperatures. Adequate and convenient storage will also enhance operations.

The menu for a FOOD ESTABLISHMENT dictates the space and EQUIPMENT requirements for the safe preparation and service of various FOOD items. The menu will determine if the proposed receiving and delivery areas, storage area, preparation and handling areas, and thawing, cooking and reheating areas are available and adequate to handle the types and volumes of FOODs being prepared and served.

When reviewing the menu, it is important to evaluate the flow patterns for the preparation of the FOOD to be sure that the lay-out of the facility provides an adequate separation of raw ingredients from READY-TO-EAT FOODs, and that the traffic patterns are not crossing paths with waste items and other sources of contamination. Cross contamination can be minimized when the flow of FOOD is considered during plan review.

With a proper understanding of the menu and flow, the plans for FOOD ESTABLISHMENTS can be reviewed to help assure that the FOOD items being considered can be protected during all aspects of the FOOD operation.

FOOD Process and Steps Required

	Receive	Store	Prepare	Cook	Cool	Reheat	Hold	Service
NO COOK	X	X	X				X	X
SAME DAY SERVICE	X	X	X	X			X	X
COMPLEX PROCESSES	X	X	X	X	X	X	X	X

Anticipated EQUIPMENT needs

Receive	Store	Prepare	Cook	Cool	Reheat	Hold	Serve
Thermometer	**Dry Storage**	**Preparation Tables**	**EQUIPMENT**	**Preparation Sink**	**Fryers**	**Refrigerators**	**Cold Holding Facilities**
	Refrigerated Storage	**Cutting Boards**	**Fryer**	**Ice Bath**	**Oven**	**Ice**	**UTENSILs**
	Frozen Storage	**UTENSILs**	**Oven**	**Blast Chiller**	**Grills**	**Cold Holding**	**Hot Holding Facilities**
	Thermometer	**Hand wash Sinks**	**Broiler**	**Shallow Plans**	**Burners**	**Hot Holding**	
		Preparation Sinks	**Grill**	**Refrigerators**	**Griddle**	**FOOD Warmers**	
		Refrigerators	**Cook Top**	**Chill Sticks**	**Other**	**Thermometer**	
			Griddle	**Thermometer**	**Hand wash Sink**	**Hand wash Sinks**	
			Other	**Hand wash Sink**			
			Thermometer	**Preparation Table**			
			Hand wash Sink	**Other**			

PREVENTIVE TOOLS FOR THE FOOD ESTABLISHMENT

Active Managerial Control (AMC)

To effectively reduce the occurrence of foodborne illness risk factors, operators of FOOD ESTABLISHMENTs must focus their efforts on achieving active managerial control. The term "active managerial control" is used to describe industry's responsibility for developing and implementing FOOD safety management systems to prevent, eliminate, or reduce the occurrence of foodborne illness risk factors.

Elements of an effective FOOD safety management system may include the following:

- Certified FOOD protection managers who have shown a proficiency in required information by passing a test that is part of an accredited program
- Standard operating procedures (SOPs) for performing critical operational steps in a FOOD preparation process, such as cooling.
- Recipe cards that contain the specific steps for preparing a FOOD item and the FOOD safety critical limits, such as final cooking temperatures, that need to be monitored and verified.
- Purchase specifications

HACCP

Hazard Analysis and Critical Control Points (HACCP) plays a vital role in proper FOOD ESTABLISHMENT design. However, the risk management tool is not considered a "stand-alone" FOOD safety system. Design and construction are essential pre-requisites and must be put in place prior to the implementation and operation of effective FOOD production practices. The purpose of quality plan review is to ensure that FOOD ESTABLISHMENTs are safe, sanitary, and efficient. Proper design, construction, and HACCP principles work to achieve these purposes and minimize the aforementioned hazards.

Effective HACCP principles are essential to a successful FOOD ESTABLISHMENT and begin with the design and layout of the facility, monitoring the FOOD flow throughout the establishment, from delivery, storage, preparation, cooking, service and consumption. A well-designed progressive FOOD flow system will minimize cross-contamination and maximize efficiency in an establishment.

Good manufacturing policies or practices, standard operating procedures (SOPs), and documentation are essential to an establishment's HACCP-based FOOD safety program and control over potential hazards. HACCP policies specifically address requirements set out in the FDA Food Code. Additional standards or good retail practices are required as foundation for FOOD safety and are detailed in the FDA Food Code. Examples include employee hygiene, employee restriction or exclusion, general sanitation, design, etc. HACCP/VARIANCE under the Plan Review & Construction Program is responsible for the review of HACCP procedures and VARIANCE applications in order for establishments to conduct specialized operations.

The FDA Food Code requires an APPROVED HACCP PLAN to be in place for some specialized processes not listed under §3-502.11. A formal HACCP PLAN review is required and needs to be APPROVED prior to conducting these operations. For information on creating a HACCP PLAN, contact the local regulatory plan reviewer or visit one of these informational hyperlinks: FDA Guidance to Implement HACCP Systems or USDAHACCPGuidelines.

FACILITIES TO MAINTAIN PRODUCT TEMPERATURE

Refrigerators and freezers are required to maintain TCS FOOD at or below 41°F and 0°F (frozen) respectively. It is recommended that refrigerators be maintained between 36°F and 38°F. All refrigeration units must have numerically scaled indicating thermometers accurate to ±3°F. Sufficient refrigeration and freezers shall be provided to support the intended menu. Consideration must be taken with the placement and installation of refrigeration units to allow for adequate ventilation. Air circulation within refrigeration and freezer units should not be obstructed and should allow for an even and consistent flow of cold air throughout the units

Refrigeration and freezer storage involves five major areas:

1. Storage for short-term holding of perishable and TCS FOOD.
2. Long-term storage.
3. Storage space for quick chilling of FOODs.
4. Space for assembling and processing of TCS FOOD.
5. Display storage for customer service.

If TCS foods are prepared a day or more in advance of service, a rapid cooling procedure capable of cooling TCS foods from 135°F to 41°F within 6 hours (135°F to 70°F within 2 hrs.) must be provided. The capacity of the rapid cooling facilities must be sufficient to accommodate the volume of food required to be cooled to 41°F within 6 hours. The location of the rapid cooling facilities (e.g., sinks for ice baths, freezer storage for ice wands, blast chillers) must be identified. Refrigerators and freezers at work stations for operations requiring preparation and handling of TCS foods should be considered. For example, it may be necessary to locate a freezer near the fryer where frozen products will be deep-fried. Refrigeration units, unless designed for such use, should not be located directly adjacent to cooking EQUIPMENT or other high heat producing EQUIPMENT which may adversely impact the cooling system's operation.

A. Refrigeration Storage Calculations

Calculating the amount of refrigeration and freezer space should be based on the menu and expected FOOD volume. The amount and location of refrigeration and freezer EQUIPMENT should complement the FOOD flow of the operation from receiving, storage and FOOD processing, to the point of service.

To plan refrigeration storage, the following items should be considered: menu, type of FOOD

operation, number of meals per day, number of deliveries per week, and adequate ventilation in the areas where the refrigeration systems will be located. When assessing the refrigeration needs, shelving space within the refrigeration and freezer units should be designed to prevent the cross-contamination of FOODs. Separating raw meats and poultry from ready-to-eat FOODs such as produce and prepared FOOD items. Thermometers must be conspicuously located in all units. Thermometer sensing elements should be located near the door

Formulas can be used to estimate refrigerated storage space. To calculate, you will need information on number of meals estimated to be served per day, days between deliveries and storage area availability. Links to example calculators can be found in Appendix C.

B. Walk-in Cooler/Freezer Units

Walk-in units should meet an ANSI accredited certification or equivalent, or deemed acceptable by the Regulatory Authority. A walk-in beverage or beer cooler is not recommended for FOOD storage. APPROVED flooring and integral cove bases need to be provided. Quarry tile, ceramic, and galvanized flooring are not recommended flooring materials for walk-in units. All gaps, cracks, penetrations, seams, and plug holes shall be SEALED SMOOTH and flush with the surface material.

Walk-in units should be installed when there is a need for long-term storage of perishable and TCS FOOD or when cooling space is needed for prepared and cooked FOODs. These coolers should be located near delivery or receiving areas. EASILY CLEANABLE curtain strips are recommended at walk-in doors. This not only helps in maintaining the temperature of the walk-in but also leads to an energy cost savings.

Exterior walk-in unit locations shall be properly designed for exterior installation and consideration given varied environmental concerns. Walk-in units should be designed with a roof, APPROVED overhead waterproof protection, and walkways shall be provided for the transportation of FOOD items. Walk-in units shall be APPROVED by the local building official and are evaluated and APPROVED on a case-by-case basis by the REGULATORY AUTHORITY.

If the walk-in floors will be water-flushed for cleaning or receive the discharge of liquid waste or excessive melt water, the floors should be sloped to drain. If the structure of the walk-in is integral with the building, properly installed floor drains may be installed inside the unit.

Each walk-in unit shall be equipped with lighting that provides 10 foot candles of light throughout the unit when it is full of product. Lights must be properly shielded or shatter resistant.

Condensate lines from walk-in units shall drain to APPROVED floor drains or alternative method APPROVED by the REGULATORY AUTHORITY. Without prior approval floor sinks or floor drain sinks shall not be installed in walk-in units. All walk-in units shall be properly

flashed off and SEALED to the ceiling and side walls. Walk-in units are not to be confused with refrigerated FOOD processing rooms. Refer to Item G-Refrigerated Processing Rooms.

C. Reach-in Refrigerators

These units are for short-term storage of perishable and TCS FOODs. These units should be considered to meet the daily storage demands of the kitchen operation. They are to be conveniently located at points of FOOD preparation and FOOD assembly. These units are not to be considered for the quick chilling of cooked and prepared FOODs.

D. Reach-in Freezers

Freezers are for long-term storage. They are not designed to be used as quick-chill units. These units should be located near delivery and DRY STORAGE AREAs.

E. Blast Chillers/Rapid Chill Units

These units are recommended for use when handling large volumes of FOOD that require quick chilling. A blast chiller is an efficient cooling mechanism for any amount of FOOD to be chilled, and where refrigeration cooling space is limited.

F. Refrigerated Worktables

These units are suggested when the menu includes assembling TCS FOODs. These units provide easy access of FOODs from the top of the unit. These units are not designed for long-term storage of FOOD or cooling.

G. Refrigerated Processing Rooms

These areas (e.g. meat cutting rooms) should be considered when there is extensive handling of cold TCS FOOD. APPROVED hand sinks should be located in these areas.

H. Display Storage Refrigerators

These units are designed to display TCS FOOD under refrigeration. Examples of these units are deli display, fresh fish, and meat and poultry cases.

I. Customer Service Display Units/ Cold Buffet Units

These units are designed for holding FOOD under refrigeration for customer access. They are designed for short-term display and are not designed for the cooling of FOOD. Beverage display coolers are not APPROVED for storing open TCS FOODs.

Cold buffets and salad bars are designed for short-term display. They should be mechanically refrigerated, and have APPROVED sneeze guards with side panel protection.

J. Ice Machines

If ice is to be used as a cooling medium for FOOD and beverage items the unit should be adequately designed and sized to meet all operational needs in an APPROVED location. Ice machines designed for outdoor dispensing will need National Automatic Merchandising Association (NAMA) certification

K. General Cooking and Hot Holding

Cooking and hot holding units are designed to heat FOOD to a required temperature within a required amount of time for FOOD safety. Cooking and reheating temperatures have been determined using scientific analysis. The time and temperature requirements are based on the pathogens that are likely to be present on the product. It is recommended that the units are commercial grade and meet NSF/ANSI standards. Consideration must be taken with the placement and installation of cooking/reheating/hot holding EQUIPMENT to ensure that proper ventilation and sanitation can occur. Construction of these units should be durable and EASILY CLEANABLE

NOTE: The commercial appliances described in this section are placed under a vent hood to evacuate grease, steam, and fumes, which could pose a potential fire or health risk. Refer to the topic on Ventilation of this Manual or your REGULATORY AUTHORITY for specific requirements.

Units used to heat FOOD are divided into two categories:

1. Cooking/Reheating
2. Hot Holding

All units in use must be able to meet the minimum required heated temperatures outlined in the FDA Food Code, Chapter 3-4 Destruction of Organisms of Public Health Concern. http://www.fda.gov/FOOD/GuidanceRegulation/RetailFOODProtection/FOODCode/default.htm

L. Stovetops and Grills

Gas, electric, or wood-burning stoves are used to cook and reheat product in pots or pans. A grill is similar to a stove with the ability to place the FOOD directly over the flame.

M. Ovens

Ovens are thermally insulated chambers used for cooking or reheating FOODs. They can be gas, electric, or wood-burning units.

N. Combination Oven/Steamer (Combi Oven)

A Combi oven/steamer is similar to a convection oven with the ability to produce dry heat, moist heat, or a combination of the two.

O. Rice Cooker/Warmer

The unit is an electric appliance that is capable of cooking rice and then hot holding the rice at 135°F or above. Scoops or ladles for serving may be stored in a running dipper well.

P. Kettle

Kettles are cooking pots used to boil large quantities of FOOD products. The units are generally clean-in-place and should have the necessary tools for sanitation. Adequate floor drains must be present for disposal of spent water.

Q. Rotisserie

Rotisseries are self-contained units that include a heat source and racks for skewers or spits. Beef, pork, or poultry is rotated over the fire to cook the FOOD to the required temperature.

R. Small Appliances

Small appliances (table top) include microwaves, Panini press, broilers, and toasters. These units are used to heat FOOD to the required cook or reheat temperature depending on the application.

S. Fryers

Fryers are cooking devices that use oil heated to a high temperature. The hot oil has a flash point that can result in a fire. Follow the manufacturer's instructions for operation, maintenance and cleaning to prevent a fire incident.

T. Hot Tables

Hot tables are gas or electrically heated units that are design to maintain temperature. They should never be used to cook or reheat TCS FOODs. The design should allow for disassembly and deep cleaning of interior surfaces. These units must be able to maintain a minimum temperature of 135°F.

U. Customer Service Display Units/Hot Buffet Units

These are gas or electrically heated units that are designed to maintain temperature. They should never be used to cook or reheat TCS FOODs. They should be constructed of durable and EASILY CLEANABLE materials. The design should allow for disassembly and deep cleaning of interior surfaces. The design should protect FOOD from contamination that could occur from the environment or customers by using sneeze shields or covers. The units must be able to maintain a minimum temperature of 135°F

EQUIPMENT AND INSTALLATION

All EQUIPMENT in a FOOD ESTABLISHMENT must comply with the design and construction standards contained in Chapter 4 of the FDA Food Code. FOOD EQUIPMENT that is certified or classified for sanitation by an ANSI accredited program is deemed to comply with Parts 4-1 and 4-2 of the FDA Food Code.

EQUIPMENT including ice makers and ice storage EQUIPMENT, shall not be located under exposed or unprotected sewer lines, open stairwells or other sources of contamination.

The following EQUIPMENT installation recommendations will help ensure proper spacing and sealing allowing for adequate and easy cleaning.

A. Floor-Mounted Equipment

EQUIPMENT should be mounted on APPROVED lockable casters, gliders or wheels to facilitate easy moving, cleaning, and flexibility of operation whenever possible. Moveable EQUIPMENT requiring utility services such as gas or electrical connections should be provided with easily accessible quick-disconnects or the utility service lines should be flexible and of sufficient length to permit moving the EQUIPMENT for cleaning. If a flexible utility line is used, a safety chain that is shorter than the utility line must be installed. Check with local fire safety and building codes to ensure that such installations are acceptable.

Floor-mounted EQUIPMENT that is not mounted on wheels or casters with the above utility connections should be:

1. Permanently SEALED to the floor around the entire perimeter of the EQUIPMENT. The sealing compound should be pliable and non-shrinking. It should retain its elasticity and provide a water- and vermin-tight joint; or
2. Installed on a solid, SMOOTH, non-absorbent masonry base. Masonry bases and curbs should have a minimum height of 2" and be coved at the junction of the platform and the floor with at least a 1/4" radius. The EQUIPMENT should overhang the base by at least 1" but not more than 4". Spaces between the masonry base and the EQUIPMENT must be SEALED as above; or
3. Elevated on legs to provide at least a 6" clearance between the floor and EQUIPMENT. The legs shall contain no hollow open ends.
4. For EQUIPMENT not readily moveable by one person, spacing between and behind EQUIPMENT must be sufficient to permit cleaning under and around the unit. EQUIPMENT shall be spaced to allow access for cleaning along the sides, behind and above. At least 6" of clear, unobstructed space under each piece of EQUIPMENT must be provided or EQUIPMENT must be SEALED to the floor.
5. If EQUIPMENT is against a wall and is not movable, the EQUIPMENT must be joined to and/or SEALED to the wall in a manner to prevent liquid waste, dust and debris from collecting between the wall and the EQUIPMENT.
6. When EQUIPMENT is joined together, or spreader plates are used between

EQUIPMENT, the resultant joint must be SEALED to prevent liquid waste, dust and debris from collecting between the EQUIPMENT.

Unobstructed and functional aisle and working spaces must be provided. A minimum width of 36" is required by fire and building codes.

All utility and service lines and openings through the floor and walls must be adequately SEALED. Penetrations through walls and floors must be minimized. Exposed vertical and horizontal pipes and lines must be kept to a minimum. The installation of exposed horizontal utility lines and pipes on the floor is prohibited. Any insulation materials used on utility pipes or lines in the FOOD preparation or dishwashing areas must be SMOOTH, non-absorbent, and easy to clean. Electrical units which are installed in areas subject to splash from necessary cleaning operations or FOOD preparation should be water-tight and washable.

B. Counter-Mounted Equipment

COUNTER-MOUNTED EQUIPMENT is defined as EQUIPMENT that is not portable and is designed to be mounted off the floor on a table, counter, or shelf. All COUNTER-MOUNTED EQUIPMENT shall be:

- SEALED to the table or counter; or
- Elevated on APPROVED legs to provide at least a 4" clearance between the table or counter and the EQUIPMENT to facilitate cleaning.

C. Other

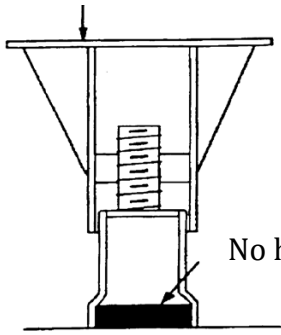
EQUIPMENT that is open underneath, such as drain boards, dish tables, and other tables that are not moveable should be spaced to allow for ease of cleaning or should be SEALED to the wall.

Non-FOOD contact surfaces of EQUIPMENT that are exposed to splash, spillage, or other FOOD soiling or that require frequent cleaning shall be constructed of corrosion-resistant, non-absorbent, and SMOOTH material.

Legs of all EQUIPMENT should not have hollow, open ends.

If running water dipper wells are installed, methods for filling and draining the units must be identified.

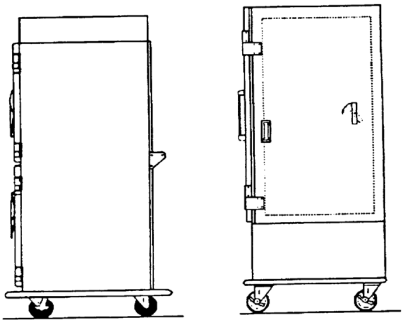
Equipment sealed to floor



No hollow open ends

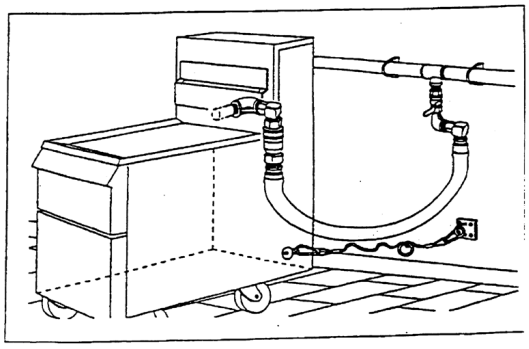
Elevate equipment for effective cleaning.

Sanitary Leg Example



Mobile Kitchen equipment mounted on Castor

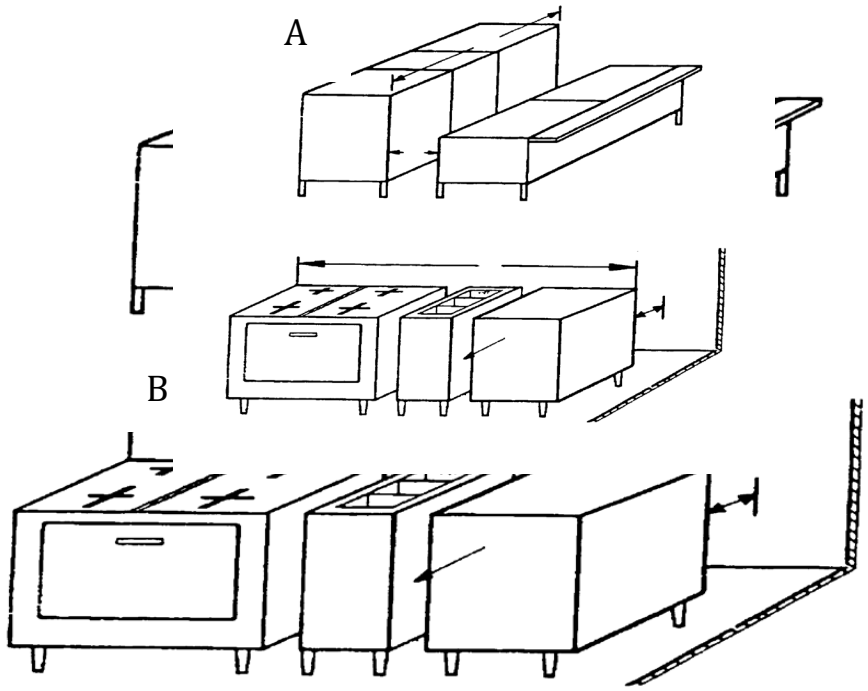
Holding Cabinet & a Reach-in Refrigerator



Refer to your Local Regulatory Authority for Gas Code Requirements

Flexible Gas Connection with Safety Chain

Equipment Spacing



Recommended EQUIPMENT spacing; provided access is available from both ends:

EQUIPMENT Length (A)	Space From Walls and Adjacent EQUIPMENT (B)
4' or less	6"
4' - 8'	12"
8' or more	18

WAREWASHING FACILITIES

The minimum requirement for WAREWASHING in a FOOD ESTABLISHMENT is a three-compartment sink. A mechanical WAREWASHING machine may be installed in addition to the three-compartment sink.

A. Manual Ware washing

For manual WAREWASHING, a stainless steel sink with no fewer than three compartments must be provided, with the exception that a two-compartment sink may be allowed by the REGULATORY AUTHORITY under certain conditions.

- The sink compartments shall be large enough to completely immerse the largest pot, pan or piece of EQUIPMENT to be used in the establishment that will not be cleaned in-place.
- Each compartment shall be supplied with adequate hot and cold potable running water, temperature of the wash solution shall be maintained at not less than 110°F, or the temperature specified on the cleaning agent manufacturer's label instructions.
- Drain boards, UTENSIL racks or tables large enough to accommodate clean and soiled UTENSILs shall be provided. The drain boards shall be self-draining.
- Adequate facilities for pre-flushing or pre-scrapping EQUIPMENT and UTENSILs must be provided.
- If hot water is used to sanitize EQUIPMENT and UTENSILs, the means for heating the water to 171°F in the 3rd compartment must be identified. The racks for the immersion of EQUIPMENT and UTENSIL must be specified.

B. Mechanical Ware washing

WAREWASHING machines shall be installed in accordance with the manufacturer's recommendations and applicable code requirements. If used, the hot water booster for WAREWASHING machines must be identified during plan review.

Adequate facilities shall be provided to air dry washed EQUIPMENT and UTENSILs. Drain boards, UTENSIL racks or tables must be large enough to allow proper and sufficient air drying of EQUIPMENT and UTENSILs.

Storage facilities shall be provided to store cleaned and sanitized UTENSILs and EQUIPMENT at least 6" above the floor; protected from splash, dust, overhead plumbing or other contamination. The plan must specify the location and facilities used for storing all UTENSILs and EQUIPMENT.

PLUMBING

A. Water Supply

The primary concerns relative to the water supply in a FOOD ESTABLISHMENT are:
1. Ensure the facility is supplied with a safe and adequate water supply, including adequate supply of hot water; and
2. Verify that the water can remain safe while it is in the facility.

Safe Source: Start at the water source. Determine if the water is potable or non-potable. The availability of an APPROVED public water supply must be verified. Any use of a non-public water source (well water) shall comply with local, state, and/or federal laws, and construction and testing standards.

Sufficient potable water: Potable water shall be provided from a source constructed and

operated according to law that meets the peak water demands of the FOOD ESTABLISHMENT.

B. Hot Water Supply:

The hot water supply shall be sufficient to satisfy peak hot water demands of the FOOD ESTABLISHMENT. Hot water for hand washing and most FOOD ESTABLISHMENT uses shall be at least 100°F. Hot water for mechanical WAREWASHING must be boosted up to 150°F-165°F for washing and 165°F-180°F for sanitizing or according to the manufacturer's data plate on the machine. The temperature of the wash solution for spray-type ware washers that use chemicals to sanitize may not be less than 120°F.
The temperature of the wash solution for manual WAREWASHING must be maintained to not be less than 110°F. The water temperature for manual hot water sanitization must be at least 171°F.

Tank less water heaters shall be installed and used in accordance with the manufacturer's recommendations.

For guidance on calculating Hot Water Requirements see Appendix C – Model Calculations

C. Sewage Disposal, Grease Interceptors/Traps

All SEWAGE including liquid waste shall be disposed into a public SEWAGE system or an individual SEWAGE disposal system constructed and operated according to law. Where individual SEWAGE disposal systems are utilized, the location shall be noted on the plans and certification of compliance with state and local regulations shall be provided.

A grease trap/interceptor is a chamber designed for wastewater to pass through and allow any grease to float to the top for retention as the remainder of the wastewater passes through. If used, a grease trap shall be located to be easily accessible for cleaning; FOOD solids entering the grease trap/interceptor should be minimized.

It is recommended that waste water from fixtures or drains which would allow fats, oils, and grease to be discharged be directed to a grease trap/interceptor. Local municipalities/jurisdictions will determine the number and size of grease traps, grease interceptors or catch basins. If installed, grease traps shall be properly spaced so they are easily accessible for servicing and cleaning. Refer to the local municipality/jurisdiction for the installation requirements.

D. Backflow Protection

Plumbing shall be sized and installed according to applicable codes. There shall be no cross connections between the potable water supply and any non-potable system or a system of unknown quality. Where non-potable water systems are permitted for purposes such as air conditioning and fire protection, the non-potable water must not contact directly or

indirectly: FOOD, potable water or EQUIPMENT that contacts FOOD or UTENSILs. The piping of any non-potable water system shall be durably identified so that it is readily distinguishable from piping that carries potable water.

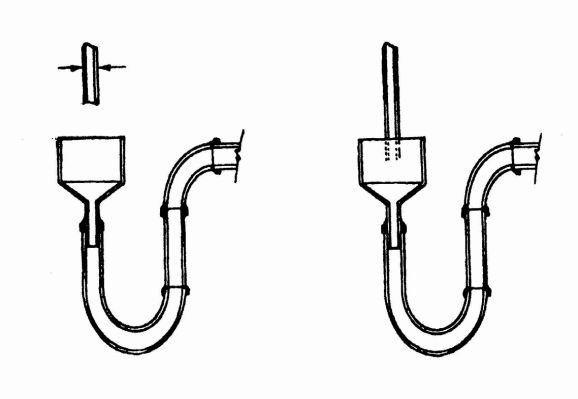
A connection to a sewer line may be direct or indirect. A direct connection may not exist between the sewerage system and any drains originating from EQUIPMENT in which FOOD, portable EQUIPMENT, or UTENSILs are placed, except if otherwise required by law. When a WAREWASHING machine is located within 5 feet of a trapped floor drain, the dishwasher waste outlet may be connected directly on the inlet side of a properly vented floor drain trap.

An **indirect connection** may be one of two types, air gap or air break:

1. For a potable water supply, an **air gap** means the unobstructed, vertical air space that separates a potable system from a non-potable system.

2. An **air break** is a waste line from a fixture that discharges used water or liquid waste to a drain where the waist line terminates below flood level.

AIR GAP AIR BREAK



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HYGIENE FACILITIES

A. Handwashing

Handwashing is a critical factor to prevent contamination of FOODs. Proper handwashing reduces the amount of pathogens that can be transmitted via cross contamination from raw

FOODs to READY-TO-EAT-FOODS. It is imperative to have adequate numbers and conveniently placed HANDWASHING SINKS to ensure employees are washing hands. It is important that handwashing be done only at properly equipped HANDWASHING SINKS to help ensure that employees effectively clean their hands and minimize contamination of FOOD and FOOD-CONTACT SURFACES.

A HANDWASHING SINK, hand drying device or disposable towels, hand cleanser and waste receptacle shall be located for convenient use by employees who work in FOOD preparation, FOOD dispensing, and WAREWASHING areas.

Nothing must block the approach to a HANDWASHING SINK.

HANDWASHING SINKS must also be located in or immediately adjacent to toilet rooms.

HANDWASHING SINKS shall be of sufficient number and conveniently located for use by all employees in FOOD preparation, FOOD dispensing, and WAREWASHING areas.

HANDWASHING SINKS shall be easily accessible and may not be used for purposes other than handwashing. Sinks used for FOOD preparation, washing EQUIPMENT or UTENSILs, or service (mop) sinks shall not be used for handwashing.

Each handwashing sink shall be provided with hot and cold water tempered by means of a mixing valve or a combination faucet to provide water at a temperature of at least 100˚F. If used, self-closing, slow-closing or metering faucets shall be designed to provide a flow of water for at least 15 seconds without the need to reactivate the faucet.

Splash from use of a handwashing sink may not contaminate FOOD, FOOD-CONTACT SURFACES, clean EQUIPMENT or UTENSILs. A washable baffle or barrier may be needed if the handwashing sink is located next to a FOOD preparation area, UTENSIL or EQUIPMENT storage, or FOOD-CONTACT SURFACE and if the space between the handwashing sink and FOOD, FOOD preparation, FOOD-CONTACT SURFACES, and clean UTENSILs and EQUIPMENT does not provide adequate protection.

Similarly, the location of soap and paper towel dispensers at HANDWASHING SINKS must be reviewed during plan review so that their use does not contaminate FOOD, FOOD-CONTACT SURFACES, UTENSILs and EQUIPMENT. In addition, the distance that employees would have to reach the faucet handles, soap and paper towels must be reviewed during plan review to assure that they will have proper access to the HANDWASHING SINKS and will not have to reach across dirty surfaces while washing their hands.

B. Toilet Rooms

Properly functioning toilet facilities must be accessible to employees at all times.

If required by federal, state, local or tribal laws and regulations, toilet facilities must be made available to the customers. If the public toilet facilities are used by employees,

separate toilet facilities may not have to be installed for the employees. Toilet facilities must be made accessible in accordance with the Americans with Disabilities Act (ADA) of 1990.

The floors, walls, and ceiling in toilet rooms shall be SMOOTH and EASILY CLEANABLE. The walls around toilets, urinals, toilet paper dispensers, soap dispensers, and paper towel dispensers should be water resistant and durable for frequent cleaning.

The minimum requirements for toilet facilities shall include:

- **Toilet:** At least one toilet and not fewer than the number of toilets required by law shall be provided. If authorized by law, urinals may be substituted for additional toilets in men's toilet rooms.
- **HANDWASHING SINK:** Each HANDWASHING SINK shall be provided with hot and cold water tempered by means of a mixing valve or a combination faucet to provide water at a temperature of at least 100˚F. If used, self-closing, slow-closing or metering faucets shall be designed to provide a flow of water for at least 15 seconds without the need to reactivate the faucet.
- **Handwashing cleanser:** Each HANDWASHING SINK or group of two adjacent HANDWASHING SINKS shall be provided with hand cleaning liquid, powder, foam or bar soap. A dispenser shall be provided for handwashing cleanser provided in liquid or powder form.
- **Hand drying facility:** Each HANDWASHING SINK or group of adjacent HANDWASHING SINKS shall be provided with individual, disposable towels; a continuous towel system that supplies the user with a clean towel; heated-air hand drying device; or hand drying device with air-knife, high velocity air at ambient temperatures.
- **Toilet paper:** A supply of toilet paper shall be provided in a dispenser at each toilet.
- **Waste receptacle:** If disposable towels are used, a waste receptacle shall be located at each sink or group of sinks. At least one covered waste receptacle shall be provided in toilet rooms used by females.
- **Ventilation:** Toilet rooms must be vented to the outside. Mechanical Ventilation shall be installed in toilet rooms according to law. If allowed by law, operable screened windows may be used in lieu of mechanical ventilation devices.
- **Toilet room doors:** Toilet room doors shall be tight-fitting and self-closing.
- **Lighting:** At least 215 lux (20 foot candles) shall be provided in toilet rooms.

STORAGE

A. Dry Storage-

The dry storage space needed depends on the menu, number of meals served between deliveries, frequency of deliveries, and the amount and type of SINGLE-SERVICE ARTICLES to be stored. The location of dry storage should be adjacent to the FOOD preparation area and convenient to receiving. Adequate ventilation should be provided. FOOD should not be

stored under exposed sewer lines. Similarly, a cabinet that is used for the storage of FOOD, shall not be located under exposed or unprotected sewer lines, open stairwells or other sources of contamination. Stationary shelving needs to have a minimum 6" floor clearance.

Shelving, dollies, racks, pallets and skids shall be corrosion-resistant, non- absorbent and SMOOTH. Pallets, racks and skids used for bulk cased or overwrapped items shall be designed to be moved by hand or by conveniently located hand trucks or forklifts. Shelving, dollies, racks, pallets and skids should be spaced away from walls to allow for cleaning and pest monitoring/inspection.

APPROVED FOOD containers with tight-fitting covers and dollies should be used for storing bulk FOODs such as flour, cornmeal, sugar, dried beans, rice and similar.

B. Dry Storage Calculations

Formulas can be used to estimate the amount of dry storage space that may be needed. To determine, you will need information on number of meals estimated to be served per day, days between deliveries and storage area availability. Links to example calculators can be found in Appendix C.

C. Poisonous or Toxic Materials Storage

Designate an area for POISONOUS OR TOXIC MATERIAL storage that is away from FOOD and clean UTENSILs. These include detergents, sanitizers, related cleaning or drying agents and caustics, acids, polishes and other chemicals. Install cabinets, cages, or physically separate shelves for storing chemicals.

D. Clean Equipment, Utensil and Linen Storage

Designate areas for clean cooking UTENSILs, cutting boards, glassware and dishware. Store them at least 6-inches off the floor in a clean, dry location where they will be protected from dust and splash.

LIGHTING

A. Intensity

The light intensity shall be at least 108 lux (10 foot candles) at a distance of 75 cm (30 inches) above the floor, in walk-in refrigeration units and dry FOOD storage areas and rooms during periods of cleaning.

The light intensity shall be at least 215 lux (20 foot candles) at a surface FOOD is provided for consumer self-service such as buffets and salad bars or where fresh product or packaged FOODS are sold or offered for consumption; inside EQUIPMENT such as reach-in

and under-counter refrigerators; at a distance of 75 cm (30 inches) above the floor in areas used for handwashing, WAREWASHING, and UTENSIL storage, and in toilet rooms.

The light intensity shall be at least 540 lux (50 foot candles) at a surface where a FOOD EMPLOYEE is working with FOOD or working with UTENSILs or EQUIPMENT such as knives, slicers, grinders, or saws where employee safety is a factor.

B. Protective Light Shielding

Shielding such as plastic shields, plastic sleeves with end caps, shatterproof bulbs and/or other APPROVED devices shall be provided for all artificial lighting fixtures located in areas where there is exposed FOOD; clean EQUIPMENT, UTENSILs, and LINENS; or unwrapped single-service and single-use articles.

Heat lamps shall be protected against breakage by a shield surrounding and extending beyond the bulb, leaving only the face of the bulb exposed.

FINISHES

A. Floors

Example floor materials are as follows:

- Quarry tile, ceramic tile
- SEALED curbed concrete
- Seamless poured epoxy minimum 3/16-inch thick.
- Commercial-grade sheet vinyl **(no felt backing)**
- Commercial-grade vinyl composition tile (VCT)

Pre-approval from the REGULATORY AUTHORITY should be obtained prior to use of carpet and/or wood.

B. Walls

Example wall materials are as follows:

- Stainless steel
- Ceramic tile
- Aluminum
- Fiber-glassed reinforced panels (FRP)
- SEALED Concrete blocks or bricks
- Epoxy or glazed drywall

C. Ceilings

Example ceiling materials may include wall finish material listed above along with the following:

- EASILY CLEANABLE, non-absorbent ceiling tiles
- Painted drywall

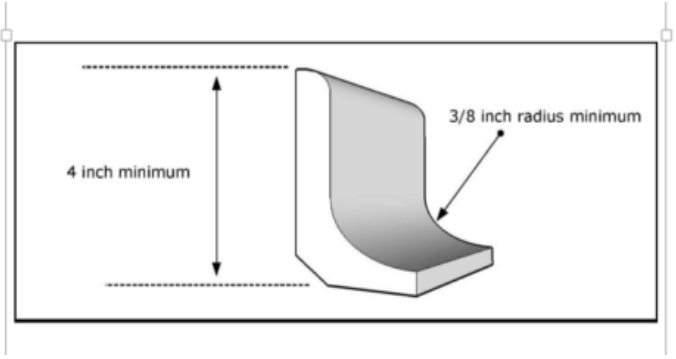
D. Coving

Coving is the floor material found at the base of walls (wall/floor junctures) and is required in most areas of the FOOD ESTABLISHMENT, such as:
FOOD preparation, storage, handling, and packaging areas

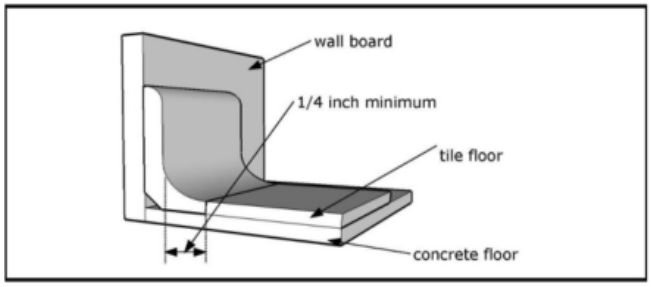
- UTENSIL washing and storage areas
- Interior waste disposal areas (garbage, REFUSE, grease)
- Restrooms
- Hand washing areas
- Janitorial facilities
- Walk-in refrigerator and freezer units (inside and outside)
- Bars (employee side)
- Customer self-serve areas where non-individually prepackaged FOODs or beverages are sold or dispensed (e.g., salad bars, buffets, bulk FOOD sales, beverage stations)
- Employee change and storage areas
- Wait stations

Coved flooring material should extend integrally up the walls. Integral coving is not required in areas used exclusively for dining, point-of-sale, or the storage of UTENSILs or FOODs contained in the original **un-opened** container

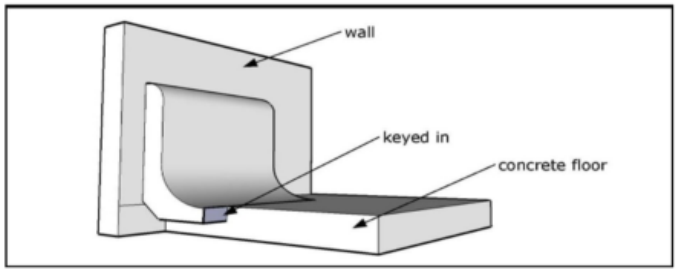
Floor Installation Diagrams



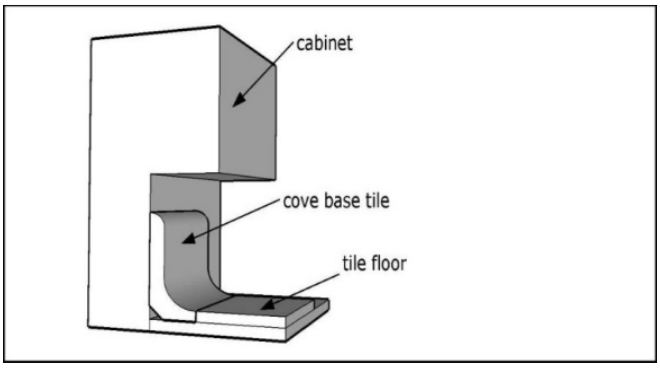
Example of quarry tile cove base.



Example of quarry tile cove base flush with floor.



Example of quarry tile cove base integral to concrete floor.



Example cove base; cabinet toe-kick

PEST CONTROL

All openings to the outside shall be effectively protected against the entrance of insects and rodents. All roller doors, sliding or bi-fold doors, or similar movable wall systems that are not self- closing and create a continuous opening to the exterior must have an effective means of pest control.

Some examples of effective barriers include:

- Solid, tight fitting, self-closing doors.
- Fixed or self-closing screens of #16 mesh or finer.
- Effective air curtains.

Example Air Curtain

This may not apply if a FOOD ESTABLISHMENT opens into a larger completely enclosed structure such as a coliseum, arena, warehouse, shopping mall, superstores, airport, or office building, where the outer openings from the larger structure are protected against the entry of insects and rodents.

A. Building

All masonry or cement foundations must be rodent proof. Seal all openings into the foundation and exterior walls, including openings & penetrations around wall and ceiling penetrations.

Cover all building vents with a minimum #16 mesh screen. Effectively seal all air ducts, skylight, transoms, and other openings to the outside.

B. Windows

Windows that open to the outside must be properly protected with minimum #16 mesh screen, with the exception of service windows.

Drive-thru and walk-up service windows must have effective means to prevent pest entry, to include minimum #16 mesh screens, properly designed and installed air curtains, or other effective means such as self-closing devices (spring-loaded, bump pad, electronic opener, or gravity operated).

C. Delivery, Customer, and Toilet Room Doors

Exterior doors: All outside doors shall be self-closing and tight fitting. Install a door sweep and weather stripping to prevent the entrance of insects and rodents. *Note: Daylight shall not be visible around the perimeter of the door.*

Garage Doors, Roller Doors, and Loading Docks: Garage and roller type delivery doors must be protected against pests. Loading docks shall have properly installed tight fitting dock seals at all loading bays. If the location of one of these doors exposes the kitchen or other FOOD service, air curtains will be required.

Toilet Room (Restroom) doors: All toilet rooms located in or adjacent to a FOOD ESTABLISHMENT shall be provided with tight fitting, self-closing doors. This requirement does not apply to a toilet room that is located outside a FOOD ESTABLISHMENT and does not open directly into the FOOD ESTABLISHMENT such as a toilet room that is provided by the management of a shopping mall.

D. Insect Control Devices, Design and Installation

Insect control devices that are used to electrocute or stun flying insects shall be designed to retain the insect within the device. These devices must not be located above FOOD preparation areas and installed to prevent the contamination of exposed FOOD, clean EQUIPMENT, UTENSILs, and LINENS, from insect fragments

MECHANICAL VENTILATION

A. Mechanical Ventilation Requirements

Commercial cooking or display EQUIPMENT, which produces smoke, steam, grease, mists, particulate matter, condensation, vapors, fumes, odors, or create sanitation or indoor air quality problems, will require a hood.

Hoods shall be designed and installed to prevent grease and condensation from collecting on walls, ceilings, and dripping into FOOD or onto FOOD contact surfaces. All hoods should comply with the current International Mechanical Code (IMC) and/or all local building and fire safety codes.

Balancing of the exhaust and make-up air must be ensured so that the system can be operated efficiently.

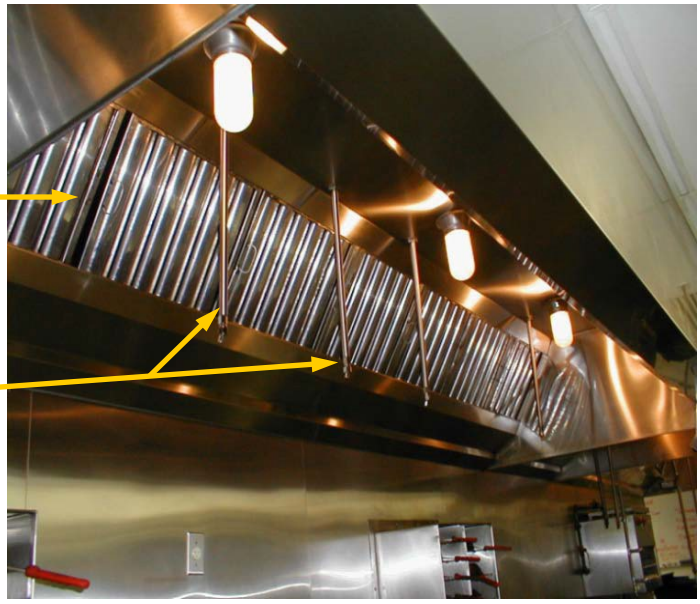
B. Mechanical Ventilation Hood Systems

Type I hoods are required over EQUIPMENT that produce grease, smoke, excessive steam, heat, condensation, particulate matter, odors, or create indoor sanitation or indoor quality problems. Examples of equipment requiring installation under a hood include: Kettles, pasta cookers, hot plates, salamanders, Mongolian-style grills, gas cooking EQUIPMENT, tableside cooking EQUIPMENT, such as Teppanyaki-style cooking, Tandoori ovens, rotisserie units, Panini grills, etc.

Type I Hood over Cook Line

Grease filters

Fire suppression system



The National Fire Protection Association provides a resource for FOOD ESTABLISHMENTS to reduce the potential fire hazard of commercial cooking operations. Refer to the NFPA link below or your local/State Fire Protection regulations.

http://www.nfpa.org/codes-and-standards/document-information-pages?mode=code&code=96

Type II hoods shall be installed over EQUIPMENT that produce steam, heat, mists, condensation, fumes, vapors, and non-grease laden FOODs.

Type II Hood over WAREWASHING Machine

Vapor hood

Vent less Hood Systems or ventilation systems integral to the cooking EQUIPMENT need to be reviewed and APPROVED by the local mechanical code, and other applicable fire safety codes.

Appendix A - MODEL PLAN REVIEW APPLICATION FOR FOOD ESTABLISHMENTS

TYPE OF APPLICATION: ☐ New ☐ Remodel ☐ Conversion	**Projected Start Date:**_____ **Projected Completion Date:** _____
TYPE OF FOOD OPERATION: ☐ Restaurant ☐ Institution ☐ Daycare ☐ Retail food store ☐ Other:_____	

FOOD ESTABLISHMENT INFORMATION

Name of Establishment:			
Establishment Address:	**City:**	**State:**	**ZIP:**

OWNERSHIP INFORMATION

Name of Owner:			
Address:	**City:**	**State:**	**ZIP:**
Email:	**Phone Number:**		

APPLICANT INFORMATION (e.g., ARCHITECT/ENGINEER)

Applicant Name:	**Contact Person:**		
Applicant Mailing Address:	**City:**	**State:**	**ZIP:**
Email:	**Phone Number:**		

FOOD OPERATION INFORMATION

Hours/Days of Operation	**Restaurant Seating Capacity**	**Type of Service (check all that apply)**	**Employees**
☐ **Sun:**_____ ☐ **Mon:**_____ ☐ **Tues:**_____ ☐ **Wed:**_____ ☐ **Thurs:**_____ ☐ **Fri:**_____ ☐ **Sat:**_____	# of Indoor Seats: _____ # of Outdoor Seats:_____ Square Feet of Facility: _____	☐ On-site consumption ☐ Off-site consumption ☐ Catering ☐ Single-use utensils ☐ Multi-use utensils ☐ Other:_____	Max per shift:_____ **Maximum meals to be served** ☐ Breakfast _____ ☐ Lunch _____ ☐ Dinner _____

The following documents must be submitted along with this application:

☐ Proposed menu or complete list of food and beverages to be offered (including seasonal, catering and banquet menus) – ***Standard Operating Procedures or HACCP plans may be required.***

☐ Plans must be clearly drawn to scale (minimum 11 x 14 inches in size) and include these items below:

- The floor plan must identify: food preparation, serving and seating areas, restrooms, office, employee change room, storage, warewashing, janitorial and trash area. Include location of any outside equipment or facilities (dumpsters, well, septic system-if applicable).
- Provide equipment layout and specifications, clearly numbered and cross-keyed with the equipment list. *Elevation drawings may be requested by the Regulatory Authority.*
- Identify handwashing, warewashing and food preparation sinks.
- Provide plumbing layout showing the sewer lines, cleanouts, floor drains, floor sinks, vents, grease trap or grease interceptor, hot and cold water lines, and direction of flow to sanitary sewer.
- Provide exhaust ventilation layout including location of hood and make-up air returns and ducts, if applicable.
- Lighting plan, indicating the exact foot candles for each area as required by the FDA Food Code (§6-303.11).
- Finish schedule showing floor, coved base, wall and ceilings for each area shown on the plans.

Note: A color coded flow chart may be requested by the Regulatory Authority demonstrating flow patterns for: food (receiving, storage, preparation, service); dishes (clean, soiled, cleaning, storage); trash (service area, holding, storage, disposal).

Signature:	**Date:**
Print Name:	**Title:**

Appendix B – REGULATORY COMPLIANCE REVIEW LIST
FOOD PREPARATION PROCEDURES

FOOD DELIVERY

1. How often will frozen foods be delivered? □ Daily □ Weekly □ Other: _____
2. How often will refrigerated foods be delivered? □ Daily □ Weekly □ Other: _____
3. How often will dry foods or supplies be delivered? □ Daily □ Weekly □ Other: _____

FOOD STORAGE* - Identify amount of space (in cubic feet) allocated for:

Dry Storage _____; Refrigerated Storage (41°F) _____; Frozen Storage _____; Utensil Storage _____

* Identify on plans where storage will be located.

INSTRUCTIONS: Describe the following with as much detail as possible. Indicate Not Applicable (NA) as appropriate.

PROCESS	IDENTIFY FOOD ITEMS	INDICATE LOCATION AND EQUIPMENT	MEETS CRITERIA (RA to circle and Initial)
Washing FDA Food Code §3-302.15			YES/NO
Thawing FDA Food Code §3-501.13			YES/NO
Cooking FDA Food Code §3-401			YES/NO
Hot Holding Hot food maintained at 135°F			YES/NO
Cooling Time/Temperature Control for Safety food will be cooled to 41°F within 6 hours; 135°F to			YES/NO
Reheating Food must be reheated to a temperature of 165° for 15 seconds within 2 hours			YES/NO

FINISH SCHEDULE

INSTRUCTIONS: Indicate which materials (quarry tile, stainless steel, fiberglass reinforced panels (RFP), ceramic tile, 4" plastic coved molding, etc.). Indicate Not Applicable (NA) as appropriate.

ROOM/AREA	FLOOR	FLOOR/WALL JUNCTURE	WALLS	CEILING	MEETS CRITERIA (RA to circle and Initial)
Food Preparation					YES/NO
Dry Food Storage					YES/NO
Warewashing Area					YES/NO
Walk-in Refrigerators and Freezers					YES/NO
Service Sink					YES/NO
Refuse Area					YES/NO
Toilet Rooms and Dressing Rooms					YES/NO
Other: Indicate					YES/NO
Identify the finishes of cabinets, countertops, and shelving:					

PHYSICAL FACILITIES

INSTRUCTIONS: Explain the following with as much detail as possible. Indicate Not Applicable (NA) as appropriate.

TOPIC	MINIMUM CRITERIA	MEETS CRITERIA (Circle and Initial)
Handwashing facilities	• Identify number of the handwashing sinks in food preparation and warewashing areas: _____Food Preparation _____ Warewashing Area • Type of hand drying device? Disposable towels □ Hand-drying device □	YES/NO
Warewashing Facilities	**MANUAL DISHWASHING** • Identify the length, width, and depth of the compartments of the 3-compartment sink: _____ • Will the largest pot/ pan fit into each compartment of the 3-compartment sink? □ Yes □ No If No, what will be the procedure for manual cleaning and sanitizing of items that will not fit into sink compartments? _____ • Describe size, location and type (drainboards, wall-mounted or overhead shelves, stationary or portable racks) of air drying space: _____ • What type of sanitizer will be used? □ Chemical Type:_____ □ Hot Water **MECHANICAL DISHWASHING** • Identify the make and model of the mechanical dishwasher:_____ • What type of sanitizer will be used? □ Chemical Type:_____ □ Hot Water • Will ventilation be provided? Yes □ No □	YES/NO
Water Supply	• Is the water supply public or non-public/private? public □ non-public/private □ o If private, has source been approved? Yes □* No □ o Attach copy of written approval and/or permit. • Is ice made on premises or purchased commercially? Made on-site □ Purchased □ • Will there be an ice bagging operation? Yes □ No □	YES/NO

Sewage Disposal	• Is the sewage system public or non-public/private? public □ non-public/private □ If private, has the sewage system been approved? Yes □* No □ Attach copy of written approval and/or permit. • Will grease traps/interceptors be provided? Yes □* No □ *Identify location on plan.	YES/NO
Backflow Prevention	• Will all potable water sources be protected for backflow? Yes □ No □ • Are all floor drains identified on the submit floor plan? Yes □ No □	YES/NO
Toilet Facilities	• Identify locations and number of toilet facilities: _____ • Hot and cold water provided? Yes □ No □	YES/NO
Dressing Rooms	• Will dressing rooms be provided? Yes □ No □ • Describe storage facilities for employee personal belongings_____	YES/NO
Linens	• Will linens be laundered on site? Yes □ No □ If yes, what will be laundered and where? _____ If no, how and where will linens be cleaned? _____ • Identify location of clean and dirty linen storage:_____ • How often will linens be delivered and picked up?	YES/NO
Poisonous/Cleaning Storage	• Identify the location and storage of poisonous or toxic materials • Where will cleaning and sanitizing solutions be stored at workstations? _____ • How will these items be separated from food and food-contact surfaces? _____	YES/NO

Pest Control	• Will all outside doors be self-closing and rodent proof? □ Yes □ No □ NA • Will screens be provided on all entrances left open to the outside? □ Yes □ No □ NA • Will all openable windows have a minimum #16 mesh screening? □ Yes □ No □ NA • Will insect control devices be used? □ Yes □ No □ NA • Will air curtains be used? If yes, where? _____ Note: All pipes and electrical conduit chases must be sealed to prevent rodent access.	YES/NO
Refuse, Recyclables, and Returnables	• Will refuse/garbage be stored inside? □ Yes □ No If yes, where _____ • Identify how and where garbage cans and floor mats will be cleaned? _____ • Will a dumpster or a compacter be used? □ Dumpster □ Compactor • Identify locations of grease storage containers:_____ • Will there be an area to store recyclables? □ Yes □ No If yes, where _____ • Will there be an area to store returnable damaged goods? □ Yes □ No If yes, where _____	YES/NO

PLAN REVIEW FORMULAS

WALK-IN REFRIGERATED STORAGE

$$\text{Estimated Space Needed (Cu. ft.)} = \frac{\text{Volume per Meal [Cu. ft.]} \times \text{Number Meals Served between Deliveries}}{0.40}$$

NOTE: Only 40% of any walk-in unit actually provides usable space

$$\frac{\text{Estimated Space (Cu. ft.)}}{\text{Height of Cooler (ft.)}} = \text{Size of Cooler Needed (Sq. ft.)}$$

Examples:

1. The number of meals between deliveries = 1000 (100 meals per day X 10 days between deliveries). Volume per meal = 0.1 cubic feet.

$$0.1 \text{ ft}^3 \text{ vol.} \times 1000 \text{ meals} = 100 \text{ ft}^3$$

$$\frac{100 \text{ ft}^3}{0.40} = 250 \text{ ft}^3 \text{ Usable Space Needed}$$

2. The usable space needed for the walk-in is 250 cubic feet. The cooler has a 6 foot high ceiling.

$$\frac{250 \text{ ft}^3 \text{ usable space needed}}{6 \text{ ft ceiling height}} = 41 \text{ ft}^2 \text{ Sized Cooler Needed}$$

REACH IN REFRIGERATED STORAGE

$$\text{Estimated Space Needed (Cu. ft.)} = \frac{\text{Volume per Meal [Cu. ft.]} \times \text{Number Meals Served between Deliveries}}{0.75}$$

NOTE: Only 75% of any reach-in unit actually provides usable space

Example:

1. The number of meals between deliveries = 1000 (100 meals per day X 10 days between deliveries). Volume per meal = 0.1 cubic feet.

$$0.1 \text{ ft}^3 \text{ vol.} \times 1000 \text{ meals} = 100 \text{ ft}^3$$

$$\frac{100 \text{ ft}^3}{0.75} = 133.3 \text{ ft}^3 \text{ Estimated Space Needed}$$

PLAN REVIEW FORMULAS

HOT WATER DEMAND

$$\text{Gallons Per Hour (GPH)} = \frac{\text{Sink Size in}^3 \times 7.5 \text{ gal/ft}^3 \times (\text{Number of compartments} \times 0.75 \text{ capacity})}{1728 \text{ in}^3/\text{ft}^3}$$

OR

$$\text{Sink Size in}^3 \times \text{Number components} \times 0.003255 \text{ in}^3$$

$$\text{British Thermal Units (BTU)} = \frac{\text{GPH} \times \text{°Rise} \times 8.33 \text{ lb/gal of water}}{\text{Thermal Efficiency}}$$

$$\text{Kilo-Watt (KW) Input} = \frac{\text{GPH} \times \text{°Rise} \times 8.33 \text{ lb/gal of water}}{3412 \text{ BTU per KW}}$$

Example:

1. How many BTU's or KW's will the booster heater need to raise the incoming hot water (140°F) to 180°F for the final rinse temperature if the dishwasher requires 64 GPH?

$$\frac{64 \text{ GPH} \times 40°\text{F Rise} \times 8.33}{0.70 \text{ (operating efficiency)}} = 30{,}464 \text{ BTU}$$

$$\frac{64 \text{ GPH} \times 40°\text{F Rise} \times 8.33}{3412 \text{ BTU per KW}} = 6.2 \text{ KW}$$

PLAN REVIEW FORMULAS

DRY STORAGE

$$\text{Required Storage Area (sq. ft)} = \frac{\text{Volume per Meal (0.1 cu. ft.)} \times \text{Number Meals between Deliveries}}{\text{Avg. Height of Area (ft.)} \times \text{Fraction of Usable Floor Area}}$$

Example: 7 ft. high ceiling, shelves 6" off the floor, 18" from ceiling
Usable Height 5 ft.

Usable Floor Space:
Depends on door swings, overhead sewer lines, electrical boxes, etc.

Examples:

1. The number of meals between deliveries = 1,000 (100 meals per day X 10 days between deliveries). A ***small fraction (3/10ths) of usable storage space*** in a store room that has 5 feet in usable height

$$\frac{0.1 \text{ cu. ft.} \times 1000 \text{ meals}}{5\text{ft} \times 0.3} = 66.67 \text{ ft}^2 \text{ Required Storage Area}$$

2. The number of meals between deliveries =1,000 (100 meals per day X 10 days between deliveries). A ***larger fraction (6/10ths) of usable storage space*** in a store room that has 5 feet in usable height

$$\frac{0.1 \text{ cu. ft.} \times 1000 \text{ meals}}{5\text{ft} \times 0.6} = 33 \text{ ft}^2 \text{ Required Storage Area}$$

LINEAR FEET OF SHELVING

$$\text{Linear Feet of Shelving Required (ft.)} = \frac{\text{Volume per Meal (0.1 cu. ft.)} \times \text{Number Meals between Deliveries}}{D \times H \times C}$$

D =Depth of Shelves (ft.)

H =Clearance bewteen shelves (ft.)

C =80% effective capacity of shelf height

Examples:

1. Assume 400 meals per day and a 10 day storage between deliveries = 4,000 meals.
   Volume of 0.1 cu. Ft. per meal, shelf depth of 18 inches, clearance of **12 inches** between shelves and 80% effective capacity of shelf height

$$\frac{0.1 \text{ cu. ft.} \times 4000 \text{ meals}}{1.5 \text{ ft.} \times 1 \text{ ft.} \times 0.80} = 333 \text{ ft. Shelving Needed}$$

2. Assume 400 meals per day and a 10 day storage between deliveries = 4,000 meals.
   Volume of 0.1 cu. Ft. per meal, shelf depth of 18 inches, clearance of **18 inches** between shelves and 80% effective capacity of shelf height

$$\frac{0.1 \text{ cu. ft.} \times 4000 \text{ meals}}{1.5 \text{ ft.} \times 1.5 \text{ ft.} \times 0.80} = 222 \text{ ft. Shelving Needed}$$

Appendix D Plan Review Web Links

These links are examples of resources available to the Food Establishment Applicant. The required plan, specifications and information must be approved by the Regulatory Authority to receive a permit to operate a food establishment.

Michigan Department of Agriculture and Rural Development

http://www.michigan.gov/mdard/0%2c4610%2c7-125-50772_45851-59764--%2c00.html

Wisconsin Department of Safety and Professional Services

http://www.dsps.wi.gov/Plan-Review

U.S. Food and Drug Administration Food Establishment Plan Review Guide

http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm101639.htm

North Carolina Public Health, Environmental Health Section

http://ehs.ncpublichealth.com/faf/food/planreview/app.htm

Minnesota Department of Agriculture

http://www.mda.state.mn.us/food/business/plan-review.aspx

Conference for Food Protection, Plan Review for Food Establishments

http://www.foodprotect.org/guides-documents/plan-review-for-food-establishments-2008/

Public Health – Seattle and King County

http://www.kingcounty.gov/healthservices/health/ehs/foodsafety/FoodBusiness/permanent.aspx

Harris County Public Health and Environmental Services

http://www.hcphes.org/divisions_and_offices/environmental_public_health/training_and_resources/information_for_food_establishments/food_establishment/

Florida Department of Health in Volusia County

http://volusia.floridahealth.gov/programs-and-services/environmental-health/food-hygiene/food-guide.html

8-201.12 Contents of the Plans and Specifications.
8-203.10 Preoperational Inspections.

In conjunction with the Conference for Food Protection Plan Review committee, FDA has participated in developing a document that is intended to assist regulators in reviewing food establishment plans, and industry in understanding what is expected in the plan review process. For several years, this FDA/CFP Food Establishment Plan Review Guide – 2000 has been used in the FDA State Training Team Plan Review courses. It can be accessed through http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm101639.htm.

At the plan review stage, the regulatory authority may be dealing with an agent of the permit applicant who is seeking a building permit and who is not in a position to discuss plans for safely conducting the food operation. Nonetheless, the plan review step presents a unique opportunity to lay a foundation that enables the proposed operation to proactively sustain compliance with the Code over time. Standard operating

procedures (SOPs) are a part of that foundation and ideally are developed in tandem with designing the facility. Consequently, as an integral part of the plan review process, discussion needs to occur about such procedures and their scope.

SOPs need to be developed by the time of the preoperational inspection and put into effect when the food operation begins. It is recommended that such procedures be written, available for reference by the person in charge, conveyed to the appropriate employees, and available for review by the regulatory authority during inspections. Operating procedures should include definitive practices and expectations that ensure that:

(1) The transmission of foodborne disease is prevented by managing job applicants and food employees as specified under Subpart 2-201,

(2) Food is received from approved sources as specified under § 3-201.11,

(3) Food is managed so that the safety and integrity of the food from the time of delivery to the establishment throughout its storage, preparation, and transportation to the point of sale or service to the consumer is protected,

(4) Time/temperature control for safety food is maintained, including freezing, cold holding, cooking, hot holding, cooling, reheating, and serving in conformance with the temperature and time requirements specified under Parts 3-4 and 3-5,

(5) Warewashing is effective, including assurance that the chemical solutions and exposure times necessary for cleaning and sanitizing utensils and food-contact surfaces of equipment are provided as specified under Parts 4-6 and 4-7, and

(6) Records that are specified under §§ 3-203.11, 3-203.12, and 5-205.13 are retained for inspection.

During the plan review stage, the regulatory authority and a management representative of the proposed food establishment should discuss available training options that may be used to train food employees and the person in charge regarding food safety as it relates to their assigned duties. By the time of the preoperational inspection, operating procedures for training should include definitive practices and expectations of how the management of the proposed food establishment plans to comply with paragraph 2-103.11(N) of this Code which requires the person in charge to assure that food employees are properly trained in food safety as it relates to their assigned duties.

Conference for Food Protection (CFP) Field Training Manual for Regulatory Retail Food Safety Inspection Officers (5-31-13 CFP Update)

» View Description of Available Documents

Crosswalk - Phases of Food Incident Response

This FSMAFederal-State Integration Team Crosswalk document is a visual representation of the essential response program components that address the roles and responsibilities of the food regulatory program at each phase of a food incident response.

» View Description of Available Documents

Crosswalk Requirements for Foodborne Illness Training Programs - Standard 5 (2021)

This Crosswalk document follows the Crosswalk-Phases of Food Incident Response. It provides information on where several foodborne illness training resources fit into the requirements of Standard 5 of the Voluntary National Retail Food Regulatory Program Standards.

Approved via Issue 2020-II-019 from the Program Standards Committee

» View Description of Available Documents

Crosswalk - Requirements for Foodborne Illness Training Programs Based on Standard 5 (2017)

This Crosswalk document follows the Crosswalk - Phases of Food Incident Response

» View Description of Available Documents

Emergency Action Plan for Retail Food Establishment

» View Description of Available Documents

Employee Food Safety Training Guidance Document

Identify what a food employee should know about food safety, prioritized by risk.

» View Description of Available Documents

Issue: 2020 II-033

Council Recommendation:	Accepted as Submitted		Accepted as Amended	**x**
Delegate Action:	Accepted	X	Rejected	

All information above the line is for conference use only.

Title:

Refer Standard 5 to Program Standards Committee for Review and Updating

Recommended Solution: The Conference recommends...

that the Program Standards Committee, a CFP standing committee, be charged with the following during the next biennium:

1. Conduct a thorough review of Standard 5 "Foodborne Illness and Food Defense Preparedness and Response of the FDA Voluntary National Retail Food Regulatory Program Standards (VNRFRPS);
2. The review should include comparing the Standard to other similar FDA standards in food;
3. Review the "Description of Requirements" to ensure the requirements provide program flexibility and include items generally part of a retail food program;
4. Review Standard 5 "Data Review and Analysis" from a sampling of jurisdictions to determine if certain data analysis requirements typically have no or such limited data to make the information not valuable;
5. Review the Center for Disease Control and Prevention's National Environmental Assessment Reporting System (NEARS), Environmental Assessment Training Series (EATS), and Council to Improve Foodborne Outbreak Response (CIFOR) to consider inclusion of specific components.
6. Propose amendments to Standard 5 of the VNRFRPS;
7. Report back committee findings and recommendations to the next Biennial Meeting.

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

PSC Issue #3 list of supporting attachments:

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC3 & PSC5 2022 Program Standard 2 Appendix B-1

PSC Issue #4 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC4, PSC13 & PSC17 2022 Program Standards 2 Trained Regulatory Staff

PSC Issue #5 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC3 & PSC5 2022 Program Standard 2 Appendix B-1
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC5 AFDO - Risk-Based Inspection Methods in Retail FD218
3. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC5 Course Descriptions and Objectives - FDA38 FDA39

PSC Issue #6 list of content documents

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC6 Draft Program Standard 2 – NCS Added

PSC Issue #6 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC 6 & PSC13 National Curriculum Standard

PSC Issue #13 list of content documents

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC13 Draft Program Standard 2 Additional Exam Based on NCS

PSC Issue #13 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC4, PSC13 & PSC17 2022 Program Standards 2 Trained Regulatory Staff
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC13 IFSS Framework Basic Advanced Feb 2021 Color Chart
3. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC13 IFSS Framework Basic Advanced Feb 2021 Descriptors tab
4. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC13 IFSS Framework Basic Advanced Feb 2021 first tab
5. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC6 & PSC13 National Curriculum Standard

STANDARD No. 2
Training Program

2.1 Purpose

This standard defines the essential elements of a training program for inspectors.

2.2 Requirement Summary

The State program uses a written training plan that promotes development and demonstrates that all inspectors who will conduct manufactured food inspections complete course curriculums, field training, and continuing education to adequately perform their work.

2.3 Program Elements

2.3.1 Training Plan and Training Records

2.3.1.1 The State program uses a written training plan that ensures all inspectors receive training required to adequately perform their work assignments. The training plan includes course curriculums which provides for basic and advanced food inspection training as well as continuing education.

2.3.1.2 Appendix 2.2 or equivalent form must be used to document and summarize all training provided to inspectors.

2.3.1.3 The State program maintains a training history for active inspectors. The training history for all inactive inspectors must be kept for three years or per the state's record retention policy.

2.3.1.4 Appendix 2.3 or equivalent form must be used to document training for each inspector.

2.3.1.5 The State training record summary and individual training records must include the inspector's START DATE. Equivalent forms including electronic records may be used for required appendices.

2.3.2 Basic Food Inspection Training

The State program requires that each inspector complete a basic food inspection training curriculum that consists of coursework and field training described here.

2.3.2.1 Timeframe

The Basic Food Inspection Training course curriculum shall be successfully completed within 24 months of the inspector's START DATE with the manufactured food program.

2.3.2.2 Course Curriculum:

The Basic Food Inspection Training consists of coursework in the subject areas listed in this section.

2.3.2.2.1 Prevailing statutes, regulations, and ordinances
2.3.2.2.2 Public health principles
2.3.2.2.3 Emergency management
2.3.2.2.4 Communications skills
2.3.2.2.5 Microbiology
2.3.2.2.6 Epidemiology
2.3.2.2.7 Basics of HACCP
2.3.2.2.8 Allergen management
2.3.2.2.9 Basic food labeling
2.3.2.2.10 Food defense awareness training
2.3.2.2.11 Sampling technique and preparation

Note: States may further subdivide their basic training by identifying courses required for inspectors who only inspect non high risk warehouses. These courses must be clearly defined in the state training plan.

Note: Appendix 2.4 provides a list of available Basic Food Inspection Training Coursework that may be used to satisfy the requirements in 2.3.2.2.

2.3.2.3 Field training

2.3.2.3.1 Each inspector who will inspect general manufactured food firms must complete:
- 2.3.2.3.1.1 Ten JOINT FIELD TRAINING INSPECTION, FIELD INSPECTION AUDITS, or EVALUATIONS with a QUALIFIED FIELD INSPECTION TRAINER; and
- 2.3.2.3.1.2 Of the ten, two must be acceptable FIELD INSPECTION AUDITS or EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

2.3.2.3.2 Each inspector who will only inspect non high risk food warehouses must complete:
- 2.3.2.3.2.1 Five JOINT FIELD TRAINING INSPECTION, FIELD INSPECTION AUDITS, or EVALUATIONS with a QUALIFIED FIELD INSPECTION TRAINER; and
- 2.3.2.3.2.2 Of the five, two must be acceptable FIELD INSPECTION AUDITS or

EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

2.3.2.3.3 Inspectors who meet 2.3.2.3.2 and advance to conduct general manufactured food firms must complete:

2.3.2.3.3.1 Five additional JOINT FIELD TRAINING INSPECTIONS, FIELD INSPECTION AUDITS, or EVALUATIONS to fulfill requirements identified in 2.3.2.3.1; and

2.3.2.3.3.2 Of the five, two must be acceptable FIELD INSPECTION AUDITS or EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

2.3.2.3.4 JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS/EVALUATIONS are conducted in firms that are representative of the firms to be inspected by the inspector. Each inspector will complete the minimum field training requirements prior to conducting independent inspections.

2.3.3 Advanced Food Inspection Training

The State program requires each inspector who will conduct specialized food inspections to complete an advanced inspection training curriculum which consists of relevant coursework and field training as described here.

2.3.3.1 Coursework

The state program requires each inspector who will perform specialized food inspections to successfully complete the coursework specific to the type of specialized food inspections they will be performing. Specialized food inspection courses include, but not limited to:

2.3.3.1.1 Acidified foods
2.3.3.1.2 Low acid canned foods
2.3.3.1.3 Juice HACCP
2.3.3.1.4 Seafood HACCP
2.3.3.1.5 Traceback Investigations[7]
2.3.3.1.6 Foodborne Illness Investigations[7]

2.3.3.2 Field training

[7] These advanced food inspection training courses are not subject to 2.3.3.2 Field Training requirements.

The State program requires that each inspector successfully complete the following before performing independent specialized food inspections.

2.3.3.2.1 Participate in two JOINT FIELD TRAINING INSPECTIONS;

2.3.3.2.2 After successful completion of the course participate in one EVALUATION or FIELD INSPECTION AUDIT that is found to be acceptable by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR prior to conducting independent inspections; and

2.3.3.2.3 Within one year after being released to do specialized food inspections complete a second EVALUATION or FIELD INSPECTION AUDIT that is found to be acceptable by QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR in the area of specialty.

2.3.4 Experienced Inspectors

The criterion for conducting a minimum of 10 JOINT FIELD TRAINING INSPECTIONS and/or required coursework is intended for new employees or employees new to the food safety program. For CURRENT EXPERIENCED STAFF or NEWLY HIRED EXPERIENCED STAFF, a State program's training plan shall include the following unless the state determines in their training plan that all staff will be required to complete the program elements in 2.3.2 and 2.3.3:

2.3.4.1 CURRENT EXPERIENCED STAFF

	Missing Record	Documentation in Employee Training File
2.3.4.1.1	JOINT FIELD TRAINING INSPECTIONS	Statement or affidavit explaining the background or experience that justifies a waiver of the basic or specialized JOINT FIELD TRAINING INSPECTIONS.
2.3.4.1.2	Basic Course Work	Document training records available. Create a statement or affidavit explaining the background or experience that justifies a waiver of the missing Basic Course Work.
2.3.4.1.3	Specialized Food Inspection Course Work Certificates	Statement or affidavit explaining the date and location that they have successfully completed the specialized training.

2.3.4.2 NEWLY EXPERIENCED STAFF

	Missing Record	Documentation in Employee Training File
2.3.4.2.1	JOINT FIELD TRAINING INSPECTIONS	Statement or affidavit explaining the background or experience that justifies a waiver of some or all of the basic or specialized JOINT FIELD TRAINING INSPECTIONS. Conduct two successful EVALUATION or FIELD INSPECTION AUDIT within 6 months of the Inspector's QUALIFIED DATE.
2.3.4.2.2	Basic Course Work	Document training records available. Statement or affidavit explaining the background or experience that justifies a waiver of the Basic Course Work.
2.3.4.2.3	Specialized Food Inspection Course Work Certificates	Statement or affidavit explaining the date and location that they have successfully completed the specialized training.

2.3.5 Continuing education

Within the scope of this standard, the goal of continuing education and training is to enhance the inspector's knowledge, skills, and ability to perform manufactured food inspections. The objective is to build upon the inspector's knowledge base.

2.3.5.1 Each inspector must accumulate 20 CONTACT HOURS of continuing education in food safety every 36 months.

2.3.5.2 The 36-month continuing education interval starts at the QUALIFIED DATE, when the basic training cycle is completed.

2.3.5.3 The program may establish an alternate timeframe to track continuing education as long as the alternate timeframe and how that timeframe still meets or exceeds the intent of the standard (at least 20 CONTACT HOURS every 36 months) are clearly identified in program procedures.

2.3.5.4 The inspector qualifies for CONTACT HOURS for participation in any of the following activities that are related specifically to manufactured food safety or manufactured food inspectional work:

- Attendance at national or regional seminars / technical conferences;
- Professional symposiums / college courses;
- Food-related training provided by government agencies (e.g., USDA, State, local);
- Food safety related conferences and workshops;
- Distance learning opportunities that pertain to food safety; or

- Training approved by a QUALIFIED FIELD INSPECTION TRAINER.

2.3.5.5 Of the accumulated 20 CONTACT HOURS of continuing education, a maximum of ten (10) CONTACT HOURS may be accrued from the following activities:

- Delivering presentations at professional conferences;
- Providing classroom and/or field training to newly hired inspectors, or being a course instructor in food safety; or
- Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

2.3.5.6 Of the accumulated 20 CONTACT HOURS of continuing education, a maximum of four (4) CONTACT HOURS may be accrued for reading technical publications related to manufactured food safety.

2.3.5.7 Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation may include:

- Certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- Transcripts from a college or university;
- A letter from the administrator of the continuing education program attended;
- A copy of the peer-reviewed article or presentation made at a professional conference; or documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports; and
- An agenda and attendance roster.
- Documentation approved by the QUALIFIED FIELD INSPECTION TRAINER.

2.3.6 Coursework Sources

Basic, advanced, and continuing education coursework must be obtained from one of the sources listed here:

2.3.6.1 Training provided by a government agency (including in house training);

2.3.6.2 Distance learning, for example, satellite downlinks or web-based training[8];

2.3.6.3 Colleges, schools, research centers, and institutes;

[8] FDA/ORA U classroom and long distance learning courses are listed at: http://www.fda.gov/ora/training/course_ora.html

STANDARD 2 TRAINED REGULATORY STAFF

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STANDARD 2 TRAINED REGULATORY STAFF

This Standard applies to the essential elements of a training program for regulatory staff.

Requirement Summary

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have the knowledge, skills, and ability to adequately perform their required duties. The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

STEP 1
Completion of curriculum courses designated as "Pre" in Appendix B-1 prior to conducting and independent routine inspections.

STEP 2
Completion of the following:

- A minimum of 25 joint field training inspections (or a sufficient number of joint inspections determined by the trainer and verified through written documentation that the FSIO has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments); and
- Successful completion of the jurisdiction's FSIO Field Training Plan similar to the process outlined in *Appendix B-2: Conference for Food Protection (CFP) Field Training Manual*.

STEP 3
Completion of the following:

- A minimum of 25 independent inspections; and
- Remaining course curriculum (designated as "post" courses) outlined in *Appendix B-1: Curriculum for Retail Food Safety Inspection Officers*.

STEP 4
Completion of a standardization process similar to the FDA standardization procedures.

STEP 5
Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

Description of Requirement

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have successfully completed the required elements of the 5-step training and standardization process:

- Steps 1 through 4 within 24 months of hire or assignment to the retail food regulatory program.
- Step 5 every 36 months after the initial 24 months of training.

Step 1: Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in pre-requisite courses designated with a "Pre" in Appendix B-1, for the following curriculum areas:

1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
2. Public Health Principles;
3. Food Microbiology; and
4. Communication Skills.

There are two options for demonstrating successful completion of the pre-inspection curriculum.

OPTION 1: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- FDA ORA U pre-requisite courses identified as "Pre" in Appendix B-1; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances.

Note: *The estimated contact time for completion of the FDA ORA U pre-requisite ("Pre") courses is 42 hours.*

OPTION 2: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- Successful completion of courses deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the FDA ORA U pre- requisite (Pre") courses; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances; and
- Successful passing of one of the four written examination options (described later in this Standard) for determining if a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the listed ORA U courses are available from the web site link at: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

> **Note:** *While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:*
>
> - *Logs/records that are completed based on sign-in sheets; or*
> - *Information validated from the certificate at the time-of-issuance; or*
> - *A college transcript with a passing grade or other indication of successful completion of the course; or*
> - *Automated attendance records, such as those currently kept by some professional associations and state agencies, or*
> - *Other accurate verification of actual attendance.*

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORAU courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the four written examination categories specified herein.

1. The Certified Food Safety Professional examination offered by the National Environmental Health Association; or

2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable; or

3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or

4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

Note: *Written examinations are part of a training process, not a standardization/certification process. The examinations listed are not to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.*

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer who has successfully completed all training elements (Steps 1 – 3) of this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "training" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

If the trainer determines that the FSIO has successfully demonstrated the required performance elements and competencies, a lower minimum number of joint field training inspections can be established for that FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan in Appendix B-2, to support the exception.

Note: *The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."*

Demonstration inspections are those in which the jurisdiction's trainer takes the lead and the candidate observes the inspection process. Training inspections are those in which the candidate takes the lead, and their inspection performance is assessed and critiqued by the trainer. The jurisdiction's trainer is

responsible for determining the appropriate combination of demonstration and training inspections based on the candidate's food safety knowledge and performance during the joint field inspections.

The joint field inspections must be conducted using a field training process and forms similar to ones presented in the *CFP Field Training Manual* included as Appendix B-2. The *CFP Field Training Manual* consists of a training plan and log, trainer's worksheets, and procedures that may be incorporated into any jurisdiction's retail food training program. It is a national model upon which jurisdictions can design basic field training and provides a method for FSIOs to demonstrate competencies needed to conduct independent inspections of retail food, restaurant, and institutional foodservice establishments.

Jurisdictions are not required to use the forms or worksheets provided in the *CFP Field Training Manual*. Equivalent forms or training processes can be developed. To meet the intent of the Standard, documentation must be maintained that confirms FSIOs are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments.

> **Note:** *The CFP Field Training Manual is designed as a training approach providing a structure for continuous feedback between the FSIO and trainer on specific knowledge, skills, and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.*
>
> - *The CFP Field Training Manual is NOT intended to be used for certification or licensure purposes.*
> - *The CFP Field Training Manual is NOT intended to be used by regulatory jurisdictions for administrative purposes such as job classifications, promotions, or disciplinary actions.*

FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2013 *FDA Food Code*). The jurisdiction's trainer/food program manager can determine if the FSIO is ready to conduct independent inspections of risk category 1 establishments (as defined in Appendix B-3) at any time during the training process.

> **Note:** *The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can in lieu of the 25 joint field inspections:*
>
> - *Include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement; and*
> - *The supervisor/training officer must observe experienced FSIOs conduct inspections to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.*

Step 3: Independent Inspections and Completion of ALL Curriculum Elements

Within 24 months of hire or assignment to the regulatory retail food program, Food Safety Inspection Officers must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1, for the following eight curricula areas, must be completed within this 24-month time frame.

1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
2. Public health principles (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
3. Communication skills (Step 1);
4. Food microbiology (some of the courses for this element are part of the pre-requisite curriculum outlined in Step 1);
5. Epidemiology;
6. Hazard Analysis Critical Control Points (HACCP);
7. Allergen Management
8. Emergency Management

All courses for each of the curriculum areas must be successfully completed within 24 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

> **Note:** *The estimated contact time for completion of the FDA ORA U "post" courses is 26 hours. The term "post" refers to those courses in Appendix B-1 that were not included as part of the pre-requisite coursework. This includes all the courses in Appendix B-1 that do not have the designation "Pre" associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.*

As with the pre-requisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses listed under each curriculum area OR by completing courses, deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the listed ORA U courses are available from the FDA website: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners.

Step 4: Food Safety Inspection Officer – Field Standardization

Within 24 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the "FDA Standardization Procedures." The jurisdiction's "training standard" must have met all the requirements for conducting field standardizations as presented in the definition section of these Standards. The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years.

Note: *The field standardization and continuing standardization (re-standardization) criteria described in Step 4 is intended to provide a jurisdiction the flexibility to use their own regulation or ordinance. In addition, the reference to using standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers, is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written standardization protocol must include the five performance areas outlined above in Step 4.*

It is highly beneficial to use the FDA Food Code, standardization forms and procedures even when a jurisdiction has adopted modifications to the Food Code. Usually, regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge, and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA's standardization procedures are based on a minimum of 8 inspections. However, to meet Standard 2, a minimum of 4 standardization inspections must be conducted.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel versed in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate

consistent evaluation of all candidates.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors and communicates vital information about the inspection in a way that can be received, understood, and acted upon by retail food management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to both the regulatory agency and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard 2 criteria within the 24- month time frame, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5: Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (24 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer.

Training on any changes in the regulatory agency's prevailing statutes, laws and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine activities that are related specifically to food safety or food inspectional work:

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local);
4. Food safety related conferences and workshops; and
5. Distance learning opportunities that pertain to food safety, such as:
    - Web based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and
    - Satellite Broadcasts.

A maximum of ten (10) contact hours may be accrued from the following activities:

1. Delivering presentations at professional conferences;
2. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
3. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period[1].

Note: *Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.*

A maximum of four (4) contact hours may be accrued for:

1. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- transcripts from a college or university;
- a letter from the administrator of the continuing education program attended;
- a copy of the peer-reviewed article or presentation made at a professional conference; or
- documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

Note: *The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of employee's continuing education activities, maintains the training records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses.*

Outcome

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);

2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process similar to that presented in Appendix B-2. **NOTE:** The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."
4. Certificates or other records showing proof of satisfactory standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successful completed the training and education steps outlined in this Standard.
7. Date of hire records or assignment to the retail food program; and
8. Summary record of employees' compliance with the Standard.

The *Standard 2: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 2.

STANDARD 4
UNIFORM INSPECTION PROGRAM

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STANDARD 4
UNIFORM INSPECTION PROGRAM

This standard applies to the jurisdiction's internal policies and procedures established to ensure uniformity among regulatory staff in the interpretation of regulatory requirements, program policies and compliance / enforcement procedures.

Requirement Summary

Program management has established a quality assurance program to ensure uniformity among regulatory staff in the interpretation and application of laws, regulations, policies, and procedures.

Description of Requirement

1) Program Management implements an on-going quality assurance program that evaluates inspection uniformity to ensure inspection quality, inspection frequency and uniformity among the regulatory staff. The quality assurance program shall:

   A. The quality assurance program shall assure that each inspector:
      1. Has required equipment and forms to conduct the inspection.
      2. Reviews the contents of the establishment file, including the previous inspection report, reported complaints on file, and, if applicable, required HACCP Plans or documents supporting the issuance of a variance.
      3. Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met. Informs the supervisor when the establishment is not in the proper risk category or when the required frequency is not met.
      4. Provides identification as a regulatory official to the person in charge and states the purpose of the visit.
      5. Interprets and applies the jurisdiction's laws, rules, policies, procedures, and regulations required for conducting retail food establishment inspections.
      6. Uses a risk-based inspection methodology to conduct the inspection.
      7. Accurately determines the compliance status of each risk factor and Food Code intervention (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable).
      8. Obtains corrective action for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdiction's policies.
      9. Discuss options for the long-term control of risk factors with establishment mangers, when the same out-of-control risk factor occurs on consecutive inspections, in accordance with the jurisdiction's policies. Options may include, but are not limited to; risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans.
      10. Verifies correction of out-of-compliance observations identified during the previous inspection. In addition, follows through with compliance and enforcement in accordance with the jurisdiction's policies.
      11. Conducts an exit interview that explains the out-of-compliance observations, corrective actions, and timeframes for correction, in accordance with the jurisdiction's policies.

12. Provides the inspection report and, when necessary, cross-referenced documents, to the person in charge or permit holder, in accordance with the jurisdiction's policies.
13. Demonstrates proper sanitary practices as expected from a food service employee.
14. Completes the inspection form per the jurisdiction's policies (i.e., observations, public health reasons, applicable code reference, compliance dates).
15. Documents the compliance status of each risk factor and intervention (IN, OUT, NA, NO).
16. Cites the proper code provisions for risk factors and Food code interventions, in accordance with the jurisdiction's policies.
17. Documents corrective action for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdiction's policies.
18. Documents that option for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans.
19. Compliance or regulatory documents (i.e., exhibits, attachments, sample forms) are accurately completed, appropriately cross-referenced within the inspection report, and included with the inspection report, in accordance with the jurisdiction's policies.
20. Files reports and other documentation in a timely manner, in accordance with the jurisdiction's policies.

B. The quality assurance program shall describe the actions that will be implemented when the program analysis identifies deficiencies in quality or consistency in any program element listed above in 1) (A).

2) The quality assurance program must achieve an overall inspection program performance rating for each of the twenty measured elements [Items1-20] of at least 75% using the self-assessment procedure and the appropriate table provided in the *Standard 4: Self-Assessment Instructions and Worksheet.*

An assessment review of each inspector's work shall be made during at least three joint on-site inspections, with a corresponding file review of at least the three most recent inspection reports of the same inspected establishments, during every self-assessment period.

[*NOTE: *Staff members who are within their initial 24 months of training and have not completed all prerequisite courses, 25 joint inspections and 25 independent inspections as required in Standard 2, are exempt from the joint on-site inspections and file reviews used in the performance measurement rating calculation in the Standard 4 Self-Assessment Worksheet.*]

Outcome

A quality assurance program exists that ensures uniform, high-quality inspections.

Documentation

The quality records needed for this standard include:

1. A written procedure that describes the jurisdiction's quality assurance program that meets the criteria under the Description of Requirement section 1) (A), including corrective actions for deficiencies, and
2. Documentation that the program achieves a 75 percent performance rating on each element using the self-assessment procedures described above.

PSC Issue #7 list of content documents

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC7 Program Standards 2022 Standard 3 Requirements
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC7 Program Standards 2022 Std 3 Self-Assessment & Verification Audit form edits

PSC Issue #7 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC7 Program Standards 2022 Standard 3 Self-Assessment and Verification Audit form
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC7 2022 Program Standards 3 Inspection Program Based on HACCP Principles

PSC Issue #15 list of content documents

1) See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC15 Proposed Revised Standard 3 Requirement to Include Plan Review
2) See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC15 Proposed Revised Standard 3 SA VA Form to Include Plan Review

PSC Issue #15 list of supporting attachments

1) See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC15 Annex 3 Ch. 8 Comp and Enf Const Insp and Approval 8-201.12 & 8-203-10
2) See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC14 & PSC15 Plan Review for Food Establishments Guide 2016

State Enforcement Policy

Keywords: STD-03, FDA

Issue Description

Background

As a result of 2019 legislation, our state implemented a new, progressive methodology for enforcement that became effective on January 1, 2020. This protocol takes into consideration not only the severity of the identified violation but also the prevalence of violations observed. The legislation provides for a uniform system to communicate inspection results which is based on an overall point system driven by assigned values of low, medium, and high pervasiveness. This point system establishes the criteria by which resources are to be directed for additional full re-inspections or enforcement activities.

Pervasiveness is the overall evaluation of specific issues observed to determine how prevalent the violation is. Using all available information such as active managerial control, previous inspection records, long term controls, and overall risk/severity of the specific situation, an inspector assigns a violation pervasiveness. This system then classifies routine and re-inspections into one of three ratings ("Pass," "Re-inspection," or "Closed") based on the total cumulative violations/ points. This rating is then used to determine the next required action: no required action (the next routine inspections is scheduled), a full facility re-inspection, or the immediate suspension of a license to operate. Facilities that score less than 50 points pass the inspection and do not have to demonstrate correction of risk factor or intervention violations through re-inspection or other follow-up activities.

We are seeking clarification for criteria 4 of standard 3 – the requirement for an implemented policy that requires on-site corrective actions or follow-up activities for out of compliance foodborne illness risk factors. The policies established in Standard 3 for onsite and long-term corrective actions link to Standard 6, Compliance and Enforcement. The violations in the Standard 6 CFP crosswalk outlines violations that should have corrective actions, these violations include interventions and core violations as well as risk factors.

Question/Problem

The CFP cross-walk contains very specific code citations within items 1-29 of the FDA inspection form for risk factors and interventions that include Priority, Priority Foundation, and Core violations. Are core and intervention violations intended to be included in the requirement for on-site corrective actions and follow-up activities?

Does our inspection program meet standard 3 if we do not require corrective action or follow-up activities for violations that pose a low risk to public health?

Rationale

Standard 3 specifically does not appear to align with Standard 6 for State and Local programs that have developed alternative systems of assessment that can also accomplish the same goal. There are situations where appropriate corrective actions cannot occur at the time of the inspection and the

violation has a low risk to the public's health. Because of the nuances in the code and a focus on mitigating risk and assessing active managerial control, it does not seem appropriate to require corrective action and follow-up activities for every situation in which risk-factors are out of compliance.

Standard 3 – Criteria 4

4. Corrective Action Policy

a) The jurisdiction has a written and implemented policy that requires on-site corrective action for foodborne illness risk factors observed to be out of compliance.

b) The jurisdiction has a written and implemented policy that requires discussion for long- term control of foodborne illness risk factors.

c) The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations.

Response from the Clearinghouse (11-30-22)

No. Standard 3 requires that a jurisdiction develop and implement a policy that requires timely corrective actions as appropriate to the type of violation. In some cases, an actual physical visit to an establishment may not be necessary, however documented activities should lead to a desired outcome where a regulatory inspection system uses HACCP principles to identify risk factors and to obtain immediate and long-term corrective action for recurring risk factors. Core violations do not require an immediate on-site correction but follow up should be performed.

According to the 2017 FDA Food Code, the following is required: 8-406.11 Time Frame for Correction.
(A) Except as specified in (B) of this section, the PERMIT HOLDER shall correct CORE ITEMS by a date and time agreed to or specified by the REGULATORY AUTHORITY but no later than 90 calendar days after the inspection.
(B) The REGULATORY AUTHORITY may approve a compliance schedule that extends beyond the time limits specified under (A) of this section if a written schedule of compliance is submitted by the PERMIT HOLDER and no health HAZARD exists or will result from allowing an extended schedule for compliance.

STANDARD No. 2
Training Program

2.1 Purpose

This standard defines the essential elements of a training program for inspectors.

2.2 Requirement Summary

The State program uses a written training plan that promotes development and demonstrates that all inspectors who will conduct manufactured food inspections complete course curriculums, field training, and continuing education to adequately perform their work.

2.3 Program Elements

2.3.1 Training Plan and Training Records

2.3.1.1 The State program uses a written training plan that ensures all inspectors receive training required to adequately perform their work assignments. The training plan includes course curriculums which provides for basic and advanced food inspection training as well as continuing education.

2.3.1.2 Appendix 2.2 or equivalent form must be used to document and summarize all training provided to inspectors.

2.3.1.3 The State program maintains a training history for active inspectors. The training history for all inactive inspectors must be kept for three years or per the state's record retention policy.

2.3.1.4 Appendix 2.3 or equivalent form must be used to document training for each inspector.

2.3.1.5 The State training record summary and individual training records must include the inspector's START DATE. Equivalent forms including electronic records may be used for required appendices.

2.3.2 Basic Food Inspection Training

The State program requires that each inspector complete a basic food inspection training curriculum that consists of coursework and field training described here.

2.3.2.1 Timeframe

The Basic Food Inspection Training course curriculum shall be successfully completed within 24 months of the inspector's START DATE with the manufactured food program.

2.3.2.2 Course Curriculum:

The Basic Food Inspection Training consists of coursework in the subject areas listed in this section.

2.3.2.2.1 Prevailing statutes, regulations, and ordinances
2.3.2.2.2 Public health principles
2.3.2.2.3 Emergency management
2.3.2.2.4 Communications skills
2.3.2.2.5 Microbiology
2.3.2.2.6 Epidemiology
2.3.2.2.7 Basics of HACCP
2.3.2.2.8 Allergen management
2.3.2.2.9 Basic food labeling
2.3.2.2.10 Food defense awareness training
2.3.2.2.11 Sampling technique and preparation

Note: States may further subdivide their basic training by identifying courses required for inspectors who only inspect non high risk warehouses. These courses must be clearly defined in the state training plan.

Note: Appendix 2.4 provides a list of available Basic Food Inspection Training Coursework that may be used to satisfy the requirements in 2.3.2.2.

2.3.2.3 Field training

2.3.2.3.1 Each inspector who will inspect general manufactured food firms must complete:
- 2.3.2.3.1.1 Ten JOINT FIELD TRAINING INSPECTION, FIELD INSPECTION AUDITS, or EVALUATIONS with a QUALIFIED FIELD INSPECTION TRAINER; and
- 2.3.2.3.1.2 Of the ten, two must be acceptable FIELD INSPECTION AUDITS or EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

2.3.2.3.2 Each inspector who will only inspect non high risk food warehouses must complete:
- 2.3.2.3.2.1 Five JOINT FIELD TRAINING INSPECTION, FIELD INSPECTION AUDITS, or EVALUATIONS with a QUALIFIED FIELD INSPECTION TRAINER; and
- 2.3.2.3.2.2 Of the five, two must be acceptable FIELD INSPECTION AUDITS or

EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

2.3.2.3.3 Inspectors who meet 2.3.2.3.2 and advance to conduct general manufactured food firms must complete:

2.3.2.3.3.1 Five additional JOINT FIELD TRAINING INSPECTIONS, FIELD INSPECTION AUDITS, or EVALUATIONS to fulfill requirements identified in 2.3.2.3.1; and

2.3.2.3.3.2 Of the five, two must be acceptable FIELD INSPECTION AUDITS or EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

2.3.2.3.4 JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS/EVALUATIONS are conducted in firms that are representative of the firms to be inspected by the inspector. Each inspector will complete the minimum field training requirements prior to conducting independent inspections.

2.3.3 Advanced Food Inspection Training

The State program requires each inspector who will conduct specialized food inspections to complete an advanced inspection training curriculum which consists of relevant coursework and field training as described here.

2.3.3.1 Coursework

The state program requires each inspector who will perform specialized food inspections to successfully complete the coursework specific to the type of specialized food inspections they will be performing. Specialized food inspection courses include, but not limited to:

2.3.3.1.1 Acidified foods
2.3.3.1.2 Low acid canned foods
2.3.3.1.3 Juice HACCP
2.3.3.1.4 Seafood HACCP
2.3.3.1.5 Traceback Investigations[7]
2.3.3.1.6 Foodborne Illness Investigations[7]

2.3.3.2 Field training

[7] These advanced food inspection training courses are not subject to 2.3.3.2 Field Training requirements.

The State program requires that each inspector successfully complete the following before performing independent specialized food inspections.

2.3.3.2.1 Participate in two JOINT FIELD TRAINING INSPECTIONS;

2.3.3.2.2 After successful completion of the course participate in one EVALUATION or FIELD INSPECTION AUDIT that is found to be acceptable by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR prior to conducting independent inspections; and

2.3.3.2.3 Within one year after being released to do specialized food inspections complete a second EVALUATION or FIELD INSPECTION AUDIT that is found to be acceptable by QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR in the area of specialty.

2.3.4 Experienced Inspectors

The criterion for conducting a minimum of 10 JOINT FIELD TRAINING INSPECTIONS and/or required coursework is intended for new employees or employees new to the food safety program. For CURRENT EXPERIENCED STAFF or NEWLY HIRED EXPERIENCED STAFF, a State program's training plan shall include the following unless the state determines in their training plan that all staff will be required to complete the program elements in 2.3.2 and 2.3.3:

2.3.4.1 CURRENT EXPERIENCED STAFF

	Missing Record	Documentation in Employee Training File
2.3.4.1.1	JOINT FIELD TRAINING INSPECTIONS	Statement or affidavit explaining the background or experience that justifies a waiver of the basic or specialized JOINT FIELD TRAINING INSPECTIONS.
2.3.4.1.2	Basic Course Work	Document training records available. Create a statement or affidavit explaining the background or experience that justifies a waiver of the missing Basic Course Work.
2.3.4.1.3	Specialized Food Inspection Course Work Certificates	Statement or affidavit explaining the date and location that they have successfully completed the specialized training.

2.3.4.2 NEWLY EXPERIENCED STAFF

	Missing Record	Documentation in Employee Training File
2.3.4.2.1	JOINT FIELD TRAINING INSPECTIONS	Statement or affidavit explaining the background or experience that justifies a waiver of some or all of the basic or specialized JOINT FIELD TRAINING INSPECTIONS. Conduct two successful EVALUATION or FIELD INSPECTION AUDIT within 6 months of the Inspector's QUALIFIED DATE.
2.3.4.2.2	Basic Course Work	Document training records available. Statement or affidavit explaining the background or experience that justifies a waiver of the Basic Course Work.
2.3.4.2.3	Specialized Food Inspection Course Work Certificates	Statement or affidavit explaining the date and location that they have successfully completed the specialized training.

2.3.5 Continuing education

Within the scope of this standard, the goal of continuing education and training is to enhance the inspector's knowledge, skills, and ability to perform manufactured food inspections. The objective is to build upon the inspector's knowledge base.

2.3.5.1 Each inspector must accumulate 20 CONTACT HOURS of continuing education in food safety every 36 months.

2.3.5.2 The 36-month continuing education interval starts at the QUALIFIED DATE, when the basic training cycle is completed.

2.3.5.3 The program may establish an alternate timeframe to track continuing education as long as the alternate timeframe and how that timeframe still meets or exceeds the intent of the standard (at least 20 CONTACT HOURS every 36 months) are clearly identified in program procedures.

2.3.5.4 The inspector qualifies for CONTACT HOURS for participation in any of the following activities that are related specifically to manufactured food safety or manufactured food inspectional work:

- Attendance at national or regional seminars / technical conferences;
- Professional symposiums / college courses;
- Food-related training provided by government agencies (e.g., USDA, State, local);
- Food safety related conferences and workshops;
- Distance learning opportunities that pertain to food safety; or

- Training approved by a QUALIFIED FIELD INSPECTION TRAINER.

2.3.5.5 Of the accumulated 20 CONTACT HOURS of continuing education, a maximum of ten (10) CONTACT HOURS may be accrued from the following activities:

- Delivering presentations at professional conferences;
- Providing classroom and/or field training to newly hired inspectors, or being a course instructor in food safety; or
- Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

2.3.5.6 Of the accumulated 20 CONTACT HOURS of continuing education, a maximum of four (4) CONTACT HOURS may be accrued for reading technical publications related to manufactured food safety.

2.3.5.7 Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation may include:

- Certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- Transcripts from a college or university;
- A letter from the administrator of the continuing education program attended;
- A copy of the peer-reviewed article or presentation made at a professional conference; or documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports; and
- An agenda and attendance roster.
- Documentation approved by the QUALIFIED FIELD INSPECTION TRAINER.

2.3.6 Coursework Sources

Basic, advanced, and continuing education coursework must be obtained from one of the sources listed here:

2.3.6.1 Training provided by a government agency (including in house training);

2.3.6.2 Distance learning, for example, satellite downlinks or web-based training[8];

2.3.6.3 Colleges, schools, research centers, and institutes;

[8] FDA/ORA U classroom and long distance learning courses are listed at: http://www.fda.gov/ora/training/course_ora.html

STANDARD No. 3
Inspection Program

3.1 Purpose

This standard describes the elements of an effective inspection program for manufactured food establishments.

3.2 Requirement Summary

The State program has a manufactured food inspection system. This system provides the foundation for inspecting food firms to determine compliance with the laws administered by Federal, State, and local governments. In addition, the State program has: (1) a risk based inspection program, (2) an inspection procedure, (3) an inspection report procedure, (4) a system to respond to CONSUMER COMPLAINTS, (5) a system to resolve INDUSTRY COMPLAINTS about inspections, (6) a recall system, and (7) a sampling procedure.

3.3 Program Elements

3.3.1 Risk-based Inspection Program

The State program has an inventory of food establishments for which the State has regulatory oversight. The inventory is categorized by the risk associated with the likelihood that a food safety or defense incident will occur.

3.3.1.1 Inspections are prioritized and frequencies assigned based on established risk categories. The State program has written procedure documenting their classification criteria and inspection frequencies.

3.3.1.2 The state program must use the risk factors and classification criteria as described in:

- Appendix 3.2; or
- FD&C Act, Section 421 (a)(1); or
- Develop its own risk factor and classification criteria. If the state chooses to develop its own risk factor and classification criteria a written rationale must be provided that demonstrates how public health is protected.

3.3.2 Inspection Procedure

The State program has a written procedure for inspecting food plants that require the inspectors to:

3.3.2.1 Review the previous inspection report and CONSUMER COMPLAINTS.

3.3.2.2 Have appropriate equipment[9] and forms (if necessary). Equipment must be verified and maintained as defined by the State's standard operating procedures or manufacture's recommendations.

3.3.2.3 Make appropriate introductions, and explain the purpose and scope of the inspection.

3.3.2.4 Establish jurisdiction.

3.3.2.5 Select an appropriate product for the inspection and, if necessary, make appropriate adjustments based on what the plant is producing.

3.3.2.6 Assess employee practices critical to the safe and sanitary production and storage of food.

3.3.2.7 Properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded or otherwise in violation of applicable law.

3.3.2.8 Recognize significant violative conditions or practices, if present, and record findings consistent with State program procedures.

3.3.2.9 Distinguish between significant and insignificant observations, and isolated incidents versus trends.

3.3.2.10 Review and evaluate the appropriate records and procedures for the establishment's operation and effectively apply the information obtained from this review [during the inspection].

3.3.2.11 Collect adequate evidence and documentation to support inspection observations in accordance with State program procedures.

3.3.2.12 Verify correction of deficiencies identified during the previous inspection.

3.3.2.13 Behave professionally and demonstrate proper sanitary practices during the inspection.

3.3.2.14 Use current versions of applicable hazard guides or other guidance, to identify and evaluate the HAZARDS associated with product(s) and process(es) when conducting inspections of specialized food and processes.

3.3.2.15 Assess the firm's implementation of sanitation monitoring for the applicable eight key areas of sanitation when required by regulation.

3.3.2.16 When appropriate review the firm's: scheduled process; HACCP plan or necessary process controls in the absence of a HACCP plan; food safety control plan and applicable monitoring, verification and deviation or corrective action records, including those related to sanitation.

3.3.2.17 Recognize deficiencies in the firm's monitoring controls and sanitation procedures through in-plant observations.

3.3.2.18 Use suitable interviewing techniques.

3.3.2.19 Explain findings clearly and adequately throughout the inspection.

3.3.2.20 Alert the firm's person in charge when an immediate corrective action is necessary.

[9] Standard number 8, Appendix 8.3 Inspection Equipment

3.3.2.21 Answer questions and provide information in an appropriate manner.
3.3.2.22 Write findings accurately, clearly, and concisely on the State document and provide a copy to the firm's person in charge.

3.3.3 Inspection Report

The State program has a written inspection report procedure that requires inspectors to:

3.3.3.1 Submit the inspection report within designated timeframes;
3.3.3.2 Complete the inspection report form completely and accurately;
3.3.3.3 Document violations and observations clearly, legibly, and concisely; and
3.3.3.4 Follow up with corrective action, compliance and enforcement.

3.3.4 Food Recalls[10]

The State program has a food recall system with written recall procedures for:

3.3.4.1 Sharing information about recalls with relevant agencies;
3.3.4.2 Ensuring recalled products are removed promptly from the market; and
3.3.4.3 Performing RECALL AUDIT CHECKS.

3.3.5 Consumer Complaints

The State program has a system for handling CONSUMER COMPLAINTS. The system contains written procedures for:

3.3.5.1 Receiving;
3.3.5.2 Tracking;
3.3.5.3 Evaluating;
3.3.5.4 Responding to; and
3.3.5.5 Closing CONSUMER COMPLAINTS.

3.3.6 Complaints Resulting from State Program Inspection Activities

The State program has a system for handling INDUSTRY COMPLAINTS about inspections. The system contains written procedures for:

3.3.6.1 Receiving;
3.3.6.2 Evaluating; and
3.3.6.3 Responding to INDUSTRY COMPLAINTS.

[10] Reference: PFP Best Practices for Improving FDA and State Communication During Recalls can be found: http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/UCM460013.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

3.3.7 Sampling Procedure[11]

The State program has a written sampling procedure to ensure its SAMPLING PROGRAM is carried out in a manner that is consistent with state procedure. The sampling procedures must be reflective of the types of food and samples that the state collects and must include:

3.3.7.1 Procedures that require sample collectors to:

- 3.3.7.1.1 Use the appropriate method and equipment to collect the sample.
- 3.3.7.1.2 Record sample chain of custody per state procedure.
- 3.3.7.1.3 Handle, package, and ship sample using procedures appropriate to prevent compromising condition of the sample and ensuring security of the sample.
- 3.3.7.1.4 Deliver or ship sample to the appropriate laboratory program within prescribed timeframes.

3.3.7.2 Instructions for documenting the sample collection must include the following unless specified by the State's SAMPLING PROGRAM:

- 3.3.7.2.1 Date of Sample Collection
- 3.3.7.2.2 Product Identification Including:
  - 3.3.7.2.2.1 Name of Product
  - 3.3.7.2.2.2 Unique Manufacturing Identification references
- 3.3.7.2.3 Description of the product
- 3.3.7.2.4 Collection information including:
  - 3.3.7.2.4.1 Method of Collection
  - 3.3.7.2.4.2 Lot Sampled
  - 3.3.7.2.4.3 Lot Size
  - 3.3.7.2.4.4 Special Sample techniques if used to collect the sample
- 3.3.7.2.5 Location where sample was collected.
- 3.3.7.2.6 Name and address of responsible party, guarantor, possessor, or distributor.
- 3.3.7.2.7 Sample type
- 3.3.7.2.8 Analysis requested *if applicable*.
- 3.3.7.2.9 Product labels or specific labeling information that is collected or reproduced per state policies.

[11] Reference: PFP Food/Feed Testing Laboratories Best Practices Manual can be found: http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/UCM404716.pdf

3.3.7.2.10 Identification of the sample with the sample number assigned by the sampler at the time of collection.

3.3.7.3 State programs are not required to have a written sampling procedure unless they collect samples. However, these programs must have a statement in lieu of sampling procedures that explains why a SAMPLING PROGRAM is not supported and how the public health is protected in the absence of such a program. An example may include: Stating that public health is protected because another state or federal agency collects samples and fulfills this need. The statement should include the name of the agency and the type of samples that it collects.

3.3.8 Records Retention

The State program must maintain records as required under Section 9.3.2.2 for the following:

3.3.8.1 Inspection reports which includes follow up activities;
3.3.8.2 Essential recall information;
3.3.8.3 CONSUMER COMPLAINTS;
3.3.8.4 INDUSTRY COMPLAINTS about inspections[12]; and
3.3.8.5 Documentation associated with sample collection.

3.4 Outcome

The State program is based on an inspection program that reduces the occurrence of foodborne illness, injury, or allergic reaction.

3.5 Documentation

The State program maintains the records listed here.

3.5.1 Appendix 3.1 Self-Assessment Worksheet
3.5.2 An inventory of food plants for which the state has regulatory oversight[13]
3.5.3 Written procedure documenting the classification criteria and inspection frequencies
3.5.4 Written rationale of the risk factor and classification criteria if a State program develops its own risk factor and classification criteria
3.5.5 Written procedures for inspecting food plants.
3.5.6 Written inspection reports procedure

[12] Records dealing with personnel actions are not subject to review during an ASSESSMENT.

[13] Refer to PFP Document Data Elements and Definitions for recommended but not required data elements for each food plant. http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/UCM404717.pdf

3.5.7 Written inspection reports, which includes follow-up activities
3.5.8 Written procedures for food recalls
3.5.9 Essential recall information
3.5.10 Written procedures for CONSUMER COMPLAINTS
3.5.11 CONSUMER COMPLAINTS
3.5.12 Written procedures for INDUSTRY COMPLAINTS about inspections
3.5.13 INDUSTRY COMPLAINTS about inspections[14]
3.5.14 Written procedures for sampling or, in the absence of any SAMPLING PROGRAM, a statement stating how public health is protected
3.5.15 Sample collection reports
3.5.16 Documentation associated with sample collection

[14] Records dealing with personnel actions are not subject to review during an ASSESSMENT.

STANDARD 2 TRAINED REGULATORY STAFF

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STANDARD 2 TRAINED REGULATORY STAFF

This Standard applies to the essential elements of a training program for regulatory staff.

Requirement Summary

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have the knowledge, skills, and ability to adequately perform their required duties. The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

STEP 1
Completion of curriculum courses designated as "Pre" in Appendix B-1 prior to conducting and independent routine inspections.

STEP 2
Completion of the following:

- A minimum of 25 joint field training inspections (or a sufficient number of joint inspections determined by the trainer and verified through written documentation that the FSIO has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments); and
- Successful completion of the jurisdiction's FSIO Field Training Plan similar to the process outlined in *Appendix B-2: Conference for Food Protection (CFP) Field Training Manual*.

STEP 3
Completion of the following:

- A minimum of 25 independent inspections; and
- Remaining course curriculum (designated as "post" courses) outlined in *Appendix B-1: Curriculum for Retail Food Safety Inspection Officers*.

STEP 4
Completion of a standardization process similar to the FDA standardization procedures.

STEP 5
Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

Description of Requirement

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have successfully completed the required elements of the 5-step training and standardization process:

- Steps 1 through 4 within 24 months of hire or assignment to the retail food regulatory program.
- Step 5 every 36 months after the initial 24 months of training.

Step 1: Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in pre-requisite courses designated with a "Pre" in Appendix B-1, for the following curriculum areas:

1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
2. Public Health Principles;
3. Food Microbiology; and
4. Communication Skills.

There are two options for demonstrating successful completion of the pre-inspection curriculum.

OPTION 1: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- FDA ORA U pre-requisite courses identified as "Pre" in Appendix B-1; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances.

Note: *The estimated contact time for completion of the FDA ORA U pre-requisite ("Pre") courses is 42 hours.*

OPTION 2: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- Successful completion of courses deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the FDA ORA U pre- requisite (Pre") courses; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances; and
- Successful passing of one of the four written examination options (described later in this Standard) for determining if a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the listed ORA U courses are available from the web site link at: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

> **Note:** *While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:*
>
> - *Logs/records that are completed based on sign-in sheets; or*
> - *Information validated from the certificate at the time-of-issuance; or*
> - *A college transcript with a passing grade or other indication of successful completion of the course; or*
> - *Automated attendance records, such as those currently kept by some professional associations and state agencies, or*
> - *Other accurate verification of actual attendance.*

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORAU courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the four written examination categories specified herein.

1. The Certified Food Safety Professional examination offered by the National Environmental Health Association; or

2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable; or

3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or

4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

Note: *Written examinations are part of a training process, not a standardization/certification process. The examinations listed are not to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.*

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer who has successfully completed all training elements (Steps 1 – 3) of this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "training" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

If the trainer determines that the FSIO has successfully demonstrated the required performance elements and competencies, a lower minimum number of joint field training inspections can be established for that FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan in Appendix B-2, to support the exception.

Note: *The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."*

Demonstration inspections are those in which the jurisdiction's trainer takes the lead and the candidate observes the inspection process. Training inspections are those in which the candidate takes the lead, and their inspection performance is assessed and critiqued by the trainer. The jurisdiction's trainer is

responsible for determining the appropriate combination of demonstration and training inspections based on the candidate's food safety knowledge and performance during the joint field inspections.

The joint field inspections must be conducted using a field training process and forms similar to ones presented in the *CFP Field Training Manual* included as Appendix B-2. The *CFP Field Training Manual* consists of a training plan and log, trainer's worksheets, and procedures that may be incorporated into any jurisdiction's retail food training program. It is a national model upon which jurisdictions can design basic field training and provides a method for FSIOs to demonstrate competencies needed to conduct independent inspections of retail food, restaurant, and institutional foodservice establishments.

Jurisdictions are not required to use the forms or worksheets provided in the *CFP Field Training Manual*. Equivalent forms or training processes can be developed. To meet the intent of the Standard, documentation must be maintained that confirms FSIOs are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments.

> **Note:** *The CFP Field Training Manual is designed as a training approach providing a structure for continuous feedback between the FSIO and trainer on specific knowledge, skills, and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.*
>
> - *The CFP Field Training Manual is NOT intended to be used for certification or licensure purposes.*
> - *The CFP Field Training Manual is NOT intended to be used by regulatory jurisdictions for administrative purposes such as job classifications, promotions, or disciplinary actions.*

FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2013 *FDA Food Code*). The jurisdiction's trainer/food program manager can determine if the FSIO is ready to conduct independent inspections of risk category 1 establishments (as defined in Appendix B-3) at any time during the training process.

> **Note:** *The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can in lieu of the 25 joint field inspections:*
>
> - *Include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement; and*
> - *The supervisor/training officer must observe experienced FSIOs conduct inspections to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.*

Step 3: Independent Inspections and Completion of ALL Curriculum Elements

Within 24 months of hire or assignment to the regulatory retail food program, Food Safety Inspection Officers must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1, for the following eight curricula areas, must be completed within this 24-month time frame.

1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
2. Public health principles (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
3. Communication skills (Step 1);
4. Food microbiology (some of the courses for this element are part of the pre-requisite curriculum outlined in Step 1);
5. Epidemiology;
6. Hazard Analysis Critical Control Points (HACCP);
7. Allergen Management
8. Emergency Management

All courses for each of the curriculum areas must be successfully completed within 24 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

> **Note:** *The estimated contact time for completion of the FDA ORA U "post" courses is 26 hours. The term "post" refers to those courses in Appendix B-1 that were not included as part of the pre-requisite coursework. This includes all the courses in Appendix B-1 that do not have the designation "Pre" associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.*

As with the pre-requisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses listed under each curriculum area OR by completing courses, deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the listed ORA U courses are available from the FDA website: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners.

Step 4: Food Safety Inspection Officer – Field Standardization

Within 24 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the "FDA Standardization Procedures." The jurisdiction's "training standard" must have met all the requirements for conducting field standardizations as presented in the definition section of these Standards. The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years.

Note: *The field standardization and continuing standardization (re-standardization) criteria described in Step 4 is intended to provide a jurisdiction the flexibility to use their own regulation or ordinance. In addition, the reference to using standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers, is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written standardization protocol must include the five performance areas outlined above in Step 4.*

It is highly beneficial to use the FDA Food Code, standardization forms and procedures even when a jurisdiction has adopted modifications to the Food Code. Usually, regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge, and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA's standardization procedures are based on a minimum of 8 inspections. However, to meet Standard 2, a minimum of 4 standardization inspections must be conducted.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel versed in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate

consistent evaluation of all candidates.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors and communicates vital information about the inspection in a way that can be received, understood, and acted upon by retail food management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to both the regulatory agency and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard 2 criteria within the 24- month time frame, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5: Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (24 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer.

Training on any changes in the regulatory agency's prevailing statutes, laws and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine activities that are related specifically to food safety or food inspectional work:

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local);
4. Food safety related conferences and workshops; and
5. Distance learning opportunities that pertain to food safety, such as:
    - Web based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and
    - Satellite Broadcasts.

A maximum of ten (10) contact hours may be accrued from the following activities:

1. Delivering presentations at professional conferences;
2. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
3. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period[1].

Note: *Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.*

A maximum of four (4) contact hours may be accrued for:

1. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- transcripts from a college or university;
- a letter from the administrator of the continuing education program attended;
- a copy of the peer-reviewed article or presentation made at a professional conference; or
- documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

Note: *The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of employee's continuing education activities, maintains the training records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses.*

Outcome

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);

2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process similar to that presented in Appendix B-2. **NOTE:** The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."
4. Certificates or other records showing proof of satisfactory standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successful completed the training and education steps outlined in this Standard.
7. Date of hire records or assignment to the retail food program; and
8. Summary record of employees' compliance with the Standard.

The *Standard 2: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 2.

Standard 2: Trained Regulatory Staff
APPENDIX B-1: Curriculum for Retail Food Safety Inspection Officers

NOTE about course information: The courses listed below are updated and moved across different learning management systems over time. The latest information will be posted on the FDA Program Standards Landing Page at https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019

For state, local, tribal, & territorial (SLTT) regulators to register on-line for free access to web courses, go to: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

Pre-requisite ("Pre") Curriculum Courses

(To be completed during the 25 joint inspection period AND prior to conducting any independent inspections)

PUBLIC HEALTH PRINCIPLES

Courses	Course Number
1-Public Health Principles	FDA36 (90)

MICROBIOLOGY

Courses	Course Number
1-Overview of Microbiology	MIC01 (60)
2A-Gram Negative Rods	MIC02 (60)
2B-Gram-Positive Rods & Cocci	MIC03 (90)
3- Foodborne Viruses	MIC04 (60)
4- Foodborne Parasites	MIC05 (90)
Mid-Series Exam	MIC16 (30)
5- Controlling Growth Factors	MIC06 (90)
6-Control by Refrigeration & Freezing	MIC07 (60)
7A-Control by Thermal Processing	MIC08 (90)
7B- Control by Pasteurization	MIC09 (90)
10- Aseptic Sampling	MIC13 (90)
12-Cleaning & Sanitizing	MIC15 (90)

PREVAILING STATUTES, REGULATIONS, ORDINANCES

Courses	Course Number
1. Basic Food Law for State Regulators	FDA35 (60)
2. Basics of Inspection: Beginning an Inspection	FDA38 (90)
3. Basics of Inspection: Issues & Observations	FDA39 (90)
4. An Introduction to Food Security Awareness	FD251 (60) A PDF/READABLE VERSION at (https://www.fda.gov/training-and- continuing-education/office-training-education-and-development-oted/introduction-food-security-awareness) Note: Required exam is available via www.compliancewire.com.

5. FDA Food Code: Specific SLTT laws and regulations to be addressed by each jurisdiction.	**Note:** Some jurisdictions may require the FDA Food Code Course in addition to SLTT food code training.

COMMUNICATION SKILLS

Courses	Course Number
1. Communication Skills	CC8030W **NOTE**: Course must be accessed through LearnEd at: https:// fdaoted.csod.com/

Curriculum ("Post") Courses

(To be completed any time prior to Food Code Standardization AND within 24 months of hire or assignment to the regulatory retail food program)

MICROBIOLOGY

Courses	Course Number
7C-Control by Retorting	MIC10 (90)
8-Technology-Based Food Processes	MIC11 (120)
9-Natural Toxins	MIC12 (90)

HACCP

Courses	Course Number
1. Overview of HACCP	FDA16 (60)
2. Prerequisite Programs & Preliminary Steps	FDA17 (60)
3. The Principles	FDA18 (60)

ALLERGEN MANAGEMENT

Courses	Course Number
1. Allergens	CC8029W Course must be accessed through LearnEd at: https:// fdaoted.csod.com/

EPIDEMIOLOGY

Courses	Course Number
1. Collecting Surveillance Data	FI01 (90)
2. Beginning the Investigation	FI02 (90)
3. Expanding the Investigation	FI03 (90)
4. Conducting a Food Hazard Review	FI04 (90)
5. Epidemiological Statistics	FI05 (90)
6. Final Report	FI06 (30)

EMERGENCY MANAGEMENT – FEMA

Incident Command System and National Incident Management System: Course available from FEMA web link http://training.fema.gov/IS/NIMS.asp

Courses	Course Number
1. Introduction to Incident Command System	IS-100.C, Introduction to the Incident Command System, (180) ICS-100 for FDA
2. Basic Incident Command System for Initial Response	IS-200.C, Basic Incident Command System for Initial Response (180)
3. An Introduction to NIMS	IS 700.B, An Introduction to NIMS, (180) ICS-700

( ) Average time in minutes required to take the course, 60 minutes equals .1 CEU, 90-120 minutes equals .2 CEUs

Estimated total hours for "Pre" courses are 42 hours.

Estimated total hours for "Post" courses are 26 hours.

Estimated total hours for completion of all Program Standard #2 coursework are 68 hours

CFP – Employee Food Safety Training (EFST) Committee

Template approved: 7/13/2021

Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME **CFP – EFST Committee**

DATE OF FINAL REPORT: 12/4/2022

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Tara Paster Cammarata and Ki Straughn

COMMITTEE CHARGE(S):

Issue # 2018-II-001

1. *Review the CFP "Employee Food Safety Training Guidance Document" for possible updates (assigned via Issue 2018-II-001); and*
2. *Report recommendations at the 2023 Biennial Meeting.*

COMMITTEE WORK PLAN AND TIMELINE:

- **A.** *Historical perspective review and acknowledgement of the 2016 - 2018 Employee Food Safety Training Committee Final Report*
- **B.** *Thank the past committee members for the completed work and recognize their commitment to CFP*
- **C.** *Welcome and organize the new committee members to complete the assigned charge using collaboration and transparency*
- **D.** *Divide and review the CFP "Employee Food Safety Training Guidance Document" for possible updates*

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

- ✓ *Friday, November 5, 2021*
  Ki Straughn, Dr. Ben Chapman from NC State, and Tara Paster Cammarata reviewed the historical perspective of the 2016 - 2018 Employee Food Safety Training Committee Final Report
- ✓ *Friday, December 10, 2021 – Committee Virtual Meeting*
  Recognized and thanked past committee members; Welcome; Orientation to Committee; Legal review; Expectations; Champions volunteered to lead the different sections of the Guidance Document and the committee accepted the plan calendar for success
- ✓ *Friday, January 14, 2022 – Committee Virtual Meeting:* ***Section 1***
- ✓ *Friday, February 11, 2022 – Committee Virtual Meeting:* ***Section 2***
- ✓ *Friday, March 11, 2022 – Committee Virtual Meeting:* ***Sections 2 & 3***
- ✓ *Friday, April 8, 2022 – Committee Virtual Meeting:* ***Section 4***
- ✓ *Friday, May 13, 2022 – Committee Virtual Meeting:* ***Section 4 and 5***
- ✓ *Friday, June 10, 2022 – Committee Virtual Meeting:* ***Sections 6***
- ✓ *Friday, July 8, 2022 – Committee Virtual Meeting:* ***Sections 5 and 6***
- ✓ *Friday, August 12, 2022 – Committee Virtual Meeting:* ***Sections 7***
- ✓ *Friday, September 9, 2022 – Meeting canceled because all sections were completed*
- ✓ *October 2022 – November 2022 –* ***Final review of all seven sections and development of issues*** *were completed via e-mail collaboration and consensus.*
- ✓ *Sunday, December 4, 2022 –* ***Final recommendations*** *were completed after receiving e-mail consensus.*

1. ***Overview of committee activities:***

*Section 1: Foundations of Food Safety review and updates were completed under the leadership of Champion **Janet Buffer**.*

*Section 2: Employee Health review and updates were completed under the leadership of two Champions **Ashley Eisenbeiser** and **Clay Hosh**.*

*Section 3: Personal Hygiene and Handwashing review and updates were completed under the leadership of Champion **Rachel Scanlan**.*

*Section 4: Preventing Cross-Contamination review and updates were completed under the leadership of Champion **Debbie Pickle**.*

*Section 5: Allergen Control review and updates were completed under the leadership of Champion **Jeff Hawley**.*

*Section 6: Time and Temperature Control for Safety (TCS) review and updates were completed under the leadership of Champion **Sharon Unkart**.*

*Section 7: Cleaning and Sanitizing review and updates were completed under the leadership of Champion **Tara Paster Cammarata**.*

2. ***Charges COMPLETED and the rationale for each specific recommendation:***

   ***Yes**, the charges were successfully completed by the Employee Food Safety Training Committee Members.*

   ***Rationale:** One of the essential elements needed for protecting public health is food employee training. It is critical to take a proactive approach in preventing food employee skill gaps, this is done by imparting knowledge to further develop the food employee's new skills and providing updates on existing skills.*

   The Employee Food Safety Committee updated and addressed food employee knowledge, skills, and abilities (KSA) in the following areas:

   1. *Foundations of Food Safety*
   2. *Employee Health Outcomes*
   3. *Personal Hygiene and Handwashing*
   4. *Preventing Cross-Contamination*
   5. *Allergen Control*
   6. *Time and Temperature Control for Safety (TCS)*
   7. *Cleaning and Sanitizing*

The bench marking of food employee training assists in identifying KSAs; as well as any gaps that may exist. Once these gaps are identified then mitigation strategies can be performed ultimately strengthening the global food supply and protecting public health.

In closing, the Employee Food Safety Training Committee Members worked diligently on both charges according to our committee's calendar of events. The committee members are passionate subject matter experts with "excellence" as the standard. The enthusiasm and engagement are best-in-class with collaboration and consensus as the driving force to complete the committee work.

*The final recommendation of this committee is to **immediately publish** the "Employee Food Safety Training Guidance Document" on the CFP website for all to use.*

3. ***Charges INCOMPLETE and to be continued to next biennium:***

*None. The recommendation is to **disband** the Employee Food Safety Training Committee.*

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

1.

2.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. ***Committee Issue #1***: *Employee Food Safety Training Committee Final Report*

   Acknowledging the Employee Food Safety Training (EFST) Committee final report with attachments and recognize by extending our sincerest gratitude and appreciation to the Committee members for their commitment and hard work.

   Attachments:

   Content Documents:

   Attachment: EFST Committee Final Report (Issues)

   Attachment: Employee Food Safety Training Guidance Document (2017 FDA Food Code)

   Supporting Attachments:

   Attachment: A 10.08.2021 Report

   Attachment: B 03.30.2022 Report

   Attachment: C 09.11.2022 Report

   Attachment: D Roster

2. ***Committee Issue #2***: *Publishing the "**Employee Food Safety Training Guidance Document** (2017 FDA Food Code)"*

   The Employee Food Safety Training (EFST) Committee recommends publishing the "Employee Food Safety Training Guidance Document (2017 FDA Food Code)" on the CFP website.

   Attachments:

   Content Documents:

   Attachment: Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Updated 12.04.2022

The Conference for Food Protection Employee Food Safety Training Committee was re-created and assigned **Issue #2018-II-01** from previous Issue 2016 II-001 that continued work initiated during the 2014 – 2016 biennium from the original Issue 2014-II-011.

The specific charges for the 2021-2023 biennium were to:

1. Review the CFP **"Employee Food Safety Training Guidance Document"** for possible updates; and
2. Report recommendations at the 2023 Biennial Meeting

Each topic category has been placed in its own section, grouped by contributing factor and foundational knowledge, based on the learning objectives. Objectives have been defined, as a roadmap for instructional designers and regulators; each objective has been assigned a KSA type (knowledge, skill, or ability).

KSA definitions:

- **Knowledge:** Understanding each of the Objectives and Measures in the Employee Food Safety Training program.
- **Skills:** Through training and experience, being able to apply each of the Objectives and Measures in the Employee Food Safety Training program.
- **Abilities:** Being able to apply effectively and efficiently each of the Objectives and Measures in the Employee Food Safety Training program in real-world applications.

One of the essential elements needed for protecting public health is **food employee training**. The Employee Food Safety Committee **updated** food employee knowledge, skills, and abilities (KSA)**.** In addition, the references to the 2017 FDA Model Food Code have been noted and specific measures provided in the following seven areas:

1. Foundations of Food Safety
2. Employee Health Outcomes
3. Personal Hygiene and Handwashing
4. Preventing Cross-Contamination
5. Allergen Control
6. Time and Temperature Control for Safety (TCS)
7. Cleaning and Sanitizing

This bench marking of food employee training assists in identifying KSAs; as well as any gaps that may exist. Once these gaps are identified then mitigation strategies can be performed ultimately strengthen the global food supply and protecting public health.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 1: Foundations of Food Safety

Section 1: Foundations of Food Safety	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
1.1	**K**	Identify food hazards (including biological, chemical, and physical).	**1-201.10** Definition: • Hazard	Lists known food hazards as it relates to employee duties: • Identifies foodborne illness as a disease transmitted to people through food.
	S	Applies methods to prevent the contamination of food from biological, chemical, and physical hazards.		• Implements appropriate corrective actions to reduce the risks of food hazards.
1.2	**K**	Identify employee role in controlling food hazards and the impact of their behavior.	**Preface ii**	• Describes the relationship between employee health and hand hygiene, time and temperature control, prevention of cross contamination, cleaning, sanitizing, allergen control and the prevention of cross-contact, and food safety.
1.3	**K**	Understands that some foods will **not** require a pathogen kill step prior to consumption.	**1-201.10** Definition: • Ready-to-Eat	• Explains ready-to-eat food as it relates to employee duties.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 2: Employee Health Outcomes

Section 2: Employee Health Outcomes	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
2.0	**K**	Identify the relationship between working when sick and foodborne illness and the importance of notifying management of reportable illness symptoms, diagnoses, or illness exposure.	**Annex 3** **2-201.11(E)**	• Recognizes that failing to notify management of reportable illness symptoms, diagnoses, and illness exposure may result in the transmission of a disease through food being prepared. • Explains role in reporting process (as required by FDA Food Code).
2.1	**K**	Identify illness symptoms, diagnoses (i.e., Big Six), and illness exposure, which are easily transmissible through food, that must be reported to management.	**2-201.11**	• Lists the illness symptoms, diagnoses, and exposures that must be reported to management.
2.2	**S**	Report required illness symptoms, diagnoses, and illness exposure to management.	**2-201.11(F)**	• Informs management when experiencing illness symptoms, diagnoses, or illness exposures that are reportable.
2.3	**A**	Food employees are aware that they are required to report required illnesses and symptoms to PIC.	**2-103.11(O)**	

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 3: Personal Hygiene and Handwashing

Section 3: Personal Hygiene and Handwashing	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
3.1	**K**	Identify the role of clean outer clothing in preventing contamination of food, equipment, utensils, linens, and single-service and single-use articles.	**2-304.11**	• Wears clean outer clothing.
3.2	**K, S**	Identify when, where, and how to wash hands according to the FDA Food Code.	**2-103.11(D)** **2-301.12** **2-301.14** **2-301.15**	• Washes hands according to the FDA Food Code.
3.3	**S**	Apply FDA Food Code standards for fingernails and jewelry.	**2-302.11** **2-303.11**	• Applies FDA Food Code standards for fingernails and jewelry.
3.4	**K**	Recognize where eating, drinking, and tobacco use is allowed.	**2-401.11**	• Eats, drinks, and smokes only in designated areas.
3.5	**K**	Identify when to use hair restraints to avoid food contamination and which restrains are appropriate according to the FDA Food Code.	**2-402.11**	• Wears appropriate hair restraints when necessary.

3.6	**K** **S**	Describe how to correctly cover a bandage, finger cot, or finger stall located on the wrists, hands, or fingers. Distinguish when and how to use and replace single-use gloves according to the FDA Food Code.	**2-401.13** **3-304.15**	• Covers bandages, finger cots, or finger stalls according to the FDA Food Code. • Uses and replaces single-use gloves according to the FDA Food Code.
3.7	**K**	Describe how to correctly cover infected wound on the hands or forearms.	**2-201.13(I)** **2-401.13**	• Covers infected wounds according to the FDA Food Code.
3.8	**K**	Understands food workers may not care for or handle animals.	**2-403.11**	• Food employees do not handle or care for animals unless allowed by the Food Code.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 4: Preventing Cross-Contamination

Section 4: Preventing Cross-Contamination	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
4.1	**A**	Prevent contamination of all food, including ice, during preparation, storage, and display. Prevent contamination of in-use utensils.	**3-304.12** **3-307.11**	• Prepares, stores, and displays all food in a manner that prevents contamination. • Store in-use utensils in a manner that prevents contamination.
4.2	**A**	Identify potential for food contamination associated with consumer self-service areas.	**3-306.13(B)** **3-306.13(C)** **3-304.17**	• Monitors and notifies a person in charge when a self-service area has potentially become contaminated.
4.3	**A**	Determine when to replace equipment and utensils with clean and sanitized equipment and utensils.	**4-601.11**	• Replaces equipment and utensils with clean and sanitized utensils.
4.4	**K**	Identify how to correctly store cleaned and sanitized utensils and equipment.	**3-304.12**	• Stores cleaned and sanitized utensils in a manner that prevents contamination.
4.5	**S**	Prevent contamination of fruits and vegetables by avoiding bare hand contact after washing raw, uncut fruits and vegetables.	**3-302.15**	• Washes raw, uncut fruits and vegetables prior to preparation or service and avoids bare hand contact once washed.
4.6	**S**	Describe proper storage of food, food containers, single service, and single use articles to prevent contamination.	**3-305.11** **3-305.12** **4-401.11**	• Properly stores food, food containers, single service, and single use articles to prevent contamination.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 5: Allergen Control

Section 5: Allergen Control	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
5.1	**K**	Identify the major food allergens as defined by the FDA Food Code 2017, which includes milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame (upon inclusion in the Food Code).	**1-201.10** Definition: • Major Food Allergen	• Lists the major food allergens as defined by the FDA Food Code.
5.2	**K**	Describe how food employees should communicate with customers to prevent allergic reactions.	**2-103-11(N)**	• Receives food allergen awareness training from person in charge, effectively executes on the training to prevent customer exposure to food allergens.
5.3	**K**	Identify methods for preventing cross-contact when preparing food.	**2-103-11(N)**	• Receives food allergen awareness training from person in charge, effectively executes on the training to prevent customer exposure to food allergens.
5.4	**K**	Recognize the signs of an allergic reaction and respond accordingly.	**2-103-11(N)**	• Receives food allergen awareness training from person in charge, and effectively executes on the training by properly describing how to respond to an allergen emergency.
5.5	**K**	Identify major food allergens on labels; is knowledgeable of proper allergen labeling.	**3-602.11 (B)(5)**	• Receives food allergen awareness training from person in charge, and effectively executes on the training by adhering to proper food allergen labeling.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 6: Time and Temperature Control for Safety (TCS)

Section 6 Time and Temperature Control for Safety	KSA Type	Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
6.1	**K**	Identify foods requiring time and temperature control to reduce the risk of foodborne illness.	**1-201.10** Definition • Time / Temperature Control for Safety Food	• Applies time/temperature controls to TCS foods such as but not limited to the following items: raw or heat-treated animal FOOD, plant FOOD that has been heat treated, raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified, or garlic in oil mixtures that are not modified.
6.2	**K**	Identify the requirements for noncontinuous cooking of TCS foods.	**3-401.14**	• Partially cooks TCS foods according to requirements.
6.3	**A**	Identify how to monitor TCS food temperatures using appropriate temperature measuring devices. Recognize that the temperature of TCS foods must be routinely monitored during cooking, holding, and cooling using a thermometer that meets requirements.	**1-201.10** Definition • Temperature measuring device **2-103.11(G)** **2-103.11(H)** **2-103.11(I)** **Annex 5:** The correct temperature measuring device and technique are essential in accurately determining the temperatures of TCS foods. The geometric center or thickest part of a product are the points of measurement of	• Use temperature measuring devices to monitor temperatures of TCS food. • Routinely monitors temperatures when cooking, holding, and cooling TCS food.

			product temperature particularly when measuring critical limits for cooking.	
6.4	**K**	Identify the appropriate cooking times and temperatures for TCS foods to reduce the risk of foodborne illness.	**3-401** (Raw animal FOOD) **3-401.13** (Plant FOOD for hot holding)	• Cooks TCS food to required minimum internal cooking times/ temperatures.
6.5	**S, A**	Identify the time/temperature requirements for cooling TCS food. Identify proper methods for cooling TCS food.	**3-501.14** **3-501.15**	• Cools TCS food according to time/temperature requirements. • Cools TCS food using a proper cooling method.
6.6	**A**	Apply corrective action to food that has fallen outside time/temperature control.	**3-501.18(A)(1)**	• Applies proper corrective action to food that has fallen outside time / temperature control.
6.7	**K**	Identify methods for safely thawing food according to the FDA Food Code.	**3-501.13**	• Thaws food safely following an approved method.
6.8	**K**	Identify time/temperature requirements for reheating TCS food for hot holding.	**3-403.11**	• Reheats TCS food for hot holding following time and temperature requirements.
6.9	**K**	Identify the time or temperature requirements for holding AND STORING hot and cold TCS food.	**3-501.16** **3-501.19**	• Holds and stores hot and cold TCS food according to time/temperature requirements.
6.10	**K**	Identify the requirements for date marking TCS food.	**3-501.17**	• Date marks TCS food according to requirements.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 7: Cleaning and Sanitizing

Section 7: Cleaning and Sanitizing	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
7.1	**K**	Identify the difference between cleaning and sanitizing.	**1-201.10** Definitions: • Easily Cleanable • Sanitization	Lists cleaning and sanitizing responsibilities as relates to employee duties: • Identifies equipment and facility cleaning activities • Identifies equipment and facility sanitizing activities.
	S	Applies appropriate cleaning and sanitizing methods to reduce the risks to food hazards.	**6-501.12** **6-501.13** **6-501.15** **6-501.16** **6-501.19**	• Demonstrates proper cleaning and sanitizing procedures to reduce the risks to food hazards.
7.2	**K**	Identify the need to follow the specific procedures when using chemicals according to the manufacturer's guidelines and properly storing chemicals in a food establishment.	**7-101.11** **7-102.11** **7-202.11** **7-202.12** **7-203.11** **7-204.11**	• Follows manufacturer's guideline when using chemicals and properly storing chemicals according to the FDA Food Code.
	S	Applies appropriate procedures when using and storing chemicals in a food establishment.		• Demonstrates proper cleaning and sanitizing procedures to reduce the risks to food hazards.

7.3	**K**	Identify food-contact surfaces.	**1-201.10** Definition: • Food-contact surface	• Lists food employee responsibilities and duties as it relates to food contact surfaces.
	S	Applies appropriate procedures on when and how to clean and sanitize food contact surfaces.	**2-103.11(K)** **4-601.11** **4-602.11** **4-602.12** **4-602.13** **4-603.11** **4-701,10** **4-702.11** **4-703.11**	• Demonstrates proper cleaning and sanitizing procedures to prevent, eliminate, and reduce hazards to a safe level when cleaning and sanitizing food contact surfaces.
7.4	**K**	Identify the need to follow the specific procedures when cleaning and sanitizing utensils and equipment.	**1-201.10** Definitions: • Utensil • Equipment • CIP cleaned in place • Counter-mounted equipment • Easily moveable **4-601.11** **4-602.11** **4-602.12** **4-602.13** **4-603.11**	• Follows specific procedures when cleaning and sanitizing utensils and equipment according to the FDA Food Code.

	S	Applies appropriate procedures when cleaning and sanitizing utensils and equipment.	**2-103.11(K)** **3-304.11**	• Demonstrates proper cleaning and sanitizing procedures to reduce the risks to food hazards when cleaning and sanitizing utensils and equipment.
7.5	**K**	Identify the need to follow the specific procedures when using mechanical warewashing.	**1-201.10** Definition: • Warewashing **4-603.12** **4-603.13** **4-603.14**	• Follows specific procedures when using mechanical warewashing according to the FDA Food Code.
	S	Applies appropriate procedures when performing mechanical warewashing.		• Demonstrates proper cleaning and sanitizing procedures to prevent, eliminate, and reduce hazards to a safe level when performing mechanical warewashing.
7.6	**K**	Identify the need to follow the specific procedures when using manual warewashing.	**1-201.10** Definition: • Warewashing **4-301.12** **4-302.14** **4-603.14** **4-603.15** **4-603.16**	• Follows specific procedures when using manual warewashing according to the FDA Food Code.
	S	Applies appropriate procedures when performing manual warewashing.		• Demonstrates proper cleaning and sanitizing procedures to prevent, eliminate, and reduce hazards to a safe level when performing manual warewashing.

7.7	**K**	Identify the need to follow the specific procedures when using and storing wiping cloths.	**3-304.14**	• Follows specific procedures when using and storing wiping cloths according to the FDA Food Code.
	S	Applies appropriate procedures when using and storing wiping cloths.		• Demonstrates proper cleaning and sanitizing procedures to reduce the risks to food hazards when using and storing wiping cloths.
7.8	**K**	Identify the need to follow specific procedures when responding to vomiting and diarrheal events in the food establishment.	**2-501.11**	• Follows specific procedures when responding to vomiting and diarrheal events in the food establishment according to the FDA Food Code.
	S	Applies appropriate procedures when responding to vomiting and diarrheal events in the food establishment.		• Recognizes that failing to follow appropriate procedures when responding to vomiting and diarrheal events in the food establishment may result in the transmission of a disease.

Template approved: 07/13/20/21

Committee Progress Reports are considered DRAFT until accepted by the Executive Board

The Conference Chair, Executive Director, Council Chair, or Issue Chair may return committee reports, Issues, or attached documents requesting edits to improve clarity or understanding, or to include missing information.

Committee-submitted documents may impact the image, credibility and integrity of the Conference as an organization. With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME: Employee Food Safety Training

DATE OF REPORT: ☒ ***Initial fall progress report*** ☐ ***Spring progress report*** ☐ ***Second fall progress report***
Date submitted: 10/8/2021 **Date amended (if applicable):** *Click here to enter a date.* **Date accepted by Executive Board:** *Click here to enter a date.*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY:

COMMITTEE CHARGE(S):

Issue # 2018-II-001

1. *Review the CFP "Employee Food Safety Training Guidance Document" for possible updates (assigned via Issue 2018-II-001); and*
2. *Report recommendations at the 2023 Biennial Meeting.*

COMMITTEE WORK PLAN AND TIMELINE:

1. *Historical perspective review and acknowledgement of the 2016 - 2018 Employee Food Safety Training Committee Final Report*
2. *Thank the past committee members for the completed work and recognize their commitment to CFP*
3. *Welcome and organize the new committee members to complete the assigned charge using collaboration and transparency*
4. *Divide and review the CFP "Employee Food Safety Training Guidance Document" for possible updates*

COMMITTEE ACTIVITIES:

1. ***Dates of committee meetings or conference calls:***

   To be determined once committee is approved by the CFP Executive Board
2. ***Overview of committee activities:***

   Proposed committee roster attached pending CFP Executive Board approval
3. ***Charges COMPLETED and the rationale for each specific recommendation:***

   To be determined
4. ***Status of charges still PENDING and activities yet to be completed:***

   To be determined

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☐ ***Board Action is NOT required and therefore the report can be placed on the consent calendar for Board review and acceptance.***
☒ ***Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.***

1. *Please approve attached committee roster*

ATTACHMENTS:

1. ***Content Documents:***
   a. ***Committee Member Roster:*** ☒ ***See changes noted above under "requested action"*** ☐ ***No changes to previously approved roster***
   "Committee Members Template" (Excel) available at: www.foodprotect.org/work/ *Committee roster to be submitted as a PDF attachment to this report.*
   b. ***Committee Generated Content Documents (OPTIONAL):*** ☐ ***No draft content documents submitted at this time***

2. ***Supporting Attachments (OPTIONAL):*** ☐ ***Not applicable***

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COMMITTEE NAME: Employee Food Safety Training

DATE OF REPORT: ☐ ***Initial fall progress report*** ☒ ***Spring progress report*** ☐ ***Second fall progress report***
Date submitted: 3/30/2022 **Date amended (if applicable):** *Click here to enter a date.* **Date accepted by Executive Board:** *Click here to enter a date.*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Tara Paster Cammarata

COMMITTEE CHARGE(S):

Issue # 2018-II-001

1. *Review the CFP "Employee Food Safety Training Guidance Document" for possible updates (assigned via Issue 2018-II-001); and*
2. *Report recommendations at the 2023 Biennial Meeting.*

COMMITTEE WORK PLAN AND TIMELINE:

1. *Historical perspective review and acknowledgement of the 2016 - 2018 Employee Food Safety Training Committee Final Report*
2. *Thank the past committee members for the completed work and recognize their commitment to CFP*
3. *Welcome and organize the new committee members to complete the assigned charge using collaboration and transparency*
4. *Divide and review the CFP "Employee Food Safety Training Guidance Document" for possible updates*

COMMITTEE ACTIVITIES:

1. ***Dates of committee meetings or conference calls:***
   - ***a.*** *Friday, November 5, 2021*
     Ki Straughn, Dr. Ben Chapman from NC State, and Tara Paster Cammarata reviewed the historical perspective of the 2016 - 2018 Employee Food Safety Training Committee Final Report
   - ***b.*** *Friday, December 10, 2021 – Committee Virtual Meeting*
     Recognized and thanked past committee members; Welcome; Orientation to Committee; Legal review; Expectations; Champions volunteered to lead the different sections of the Guidance Document and the committee accepted the plan calendar for success
   - ***c.*** *Friday, January 14, 2022 – Committee Virtual Meeting:* ***Section 1***
   - ***d.*** *Friday, February 11, 2022 – Committee Virtual Meeting:* ***Section 2***
   - ***e.*** *Friday, March 11, 2022 – Committee Virtual Meeting:* ***Sections 2 & 3***
2. ***Overview of committee activities:***
   - ***a.*** *Section 1: Foundations of Food Safety review and updates were completed under the leadership of Champion* ***Janet Buffer****.*
   - ***b.*** *Section 2: Employee Health review and updates were completed under the leadership of two Champions* ***Ashley Eisenbeiser*** *and* ***Clay Hosh****. This section took two meetings to complete.*
   - ***c.*** *Section 3: Personal Hygiene and Handwashing review and updates were completed under the leadership of Champion* ***Rachel Scanlan****.*
3. ***Charges COMPLETED and the rationale for each specific recommendation:***

   The Employee Food Safety Training Committee Members are working diligently on both charges according to our committee's calendar of events. The committee members are an all-star cast of ***passionate subject matter experts*** *with "****excellence****" as the standard. The enthusiasm and engagement are* ***best-in-class*** *with collaboration and consensus as our driving force to complete the committee work.*

4. ***Status of charges still PENDING and activities yet to be completed:***
   The Employee Food Safety Training Committee is absolutely an amazing group of professionals, and we are 100% on track to complete both charges on time.
   - ***a.*** ***Section 4*** *is schedules for review Friday, April 8, 2022.*
   - ***b.*** ***Section 5*** *is scheduled for review Friday, May 13, 2022.*
   - ***c.*** ***Section 6*** *is scheduled for review Friday, June 10, 2022.*
   - ***d.*** ***Section 7*** *is scheduled for review Friday, July 8, 2022.*

   Our committee would like to thank Jo DeFrancesco and Courtney Halbrook for their support and assistance.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***Board Action is NOT required and therefore the report can be placed on the consent calendar for Board review and acceptance.***

☐ ***Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.***

ATTACHMENTS:

1. ***Supporting Attachments (OPTIONAL):*** ☒ ***Not applicable***

Committee Progress Reports are considered DRAFT until accepted by the Executive Board

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COMMITTEE NAME: Employee Food Safety Training

DATE OF REPORT: ☐ ***Initial fall progress report*** ☐ ***Spring progress report*** ☒ ***Second fall progress report***
Date submitted: 9/11/2022 **Date amended (if applicable):** *Click here to enter a date.* **Date accepted by Executive Board:** *Click here to enter a date.*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Tara Paster Cammarata

COMMITTEE CHARGE(S):

Issue # 2018-II-001

1. *Review the CFP "Employee Food Safety Training Guidance Document" for possible updates (assigned via Issue 2018-II-001); and*
2. *Report recommendations at the 2023 Biennial Meeting.*

COMMITTEE WORK PLAN AND TIMELINE:

1. *Historical perspective review and acknowledgement of the 2016 - 2018 Employee Food Safety Training Committee Final Report*
2. *Thank the past committee members for the completed work and recognize their commitment to CFP*
3. *Welcome and organize the new committee members to complete the assigned charge using collaboration and transparency*
4. *Divide and review the CFP "Employee Food Safety Training Guidance Document" for possible updates*

COMMITTEE ACTIVITIES:

1. ***Dates of committee meetings or conference calls:***
   - ***a.*** *Friday, April 8, 2022 – Committee Virtual Meeting:* ***Section 4***
   - ***b.*** *Friday, May 13, 2022 – Committee Virtual Meeting:* ***Section 4 and 5***
   - ***c.*** *Friday, June 10, 2022 – Committee Virtual Meeting:* ***Sections 6***
   - ***d.*** *Friday, July 8, 2022 – Committee Virtual Meeting:* ***Sections 5 and 6***
   - ***e.*** *Friday, August 12, 2022 – Committee Virtual Meeting:* ***Sections 7***
   - ***f.*** *Friday, September 9, 2022 – Meeting canceled because all sections were completed*
2. ***Overview of committee activities:***
   - ***a.*** *Section 4: Preventing Cross-Contamination review and updates were completed under the leadership of Champion* ***Debbie Pickle****.*
   - ***b.*** *Section 5: Allergen Control review and updates were completed under the leadership of two Champions* ***Jeff Hawley****.*
   - ***c.*** *Section 6: Time and Temperature Control for Safety (TCS) review and updates were completed under the leadership of Champion* ***Sharon Unkart****.*
   - ***d.*** *Section 7: Cleaning and Sanitizing review and updates were completed under the leadership of Champion* ***Lindy Wiedmeyer****.*
3. ***Charges COMPLETED and the rationale for each specific recommendation:***

   The Employee Food Safety Training Committee Members are working diligently on both charges according to our committee's calendar of events. The committee members are an all-star cast of ***passionate subject matter experts*** *with "****excellence****" as the standard. The enthusiasm and engagement are* ***best-in-class*** *with collaboration and consensus as our driving force to complete the committee work.*

4. ***Status of charges still PENDING and activities yet to be completed:***
   The Employee Food Safety Training Committee is absolutely an amazing group of professionals, and we are 100% on track to complete both charges on time.
   - ***a.*** ***Final Report including review of All 7 Sections*** *is scheduled for review Friday, October 14, 2022.*
   - ***b.*** ***Final Report Recommendation presentation*** *is scheduled for review Friday, November 11, 2022.*

Our committee would like to thank Courtney Halbrook for her support and assistance.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***Board Action is NOT required and therefore the report can be placed on the consent calendar for Board review and acceptance.***

☐ ***Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.***

ATTACHMENTS:

1. ***Supporting Attachments (OPTIONAL):*** ☒ ***Not applicable***

2021-2023 Employee Food Safety Training
CFP Committee Roster

Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Straughn	Ki	Chair	Regulatory - Local	PHSKC	Seattle	WA	2062638088	kstraughn@kingcounty.gov
Cammarata	Tara Paster	Co-Chair	Industry - Support	Paster Training, Inc.	Gilbertsville	PA	4844318240	tara.paster@pastertraining.com
Pickle	Debbie	Member	Regulatory - State	TN Department of Health	Nashville	TN	9312154527	Debbie.Pickle@tn.gov
Doherty	Brenden	Member	Regulatory - State	Florida DBPR - Division of Hotels & Restaurants	Tallahassee	FL	8507171260	brenden.doherty@myfloridalicense.com
Mickiewicz	Courtney	Member	Regulatory - State	VDACS	Virginia Beach	VA	7574780307	Courtney.Mickiewicz@vdacs.virginia.gov
Unkart	Sharon	Member	Regulatory - State	National Environmental Health Association	Denver	CO	7203413957	sdunkart@neha.org
Wiedmeyer	Lindy	Member	Regulatory - Local	City of West Allis Health Department	West Allis	WI	2623530344	lwiedmeyer@wesetalliswi.gov
Irving	Felicia	Member	Regulatory - Local	Harris County Enviromental Public Health	Houston	TX	8328400167	felicia.irving@phs.hctx.net
Barajas	Alexis	Member	Regulatory - Local	SNHD	Las Vegas	NV	7029278421	barajas@snhd.org
Henrichs	Amanda	Member	Regulatory - Local	Tulsa Health Department	Tulsa	OK	Need	ahenrichs@tulsa-health.org
Johnson	Jennifer	Member	Industry - Food Service	Yum!	Plano	TX	4077398555	jennifer.johnson@yum.com
Yoo	Joey (Woo Jin)	Member	Industry - Food Service	Compass Group USA	Charlotte	NC	4013270937	woojin.yoo@compass-usa.com
Morrison	Laura	Member	Industry - Food Service	Ohio Restaurant Association	Columbus	OH	6145634495	lmorrison@ohiorestaurant.org
Luebkemann	Geoffrey	Member	Industry - Food Service	Florida Restaurant and Lodging Assn	Tallahassee	FL	8508792581	gluebkemann@frla.org
Payton	Larry	Member	Industry - Retail Food	Tokyo Gardens Catering, LLC	Houston	TX	281515 3132	payton.larry@tgcsushi.com
Hsieh	Hsing-Yi	Member	Industry - Retail Food	Skogen's Festival Foods	De Pere	WI	9205405644	hhsieh@festfoods.com
Boyer	Ellen	Member	Industry - Retail Food	Wakefern Food Corp	Elizabeth	NJ	4843001637	ellen.boyer@wakefern.com
Hawley	Jeffrey	Member	Industry - Retail Food	Harris Teeter	Matthews	NC	7042360890	jhawley@harristeeter.com
Eisenbeiser	Ashley	Member	Industry - Support	FMI	Arlington	VA	2022200689	aeisenbeiser@fmi.org
Chapman	Bryan	Member	Industry - Support	StateFoodSafety	Orem	UT	8013606149	bchapman@statefoodsafety.com
Hosh	Clay	Member	Industry - Support	National Restaurant Association	Chicago	IL	8152630566	chosh@restaurant.org
Dolhanyk	Anne	Member	Consumer	STOP Foodborne Illness	West Linn	OR	3606014264	adolhanyk@gmail.com
Reich	Allen	Member	Academia	Northern Arizona University	Flagstaff	AZ	9288536340	allen.reich@nau.edu

Non-Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
		FDA Consultant	Regulatory - Federal					
		USDA Consultant	Regulatory - Federal					
		CDC Consultant	Regulatory - Federal					
McClellan	Hunter	Alternate	Regulator - State	Nebraska Department of	Lincoln	NE	4024716813	hunter.mcclellan@nebraska.gov
Walker	Matthew	Alternate	Regulator - State	Idaho Department of Health & Welfare	Boise	ID	2089855403	matthew.walker@dhw.idaho.gov
Huffman	Troy	Alternate	Regulator - State	Colorado Dept. of Public Health & Environment	Denver	CO	3036923664	troy.huffman@state.co.us
Hilton	DeBrena	Alternate	Regulator - Local	Tulsa Health Department	Tulsa	OK	9187201618	dhilton@tulsa-health.org
Woods	Yolanda	Alternate	Regulator - Local	Shelby County Government	Memphis	TN	19012229190	yolanda.woods@shelbycountytn.gov
Hernandez	Cris	Alternate	Regulator - Local	Washington County Environmental Health	Hillsboro	OR	5038907637	cris_hernandez@co.washington.or.us
Roughan	George	Alternate	Industry - Support	TAP Series	Westlake Vill	CA	8052178605	groughan@chimsol.com
Koester	Laura	Alternate	Industry - Retail Food	Harmons	Salt Lake Cit	UT	8013490407	laurakoester@harmonsgrocery.com
Allen	Consuelo	Alternate	Industry - Retail Food	Whole Foods Market	Austin	TX	15124268709	consuelo.allen@wholefoods.com
Mello	Wayne	Alternate	Industry - Retail Food	Ahold Delhaize/Retail Business Services	Scarborough	ME	2076329017	wayne.mello@retailbusinessservices.com
Buffer	Janet	Alternate	Industry - Food Service	Amazon	Mount Verno	OH	6145994541	jlbuffer@amazon.com
ONeal	James	Alternate	Industry - Food Service	Denny's	Spartanburg	SC	8034802079	joneal@dennys.com
Zaziski	Linda	Alternate	Industry - Food Service	Little Caesar Enterprises/Blue Line Distribution/Champion Food Service	Detroit	MI	5862436932	linda.zaziski@lcecorp.com
Hill	Michelle	Alternate	Consumer	Allergen Free Cooking	Woodbury	MN	6127014004	michelle@allergenfreecook.com
Chapman	Ben	Alternate	Academia	NC State University	Raleigh	NC	9198093205	bjchapma@ncsu.edu

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Updated 12.04.2022

The Conference for Food Protection Employee Food Safety Training Committee was re-created and assigned **Issue #2018-II-01** from previous Issue 2016 II-001 that continued work initiated during the 2014 – 2016 biennium from the original Issue 2014-II-011.

The specific charges for the 2021-2023 biennium were to:

1. Review the CFP **"Employee Food Safety Training Guidance Document"** for possible updates; and
2. Report recommendations at the 2023 Biennial Meeting

Each topic category has been placed in its own section, grouped by contributing factor and foundational knowledge, based on the learning objectives. Objectives have been defined, as a roadmap for instructional designers and regulators; each objective has been assigned a KSA type (knowledge, skill, or ability).

KSA definitions:

- **Knowledge:** Understanding each of the Objectives and Measures in the Employee Food Safety Training program.
- **Skills:** Through training and experience, being able to apply each of the Objectives and Measures in the Employee Food Safety Training program.
- **Abilities:** Being able to apply effectively and efficiently each of the Objectives and Measures in the Employee Food Safety Training program in real-world applications.

One of the essential elements needed for protecting public health is **food employee training**. The Employee Food Safety Committee **updated** food employee knowledge, skills, and abilities (KSA)**.** In addition, the references to the 2017 FDA Model Food Code have been noted and specific measures provided in the following seven areas:

1. Foundations of Food Safety
2. Employee Health Outcomes
3. Personal Hygiene and Handwashing
4. Preventing Cross-Contamination
5. Allergen Control
6. Time and Temperature Control for Safety (TCS)
7. Cleaning and Sanitizing

This bench marking of food employee training assists in identifying KSAs; as well as any gaps that may exist. Once these gaps are identified then mitigation strategies can be performed ultimately strengthen the global food supply and protecting public health.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 1: Foundations of Food Safety

Section 1: Foundations of Food Safety	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
1.1	**K**	Identify food hazards (including biological, chemical, and physical).	**1-201.10** Definition: • Hazard	Lists known food hazards as it relates to employee duties: • Identifies foodborne illness as a disease transmitted to people through food.
	S	Applies methods to prevent the contamination of food from biological, chemical, and physical hazards.		• Implements appropriate corrective actions to reduce the risks of food hazards.
1.2	**K**	Identify employee role in controlling food hazards and the impact of their behavior.	**Preface ii**	• Describes the relationship between employee health and hand hygiene, time and temperature control, prevention of cross contamination, cleaning, sanitizing, allergen control and the prevention of cross-contact, and food safety.
1.3	**K**	Understands that some foods will **not** require a pathogen kill step prior to consumption.	**1-201.10** Definition: • Ready-to-Eat	• Explains ready-to-eat food as it relates to employee duties.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 2: Employee Health Outcomes

Section 2: Employee Health Outcomes	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
2.0	**K**	Identify the relationship between working when sick and foodborne illness and the importance of notifying management of reportable illness symptoms, diagnoses, or illness exposure.	**Annex 3** **2-201.11(E)**	• Recognizes that failing to notify management of reportable illness symptoms, diagnoses, and illness exposure may result in the transmission of a disease through food being prepared. • Explains role in reporting process (as required by FDA Food Code).
2.1	**K**	Identify illness symptoms, diagnoses (i.e., Big Six), and illness exposure, which are easily transmissible through food, that must be reported to management.	**2-201.11**	• Lists the illness symptoms, diagnoses, and exposures that must be reported to management.
2.2	**S**	Report required illness symptoms, diagnoses, and illness exposure to management.	**2-201.11(F)**	• Informs management when experiencing illness symptoms, diagnoses, or illness exposures that are reportable.
2.3	**A**	Food employees are aware that they are required to report required illnesses and symptoms to PIC.	**2-103.11(O)**	

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 3: Personal Hygiene and Handwashing

Section 3: Personal Hygiene and Handwashing	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
3.1	**K**	Identify the role of clean outer clothing in preventing contamination of food, equipment, utensils, linens, and single-service and single-use articles.	**2-304.11**	• Wears clean outer clothing.
3.2	**K, S**	Identify when, where, and how to wash hands according to the FDA Food Code.	**2-103.11(D)** **2-301.12** **2-301.14** **2-301.15**	• Washes hands according to the FDA Food Code.
3.3	**S**	Apply FDA Food Code standards for fingernails and jewelry.	**2-302.11** **2-303.11**	• Applies FDA Food Code standards for fingernails and jewelry.
3.4	**K**	Recognize where eating, drinking, and tobacco use is allowed.	**2-401.11**	• Eats, drinks, and smokes only in designated areas.
3.5	**K**	Identify when to use hair restraints to avoid food contamination and which restrains are appropriate according to the FDA Food Code.	**2-402.11**	• Wears appropriate hair restraints when necessary.

3.6	**K** **S**	Describe how to correctly cover a bandage, finger cot, or finger stall located on the wrists, hands, or fingers. Distinguish when and how to use and replace single-use gloves according to the FDA Food Code.	**2-401.13** **3-304.15**	• Covers bandages, finger cots, or finger stalls according to the FDA Food Code. • Uses and replaces single-use gloves according to the FDA Food Code.
3.7	**K**	Describe how to correctly cover infected wound on the hands or forearms.	**2-201.13(I)** **2-401.13**	• Covers infected wounds according to the FDA Food Code.
3.8	**K**	Understands food workers may not care for or handle animals.	**2-403.11**	• Food employees do not handle or care for animals unless allowed by the Food Code.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 4: Preventing Cross-Contamination

Section 4: Preventing Cross-Contamination	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
4.1	**A**	Prevent contamination of all food, including ice, during preparation, storage, and display. Prevent contamination of in-use utensils.	**3-304.12** **3-307.11**	• Prepares, stores, and displays all food in a manner that prevents contamination. • Store in-use utensils in a manner that prevents contamination.
4.2	**A**	Identify potential for food contamination associated with consumer self-service areas.	**3-306.13(B)** **3-306.13(C)** **3-304.17**	• Monitors and notifies a person in charge when a self-service area has potentially become contaminated.
4.3	**A**	Determine when to replace equipment and utensils with clean and sanitized equipment and utensils.	**4-601.11**	• Replaces equipment and utensils with clean and sanitized utensils.
4.4	**K**	Identify how to correctly store cleaned and sanitized utensils and equipment.	**3-304.12**	• Stores cleaned and sanitized utensils in a manner that prevents contamination.
4.5	**S**	Prevent contamination of fruits and vegetables by avoiding bare hand contact after washing raw, uncut fruits and vegetables.	**3-302.15**	• Washes raw, uncut fruits and vegetables prior to preparation or service and avoids bare hand contact once washed.
4.6	**S**	Describe proper storage of food, food containers, single service, and single use articles to prevent contamination.	**3-305.11** **3-305.12** **4-401.11**	• Properly stores food, food containers, single service, and single use articles to prevent contamination.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 5: Allergen Control

Section 5: Allergen Control	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
5.1	**K**	Identify the major food allergens as defined by the FDA Food Code 2017, which includes milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame (upon inclusion in the Food Code).	**1-201.10** Definition: • Major Food Allergen	• Lists the major food allergens as defined by the FDA Food Code.
5.2	**K**	Describe how food employees should communicate with customers to prevent allergic reactions.	**2-103-11(N)**	• Receives food allergen awareness training from person in charge, effectively executes on the training to prevent customer exposure to food allergens.
5.3	**K**	Identify methods for preventing cross-contact when preparing food.	**2-103-11(N)**	• Receives food allergen awareness training from person in charge, effectively executes on the training to prevent customer exposure to food allergens.
5.4	**K**	Recognize the signs of an allergic reaction and respond accordingly.	**2-103-11(N)**	• Receives food allergen awareness training from person in charge, and effectively executes on the training by properly describing how to respond to an allergen emergency.
5.5	**K**	Identify major food allergens on labels; is knowledgeable of proper allergen labeling.	**3-602.11 (B)(5)**	• Receives food allergen awareness training from person in charge, and effectively executes on the training by adhering to proper food allergen labeling.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 6: Time and Temperature Control for Safety (TCS)

Section 6 Time and Temperature Control for Safety	KSA Type	Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
6.1	**K**	Identify foods requiring time and temperature control to reduce the risk of foodborne illness.	**1-201.10** Definition • Time / Temperature Control for Safety Food	• Applies time/temperature controls to TCS foods such as but not limited to the following items: raw or heat-treated animal FOOD, plant FOOD that has been heat treated, raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified, or garlic in oil mixtures that are not modified.
6.2	**K**	Identify the requirements for noncontinuous cooking of TCS foods.	**3-401.14**	• Partially cooks TCS foods according to requirements.
6.3	**A**	Identify how to monitor TCS food temperatures using appropriate temperature measuring devices. Recognize that the temperature of TCS foods must be routinely monitored during cooking, holding, and cooling using a thermometer that meets requirements.	**1-201.10** Definition • Temperature measuring device **2-103.11(G)** **2-103.11(H)** **2-103.11(I)** **Annex 5:** The correct temperature measuring device and technique are essential in accurately determining the temperatures of TCS foods. The geometric center or thickest part of a product are the points of measurement of	• Use temperature measuring devices to monitor temperatures of TCS food. • Routinely monitors temperatures when cooking, holding, and cooling TCS food.

			product temperature particularly when measuring critical limits for cooking.	
6.4	**K**	Identify the appropriate cooking times and temperatures for TCS foods to reduce the risk of foodborne illness.	**3-401** (Raw animal FOOD) **3-401.13** (Plant FOOD for hot holding)	• Cooks TCS food to required minimum internal cooking times/ temperatures.
6.5	**S, A**	Identify the time/temperature requirements for cooling TCS food. Identify proper methods for cooling TCS food.	**3-501.14** **3-501.15**	• Cools TCS food according to time/temperature requirements. • Cools TCS food using a proper cooling method.
6.6	**A**	Apply corrective action to food that has fallen outside time/temperature control.	**3-501.18(A)(1)**	• Applies proper corrective action to food that has fallen outside time / temperature control.
6.7	**K**	Identify methods for safely thawing food according to the FDA Food Code.	**3-501.13**	• Thaws food safely following an approved method.
6.8	**K**	Identify time/temperature requirements for reheating TCS food for hot holding.	**3-403.11**	• Reheats TCS food for hot holding following time and temperature requirements.
6.9	**K**	Identify the time or temperature requirements for holding AND STORING hot and cold TCS food.	**3-501.16** **3-501.19**	• Holds and stores hot and cold TCS food according to time/temperature requirements.
6.10	**K**	Identify the requirements for date marking TCS food.	**3-501.17**	• Date marks TCS food according to requirements.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 7: Cleaning and Sanitizing

Section 7: Cleaning and Sanitizing	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
7.1	**K**	Identify the difference between cleaning and sanitizing.	**1-201.10** Definitions: • Easily Cleanable • Sanitization	Lists cleaning and sanitizing responsibilities as relates to employee duties: • Identifies equipment and facility cleaning activities • Identifies equipment and facility sanitizing activities.
	S	Applies appropriate cleaning and sanitizing methods to reduce the risks to food hazards.	**6-501.12** **6-501.13** **6-501.15** **6-501.16** **6-501.19**	• Demonstrates proper cleaning and sanitizing procedures to reduce the risks to food hazards.
7.2	**K**	Identify the need to follow the specific procedures when using chemicals according to the manufacturer's guidelines and properly storing chemicals in a food establishment.	**7-101.11** **7-102.11** **7-202.11** **7-202.12** **7-203.11** **7-204.11**	• Follows manufacturer's guideline when using chemicals and properly storing chemicals according to the FDA Food Code.
	S	Applies appropriate procedures when using and storing chemicals in a food establishment.		• Demonstrates proper cleaning and sanitizing procedures to reduce the risks to food hazards.

7.3	**K**	Identify food-contact surfaces.	**1-201.10** Definition: • Food-contact surface	• Lists food employee responsibilities and duties as it relates to food contact surfaces.
	S	Applies appropriate procedures on when and how to clean and sanitize food contact surfaces.	**2-103.11(K)** **4-601.11** **4-602.11** **4-602.12** **4-602.13** **4-603.11** **4-701,10** **4-702.11** **4-703.11**	• Demonstrates proper cleaning and sanitizing procedures to prevent, eliminate, and reduce hazards to a safe level when cleaning and sanitizing food contact surfaces.
7.4	**K**	Identify the need to follow the specific procedures when cleaning and sanitizing utensils and equipment.	**1-201.10** Definitions: • Utensil • Equipment • CIP cleaned in place • Counter-mounted equipment • Easily moveable **4-601.11** **4-602.11** **4-602.12** **4-602.13** **4-603.11**	• Follows specific procedures when cleaning and sanitizing utensils and equipment according to the FDA Food Code.

	S	Applies appropriate procedures when cleaning and sanitizing utensils and equipment.	**2-103.11(K)** **3-304.11**	• Demonstrates proper cleaning and sanitizing procedures to reduce the risks to food hazards when cleaning and sanitizing utensils and equipment.
7.5	**K**	Identify the need to follow the specific procedures when using mechanical warewashing.	**1-201.10** Definition: • Warewashing **4-603.12** **4-603.13** **4-603.14**	• Follows specific procedures when using mechanical warewashing according to the FDA Food Code.
	S	Applies appropriate procedures when performing mechanical warewashing.		• Demonstrates proper cleaning and sanitizing procedures to prevent, eliminate, and reduce hazards to a safe level when performing mechanical warewashing.
7.6	**K**	Identify the need to follow the specific procedures when using manual warewashing.	**1-201.10** Definition: • Warewashing **4-301.12** **4-302.14** **4-603.14** **4-603.15** **4-603.16**	• Follows specific procedures when using manual warewashing according to the FDA Food Code.
	S	Applies appropriate procedures when performing manual warewashing.		• Demonstrates proper cleaning and sanitizing procedures to prevent, eliminate, and reduce hazards to a safe level when performing manual warewashing.

7.7	**K**	Identify the need to follow the specific procedures when using and storing wiping cloths.	**3-304.14**	• Follows specific procedures when using and storing wiping cloths according to the FDA Food Code.
	S	Applies appropriate procedures when using and storing wiping cloths.		• Demonstrates proper cleaning and sanitizing procedures to reduce the risks to food hazards when using and storing wiping cloths.
7.8	**K**	Identify the need to follow specific procedures when responding to vomiting and diarrheal events in the food establishment.	**2-501.11**	• Follows specific procedures when responding to vomiting and diarrheal events in the food establishment according to the FDA Food Code.
	S	Applies appropriate procedures when responding to vomiting and diarrheal events in the food establishment.		• Recognizes that failing to follow appropriate procedures when responding to vomiting and diarrheal events in the food establishment may result in the transmission of a disease.

Template approved: 7/13/2021

Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME Local Regulatory Representation

DATE OF FINAL REPORT: *11/09/22*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Chair Pieter A. Sheehan, Vice Chair, Jo DeFrancesco

COMMITTEE CHARGE(S):

Issue # 2020 II-10 To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:

- Examining the current Bylaws to include an historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
- Report back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
- Include representation from the Constitution and Bylaws Committee to assist in the development of recommendations and amendments from the findings determined in this charge.

COMMITTEE WORK PLAN AND TIMELINE:

1. Ongoing: Historical perspective review of CFP Constitution and Bylaws.
2. April 2022 :Organizational call
3. May 2022- July: Finalize survey and obtain recipient list. Survey current CFP local regulatory members to gather perspectives on the level to which CFP's organizational structure and biennial activities promote communication and collaboration among local regulators and between state and local regulators. Determine if there is outreach to locals from their elected representatives serving on the Executive Board; and is local regulatory participation extending beyond serving on the Board, Standing Committees, Council Committees, and Councils to voting representation on the Assembly of Delegates important to local regulators. Use survey results to inform committee's work to explore representation of local regulators on the Assembly of Delegates.
4. June 2022: Request assistance from Constitution & Bylaws/Procedures Committee for development of any recommendations to amend the Constitution & Bylaws or other governing documents based on outcome of work from charge #1.
5. July -August of 2022: review tentative survey data and determine further actions needed. Potentially survey other groups for information. Compile survey data and look for other ways to obtain local input on the issue.
6. September 2022: begin wrapping up survey activities and determine if enough data has been gathered to make a recommendation to change the Constitution and Bylaws. Begin work on any suggested changes.
7. October 2022: Committee met to discuss the final report to the board and any issues to be submitted.

8. November 2022: Prepare final report to the board and finalize issue from committee work.

, COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

1. ***Overview of committee activities:***

   04/26/22, 05/06/2022, 06/03/22, 07/15/22, 08/09/22, 09/05/22, 09/16/22, 10/07/22, 110/28/22, 11/4/2022

2. ***Charges COMPLETED and the rationale for each specific recommendation:***

   Charge 1: Examining the current Bylaws to include an historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates. This work resulted in recommendations to the Board to consider rewriting the responsibilities of Executive Board members.

   Charge 2: Report back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium. The committee did report back to the Executive Board during the October, 2022 Executive Board meeting as charged in Issue 2020-II-010. That meeting resulted in the Board accepting rewritten responsibilities of Executive Board members.

   Charge 3: Include representation from the Constitution and Bylaws Committee to assist in the development of recommendations and amendments from the findings determined in this charge.
   Member of Constitution and Bylaws Committee was present on all calls beginning 05/06/22 and provided clarification when necessary. Mr. Sean Dunleavy served as the representative of the Constitution and Bylaws Committee.

3. ***Charges INCOMPLETE and to be continued until the next biennium: n/a***

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. Local Regulatory Voting Representation

- Acknowledge the Committee report and thank the Committee members for their time.
- Acknowledge that the Committee did examine the current Bylaws, including a historical perspective and did explore methods to provide representation of local regulators on the Assembly of State Delegates, as charged in Issue 2020-II-010. This work resulted in recommendations to the Board to consider rewriting the responsibilities of Executive Board members.
- Acknowledge that the Committee did report back to the Executive Board during the October 2022 Executive Board meeting as charged in Issue 2020-II-010. That meeting resulted in the Board accepting rewritten responsibilities of Executive Board members.
- Acknowledge that the Committee did include representation from the Constitution and Bylaws Committee to assist in the development of recommendations and amendments from the findings determined as charged in Issue 2020-II-010. Mr. Sean Dunleavy served as the representative of the Constitution and Bylaws Committee.
- Disband the Committee as all charges from Issue 2020-II-010 have been completed.

a. ***Report – Committee Name:*** *Local Regulatory Representation Committee*

b. **List of content documents submitted with this Issue:** *Committee Member Roster*

☐ ***See attached revised roster PDF*** ☒ ***No changes to previously approved roster***

c. ***Other content documents:*** **List of supporting attachments:** ☐ ***Not applicable***

(c.i.1) **Survey Results II 22 10, PPT 22 11 10, Master Agenda and Minutes**

1. ***Committee Issue #2***:
2. ***Committee Issue #3***:

Committee Name: Local Regulatory

Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Sheehan	Pieter	Co-Chair	Regulatory -Local	Fairfax County Health Department	Fairfax	VA	7032468470	pieter.sheehan@fairfaxcounty.gov
DeFrancesco	Joetta	Co-Chair	Industry-Support	NEHA	Tallahassee	FL	2394052211	jdefrancesco@NEHA.org
Carmody	Steve	Member	Regulatory- State	FDACS, Division of Food Safety	Orlando	FL	8507288849	stephen.carmody@fdacs.gov
Hutson	Jennifer	Member	Regulatory- State	WV DHHR Bureau for Public Health	Charleston	WV	(304)550-5292	jennifer.eb.hutson@wv.gov
Copeland	Deanna	Member	Regulatory -Local	Harris County Public Health	Houston	TX	713-248-4396	dcopeland@hcphes.org
Ferris	Leah	Member	Regulatory -Local	Clay County Public Health Center	Liberty	MO	8162605542	lferris@clayhealth.com
Walker	Stevan	Member	Regulatory -Local	City of Lubbock	Lubbock	TX	8067752116	mswalker@mylubbock.us
Sigler	Larry	Member	Industry - Food Service	Waffle House	Norcross	GA	(404) 518 – 2041	larrysigler@wafflehouse.com
Westbrook	Tim	Member	Industry - Retail Food	Publix Super Markets, Inc.	Orlando	FL	352-989-7314	tim.westbrook@publix.com
Guzzle	Patrick	Member	Industry - Support	National Restaurant	Boise	ID	208-515-8688	pguzzle@restaurant.org
Wood	Sharon	Member	Emeritus		San Antonio	TX	210-913-1333	spwood1983@outlook.com
Crawford, Ed.D.	Herman	Member	Academia	Nutri-Rific LLC	Webster	NY	9728850067	NUTRIRIFIC@GMAIL.COM

Non-Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Sudler	Robert	FDA Consultant	Regulatory - Federal	FDA	College Park	MD	240-402-1943	Robert.Sudler@fda.hhs.gov
Nattrass	Steve	FDA Alternate	Regulatory - Federal	FDA			860-240-4289 x 18	Steven.Nattrass@fda.hhs.gov
No appointee		USDA Consultant	Regulatory - Federal					
No appointee		CDC Consultant	Regulatory - Federal					
Dimaggio	Michele	Alternate	Regulatory -Local	Contra Costa County Environmental Health	Concord	CA	9253833053	michele.dimaggio@cchealth.org
Michael	Otzelberger	Alternate	Regulatory - Local	City of Milwaukee Health	Milwaukee	WI	414-708-1591	motzel@milwaukee.gov
Botsford	Jennifer	Alternate	Regulatory- State	ADHS	Phoeniz	AZ	6023643142	jennifer.botsford@azdhs.gov
McClellan	Hunter	Alternate	Regulatory- State	Nebraska Department of	Lincoln	NE	4024716813	hunter.mcclellan@nebraska.gov
Peri	Pearson	Alternate	Regulatory- State	Virginia Department of	Richmond	VA	8043047433	peri.pearson@vdh.virginia.gov
Modi	Rupesh	Alternate	Industry - Retail Food	HISSHO SUSHI	Charlotte	NC	6519556520	rmodi@hisshosushi.com
Sanchez	Angela	Alternate	Industry - Retail Food	AMAZON	Nashville	TN	951-201-4168	ajaynethomas@yahoo.com
Sweet	Bridget	Chair	Industry Retail Food	Amtrack	Providence	RI	4015985171	blsweet9@gmail.com

Note: *Minimum council committee size is 11 (as noted above): 1-Chair; 1-Vice Chair; 1-State; 1-Local; 2-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise; 6-Non-voting alternates. Maximum council committee size is 23 voting members: 1-Chair; 1-Vice Chair; 4-State; 4-Local; 8-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise; 18-Non-voting alternates.*
Membership on standing committees is defined by the Executive Board. On all CFP committees, the committee chair, co-chair(s), and vice chair(s) all count towards constituency balance.

Local Regulatory Representation Agenda and Minutes

10/28/22

- To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:
    1. Examining the current by-laws to include a historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
    2. Reporting back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
    3. Including representation from the Constitution and By-laws Committee to assist in the development of recommendations and amendments from the findings determined in charges.

- Welcome – Jo
- Attendance- 7 voting members needed for a quorum – only 5 voting members present, Jo, Patrick Guzzle, Steve Carmody, Tim Westbrook, Herman Crawford

Reviewed Information on the Constitution and Bylaws pertaining to charges. Several Key items noted:

1) The Body of Delegates exists to ratify the votes that have already taken place in Council
2) Industry, Academia, and other constituencies also do have a vote on the Assembly of Delegates
3) The final guiding principle was the need to ensure that the Conference would provide a national and, to the extent possible, international dialogue on food safety on a regular, periodic basis, and that this dialogue would be among representatives of regulatory, industry, and other non-regulatory organizations.

Discussion on issues to submit to Council II.

1) Options were to reform the committee with better charges or dissolve the committee and make and respectfully make recommendations to the board in our final report. (Our final Report goes to the Board).

2) The consensus among the group on the call was to not reform the committee for the next biennium due to reasons listed below.

- Like Industry, Local Regulators can take part in the CFP process and have a voice by participating in committee work, and on councils.
- Local regulators can use the caucus process to aid in addressing concerns.
- We will ask the board to continue working towards increased communication with and to Local Regulators to promote greater involvement.
- Points 1 through 3 above
- This committee has been unable to obtain a quorum for the last several meetings thus making it harder to complete work or have in-depth discussion on issues. There has been minimal

committee participation throughout the last 6 months. It is hard to ask to extend the committee work with low attendance and participation.

Discussion for Call:

Reminder of information provided to Board at beginning of meetings on the Constitution and Bylaws

Constitution and Bylaws Discussion

- The rules for the Assembly of Delegates are spelled out in XIX (19) of the C&B
- All Delegates are required to list their alternate should they (Delegate) not be able to attend. The chosen alternate is at the discretion of the Delegate. There have been instances where the Delegate named a local regulatory representative to be the alternate Delegate and where a State Delegate named a neighboring State to be their alternate. (Side note: One possible consideration is to have the Local Regulatory Board members be Delegates. If this were decided, we would place that Local Regulatory Board member in a position where he/she is now responsible for representing hundreds of other local jurisdictions at the Delegates meeting. Additionally, let's suppose that Local Regulatory Board member is from Florida – we are now watering down Florida's vote to ¼ instead of the current 1/3 vote). It is possible that many members are not aware that all Delegates are required to list an alternate – and that the alternate is at the discretion of the Delegate.
- While the C&B is certainly open for revisions, the logistics of including local regulatory representatives in the Body of Delegates presents difficulty. Specifically, there are over 3300 local health departments in the United States and just over 50 state agencies. It should be recognized that trying to manage 50+ delegates is vastly easier than trying to account for the 3300+ local agencies.
- Page iii of the C&B describes the history in more detail – including the format and ratification process (which was modeled after the National Conference on Interstate Milk Shipments) that was decided in the 1980's. From page iii:
    - The final step in the decision to upgrade the Conference organization was taken at the 1986 Conference. The Program Committee reported that: "It was the unanimous view of the committee that the Conference should operate as an action organization, existing not merely to identify problems and formulate recommendations, but to resolve issues through the implementation of recommendations, much as the Weights and Measures Conference and the Interstate Milk Shippers do. Specific recommendations in this regard will be presented prior to the next Conference." (Page 410, Proceedings) To accomplish this, the 1986 Conference agreed: • To develop a state regulatory ratification mechanism whereby each of the 50 states will have one vote; and • To create a Constitution and Bylaws Committee to review the entire Constitution and Bylaws and to formulate recommendations for the Executive Committee to consider.
- Body of Delegates *ratifies* the vote that has already taken place in Council (where local regulatory representatives ARE involved in the vote)
- Pages iv and v of the C&B provide additional insight. From page iv:

    - The second principle that guided the review process was the need for the Conference to be more successful in promoting food safety, mutual respect, and uniformity. This was accomplished through the following changes: 1. The final actions taken by the Conference regarding such items as food safety controls, certification procedures, and Memoranda of Understanding, were to be adopted by the regulatory delegates of the Conference with the advice of industry and other non-regulatory members;
- Page v:
    - The final guiding principle was the need to ensure that the Conference would provide a national and, to the extent possible, international dialogue on food safety on a regular, periodic basis, and that this dialogue would be among representatives of regulatory, industry, and other non- regulatory organizations.

Discussion Points to turn into Potential Issues

The group produced several problems to be addressed when writing issues. They are placed into 3 categories

1) There is no Local Regulatory Representation voting during the Assembly of Delegates since only states are allowed to vote.
    - Many local jurisdictions are active in CFP and their state counterparts less so.
    - States and local jurisdictions may not use the same standards to protect food safety. (Local jurisdiction using the 2017 Food Code, the State still using 2005)
2) Communication to Local Regulators from States is usually top down and appears not to happen frequently, specifically on issues and voting.
    - States may not take into consideration the impacts of their votes on Local jurisdictions.
    - This could be potentially tasked to the Strategic Planning Committee on the board of Directors.

    Clarity is needed on the position description for members of the Assembly of Delegates (Is there one?) and a deep dive historical look at the Constitution and Bylaws and sates roles in the process. (This was addressed in first two meetings.)
    - Constitution and by-laws may be biased in favor of the states.
    - Constitution and by laws may make assumptions about the roles of both State and Local Jurisdictions in the CFP process as well as to what is occurring at the state level.

An additional idea, that had support is to ask the board if we can survey the members of CFP at the Biennium conference. The survey could be provided electronically or in paper form and, if approved the committee could man a table at the conference to gather as much input as possible.

Lastly a committee member reached out to Jo on bringing up the possibility of allowing the Regional Local representative to vote. Although this has been discussed I wanted to make sure all voices were heard

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10/07/2022

Charges

- To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:
    4. Examining the current by-laws to include a historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
    5. Reporting back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
    6. Including representation from the Constitution and By-laws Committee to assist in the development of recommendations and amendments from the findings determined in charges.

Meeting Agenda

- Welcome – Jo
- Attendance- 7 voting members needed for a quorum
- Sharon Wood and Patrick Guzzle proposed that the committee suggest a change in the language of the Executive Board Member job description.
- Old Language:
    - Communicates with and updates their respective constituencies on the progress of CFP.
- Suggested New Language:
    - Actively and regularly communicates and reports CFP business and updates to their associated constituency using appropriate venues to include, but not limited to, professional groups, institutions, associations, newsletters, social media groups, and / or presentations to maintain a high level of knowledge on the status of CFP activities and pending issues being addressed.
- The group agreed to suggestions on the language change and to ask the board to reform the committee to be able to expand the study of the issue. This committee did not have a great deal of time, and the last few meetings did not have a quorum when voting was necessary
- Jo will put the two items to an e-vote and amend the report to the executive board.
- E- Vote to accept previous meeting minutes from 08.05.2022 and from 09.02.22 minutes accepted with 7 yes votes.
- The executive board voted to pass the change to the position description and understands that additional work is needed on Local Representation. A big thank you to Sharon and Patrick for their work on this matter.
- Discussion now needed on issue submission to reform committee and drafting charges to further guide the process.

09/16/2022

Charges

- To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:
    7. Examining the current by-laws to include a historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
    8. Reporting back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
    9. Including representation from the Constitution and By-laws Committee to assist in the development of recommendations and amendments from the findings determined in charges.

Meeting Agenda

- Welcome – Jo
- Attendance- 7 voting members needed for a quorum – Quorum not present
- Current survey results – Still at 25
- From 09/02 Need someone to sort through information that we do have to determine if anything can be inferred. Steve Carmody will evaluate data and the group will discuss it on 09/16. Steve was unable to fully evaluate due to promotion.
- The committee discussed the survey and implications of information flow to local regulators.
- Sharon Wood and Patrick Guzzle proposed that the committee suggest a change in the language of the Executive Board Member job description.
- Old Language:
    - Communicates with and updates their respective constituencies on the progress of CFP.
- Suggested New Language:
    - Actively and regularly communicates and reports CFP business and updates to their associated constituency using appropriate venues to include, but not limited to, professional groups, institutions, associations, newsletters, social media groups, and / or presentations to maintain a high level of knowledge on the status of CFP activities and pending issues being addressed.
- The group agreed to suggestions on the language change and to ask the board to reform the committee to be able to expand the study of the issue. This committee did not have a great deal of time, and the last few meetings did not have a quorum when voting was necessary.
- The group recognizes the implications of changing the Constitution and Bylaws and the amount of time and effort it could take to adopt and implement any changes to include local representation

- Jo will put the two items to an e-vote and amend the report to the executive board.
- E- Vote to accept previous meeting minutes from 08.05.2022 and from 09.02.22 minutes accepted with 7 yes votes.

Reminder, final report is to be submitted to the Executive Board.
Call ended at 1:00 pm EST

09/02/2022 Minutes

Charges

- To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:
  10. Examining the current by-laws to include an historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
  11. Reporting back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
  12. Including representation from the Constitution and By-laws Committee to assist in the development of recommendations and amendments from the findings determined in charges.

Meeting Agenda

- Welcome – Jo
- Attendance- 7 voting members needed for a quorum – Quorum not present until end of meeting.
- Antitrust Statement reminder- Jo
- Vote to accept previous meeting minutes from 08.05.2022 and from 09.02.22, e-vote

Reminder, final report is to be submitted to the Executive Board.

Survey

Current Results – Still at 25

- How do we obtain additional information prior to final report?
- Need someone to sort through information that we do have to determine if anything can be inferred. Steve Carmody will evaluate data and group will discuss on 09/16

Other Items

- Discussion needed on the impact of changes to the Constitution and Bylaws.
- Discussion on issues facing Local regulators and the impacts on knowledge of and involvement in CFP

- Jo will schedule call for 09/16 for discussion on survey data and ideas that can be presented to Executive Board in Lieu of changes to Constitution and By Laws. Group agreed on date.

08.05.2022 Minutes

Charges

- To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:
  13. Examining the current by-laws to include an historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
  14. Reporting back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
  15. Including representation from the Constitution and By-laws Committee to assist in the development of recommendations and amendments from the findings determined in charges.

Meeting Agenda

- Welcome – Jo
- Attendance- 7 voting members needed for a quorum- quorum was present
- Antitrust Statement reminder- Jo
- Vote to accept previous meeting minutes from 05.06.22 and 06.04.22 due to lack of quorum on previous call – unable to vote no quorum present
- Online vote for meeting minutes 9 yes votes. Motion to accept minutes from 05.06.22 and 06.04.22 passes.
- Vote to accept previous meeting minutes from 07.15.22

Survey

- Current Status
  - Pieter to send out survey next week to CFP Local members.
- Need to try to reach larger audience. To that end we are reaching out to other potential groups of locals for input.
- Deadline to send out survey to other organizations and obtain results- end of September.
- Remember issue submission is fast approaching. We will need recommendations for potential realistic wording for representation and placement in Constitution and Bylaws.
- Discussion on ways to potentially get more information to use in the final report.
- Meeting Adjourned

07.15.2022

Charges

- To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:
  16. Examining the current by-laws to include an historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
  17. Reporting back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
  18. Including representation from the Constitution and By-laws Committee to assist in the development of recommendations and amendments from the findings determined in charges.

Meeting called to order

- Welcome – Jo called meeting to order
- Attendance- 7 voting members needed for a quorum- no quorum present
- Antitrust Statement reminder- Jo
- Vote to accept previous meeting minutes from 05.06.22 and 06.04.22 due to lack of quorum on previous call – unable to vote no quorum present

Survey

- Current Status
  - Link and voting information emailed out on 05.03.22
  - Pieter sent out survey next week to CFP Local members.
- Sam Gaber- Member of Pieter Sheehan's staff- gave brief overview of survey results and a couple key comments.
- Group discussed next steps with Survey-
- Need to try to reach larger audience. To that end we are reaching out to other potential groups of locals for input
  Michelle DiMaggio will reach out to NEHA
  Deanna Copeland will reach out to AFDO
  Pieter Sheehan will reach out to NACCHO
- New Overview/Intro Paragraph to be drafted – Hunter McClellan has agreed to draft
- Deadline for outreach to other organizations and for intro to survey set as Friday July 22nd. Please, report back to committee with information on outreach.
- A big thank you to everyone that has agreed to step up and help out.
- Once results are back we will need to determine actions needed to address issue.
  Jo reminded everyone to become familiar with the Constitution and By-laws
- Jo will start email thread to vote on minutes as well as discuss any needed committee work.
- Next meeting August 5th at 12:00.

Meeting adjourned 12:23

- Group to work on data- July Call
- Next steps for use of information?? Discussion
- Discussion to determine where changes may be needed in Constitution and Bylaws when survey is complete (LINK)

Increasing Local Regulatory Involvement in CFP and committee work

- Comment from voting process – will add to agenda of next call
- Discuss with group

New Business

- **It was brought up that the next call was right before a holiday weekend. Call Changed to the 15th of July to avoid any issues for people traveling for the Holiday.**

Motion to adjourn: Second:

Local Regulatory Representation Agenda

Local Regulatory Representation Minutes

06.03.22

Charges

- To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:
  19. Examining the current by-laws to include an historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
  20. Reporting back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
  21. Including representation from the Constitution and By-laws Committee to assist in the development of recommendations and amendments from the findings determined in charges.

Meeting called to order

- Welcome – Jo
- Attendance- 7 voting members needed for a quorum- no Quorum 4 Voting members
- Antitrust Statement reminder- Jo
- Vote to accept previous meeting minutes from 05.06.22: Unable to vote will vote on next call

Survey

- Current Status
  - Link and voting information emailed out on 05.03.22

- Motion made by Steven Carmody to accept the Survey as it was currently written, Seconded by Deana Copeland
- Vote passed on 05/16 with 8 voting members agreeing to send out survey with adjustments from last call to CFP local members
- Survey has not yet been sent out to Local Members
- Pieter will send out survey next week to CFP Local members. Jo will resend list of emails

- Group to work on data- July Call
- Next steps for use of information?? Discussion

- Jo requested everyone work to become familiar with Constitution and By Laws to help determine where changes may need to be requested when survey is complete

Increasing Local Regulatory Involvement in CFP and committee work

- Comment from voting process – will add to agenda of next call
- Discuss with group

New Business

- **It was brought up that the next call was right before a holiday weekend. Call Changed to the 15th of July to avoid any issues for people traveling for the Holiday.**

Motion to adjourn: Larry Second: Michelle

Local Regulatory Representation Agenda

05.06.22

Charges

- To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:
  22. Examining the current by-laws to include an historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
  23. Reporting back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
  24. Including representation from the Constitution and By-laws Committee to assist in the development of recommendations and amendments from the findings determined in charges.

Jo DeFrancesco called the meeting to order at 12:05

- Welcome
- Attendance- 7 voting members needed for a quorum, 9 voting members present
- Antitrust Statement- Jo reminded group of statement.
- Jo reminded group the meeting is being recorded.
- Group was reminded that Courtney Halbrook was the new Council II Chair, and that Wendy Bell has stepped up as Vice Chair of the Council.

- It was announced that Sean Dunleavy would be attending the meetings as a representative of the Constitution and By-Laws Committee. Sean was present on the call to add input as needed.
- Discuss Survey and Feedback from group
    - Discussion – Led by Pieter Sheehan
        - Sharon Wood agreed to draft introductory statement giving issue background information to survey respondents. This was felt to be necessary by the group to aid in educating respondents.
    - Several Questions need minor clarification to ensure respondents understand the intent of the question.
        - Questions #3 and #5: Wording needs adjustment to change the sord issues to "topics" or similar.
        - Question #4: Group felt it would be appropriate to place CFP in front of the word Issue and capitalize the word Issue.
        - Questions 11 and 13 were perceived to be leading questions.
            - Suggestion was made to remove the language, "..we understand that you rely on state delegates…" on question 11
            - Suggestion was made to remove language and have it state, "Please, indicate your reasons for participating in CFP."
    - Jo will follow up with appropriate board members for mailing list.
    - Pieter and Jo will send out revised survey to Committee with a tight turnaround for discussion and voting. This will occur once suggested revisions are completed.
    - After vote survey will go out immediately.
- Future Committee Work
    - Future steps potentially include a second survey, should data from the current survey provide sufficient evidence to warrant, to local jurisdictions outside of CFP.
    - Suggest recommendations to be put in place for Local Representation voting process.
    - Coordinate with Constitution and By Laws Committee where/how to place recommendations
    - Draft Issues
- Scheduling remaining calls
    - Group agreed that Fridays at 12:00 EST is an acceptable time for meetings
    - Additional meetings are anticipated once survey results are in.

- New Business
    - None

- Motion to Adjourn: Patrick Guzzle
- Second: Tim Westbrook

Next Meeting: June 3, 2022 12:00 EST – Jo will send invite

ID	Start time	Completion time	Email	Name	Is your local jurisdiction adequately* represented by your State Delegate (ST-D)? *Note: Adequately refers to how state delegation communicates and represents your jurisdiction's specific needs o...	If you selected "no", please explain.	Does your jurisdiction have the opportunity to discuss big-picture items that effect your local food safety program with the State Delegate or representatives of the Delegate's agency/office durin...	Please indicate how often you meet with your State Delegates or representatives to discuss CFP Issues that impact voting decisions in the Assembly.	Does your State Delegate initiate dialogue regarding unique local, developing, or historically problematic concerns that require a "birds eye" view to get a solution?	If you selected "yes" to the previous question, what are some examples of concerns being discussed?	Does your local food safety program have the opportunity to discuss the impact of CFP Issues on your jurisdiction with State Delegate(s) in a regularly scheduled manner?	How often does your State Delegate(s) consult with your local jurisdiction when voting on CFP Issues? Are you always clear on the CFP Issues being discussed and evaluated?	How would you classify the intra-communication between your state and local agencies that handle food safety?	If you selected "ad-hoc" or "limited" to the previous question, please explain.	As an active local regulator and participant in CFP, would additional local voting rights in the Assembly of Delegates cause you to get more involved in CFP?	Please explain your answer to the previous question.	The Assembly of Delegates is made up of states and territories who have complete voting rights. As a local regulator, please indicate your reasons for participating in CFP.	Have you previously attended the regulator's caucus meetings during the Biennial Meeting in which the CFP Issues are discussed among all regulators?	Are you going to participate in the 2023 Biennial Meeting of the Conference of Food Protection?
1	6/13/22 14:33:37	6/13/22 14:42:43	anonymous		Yes		Yes	3-4 times per year and as needed.	No		Yes	As needed	Open		No	I am already actively involved	To give a local voice on a national level	Yes	Yes
2	6/13/22 14:39:56	6/13/22 14:45:31	anonymous		No	State does not communicate with local health dept.'s.	No	N/A	No	N/A	No	N?A	Limited		Yes	State needs to discuss CFP with locals. Most do not even know it exists.	To be part of the process.	Yes	Yes
3	6/13/22 14:39:15	6/13/22 14:49:34	anonymous		Yes		No	We have a regularly monthly state conference call on local issues but not exclusively on big picture CFP issues. It would be nice to connect quarterly with our state to bring everyone up to speed on the various committee work within each Council that LHJs may be working on.	Yes		No	Not sure unless you're heavily involved with CFP issues within each Council or following CFP issues?	Open	Regular monthly state conference calls with LHJs is being held in WA State especially now we're adopting the 2017 FDA Food Code.	Yes	But not at the expense of aligning with the State on issues and voting - need to communicate closely. Voting rights does not necessarily mean getting more involved with CFP as time constraints and subject matter expertise of the individual factors in more.	Dual purposes of contributing to the CFP issues and ultimately current Model Food Code final drafts but also to understand the science/issues of food safety and regulator oversight that makes sense to LHJs jurisdiction frontline impacts.	Yes	Yes
4	6/13/22 14:50:27	6/13/22 14:59:04	anonymous		Yes		Yes	Sometimes right before CFP vote if delegate is available.	No		Yes	Historically, CFP issues haven't been discussed between local and State delegate prior to voting on CFP issues. Mostly clear on CFP issues being discussed & evaluated but think that it would be valuable for state and locals to visit prior to voting to be sure that all things are considered regarding voting outcomes.	Open		Yes	If local voting rights were provided, would speak to issues that affect jurisdiction	To hear about what's happening on a national level and work to build consistent approaches with states and territories that have similar demographics and food establishments.	Yes	Yes
5	6/13/22 14:54:36	6/13/22 15:06:16	anonymous		No	I believe they have requested feedback on topics to bring to CFP but never hear anything else from them. We are the largest jurisdiction (population and facility count) in our State and have never been asked questions related to topics or concerns at CFP.	No	We do not. We meet regularly with them but it is always around issues we see in our community, not related to CFP issues	No		No	They have never consulted with us being the largest in the State. No, unaware of the CFP issues being discussed.	Limited	The State is currently down multiple employees so they attend our statewide meeting every other month though seem to only be collecting information not providing responses. This makes things incredibly difficult to run a program at the County level when we have to ask the State for guidance as it is a State-wide program.	Yes	I think so, yes		No	No
6	6/13/22 14:59:21	6/13/22 15:08:13	anonymous		No	State delegate does not adequately represent our jurisdiction and does not request feedback based on our community's needs and goals for public heath and food safety	No	never	No		No	does not clearly solicit feedback on issues under discussion	Ad-hoc	State only reaches out when they see a need. They do not ask if we need items addressed and there is only a single meeting each year for general conversation, no specific to CFP issues.	No	Since we are already actively involved, this would not increase our involvement. I do feel that it would better represent the community in our jurisdiction since many CFP issues to directly impact the community.	Interest in issues and committee work for addressing those issues.	Yes	Yes
7	6/13/22 16:00:03	6/13/22 16:11:29	anonymous		No	This past year, there was no-one to represent my State. In my state, there are many different local authorities that cover Retail food while the State covers Manufactured foods.	No	We do not meet.	No		No	N/A	Open	There is open dialogue between us and the state, however it is very rare. We have our own code, with our own authority.	Yes	If we had a seat at the table when voting it would be nice. Since we are not represented at all currently.	I got involved, because I believe its a good cause. It's fascinating to see everyone come together.	Yes	Yes
8	6/13/22 16:43:56	6/13/22 16:53:01	anonymous		No	I think the answer to this is "unsure" - I don't know who at the state attends these meetings and we are not consulted on issues they are voting on. We are not asked for input on issues or what local needs might be.	No	Never.	No		No	Never consulted. Only clear if I do research through the CFP website on items that interest me, that is, if I know about them through another source.	Limited	Communication with the state on food safety issues is extremely limited. There are no regularly scheduled meetings for this. I came from out of state and was surprised to find no solid network of food safety programs/program managers or department directors in the state. They do reach out if the food code is being updated, but that is not very often.	Yes	Yes. What is the point of attendance/involvement if I really don't have a say/vote? I can follow what is happening online if I need to.	To keep up on what is happening from a big picture standpoint, which could lead to a more progressive local food safety program. Additionally, the locals are the boots on the ground and have first-hand knowledge of the practicalities of how retail food establishments operate which should be considered when voting is happening. This could be very helpful to the process.	No	Yes
9	6/13/22 23:50:50	6/14/22 0:02:16	anonymous		No	Infrequent contact from state delegation on local health needs. The state rarely reaches out for our input and does not communicate on their dealings with CFP.	No	Never. In the 15 yrs I have been in the field the state delegates have never reached out to individual jurisdictions for their input.	Yes	Sous vide process, ROP	No	Never, no	Limited	State delegation does not ask for local input.	Yes	Since local health is never consulted for input by the state delegates, this is a deterrent to getting more involved.	To gain more knowledge of the FDA food code as CT uses a state code. To keep abreast of current issues that CFP addresses. To meet industry and government regulators for all over.	Yes	Yes

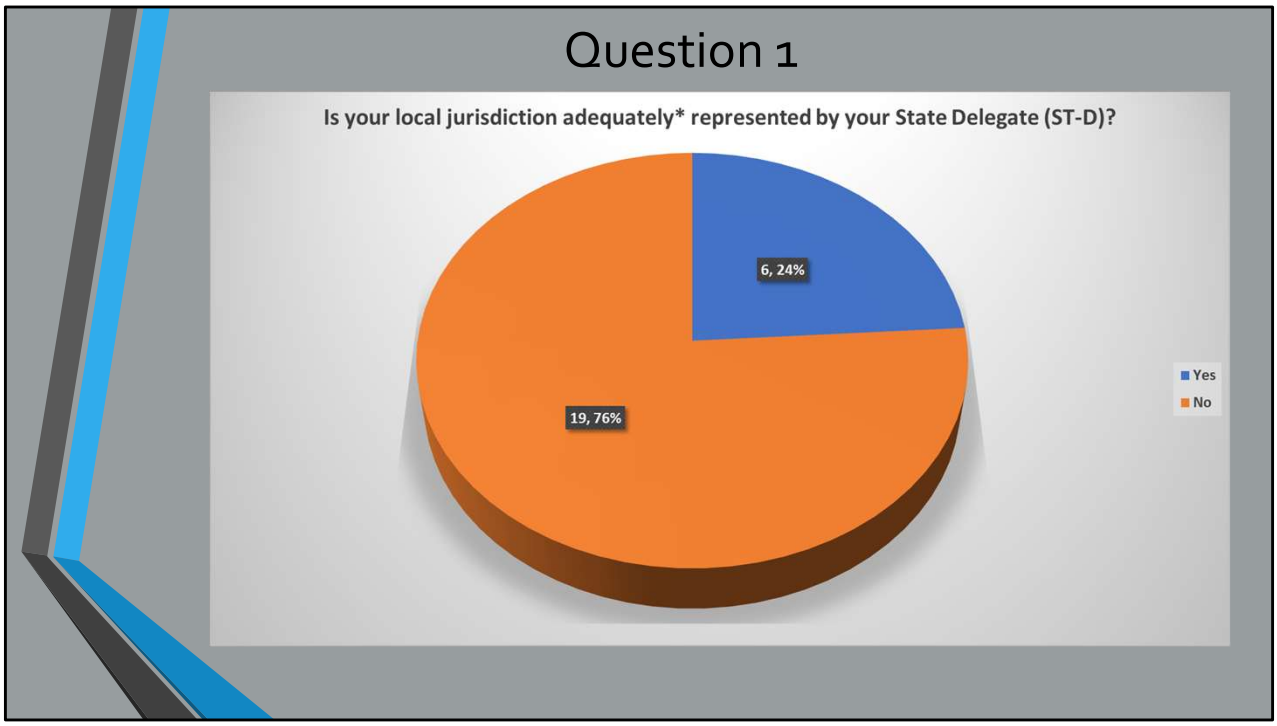
10	6/14/22 7:43:30	6/14/22 7:47:57	anonymous	Yes		No	never	No	No	Never, to my knowledge. No, not clear.	Ad-hoc	Communication as needed.	Yes	I'd try to understand the issues more than I do now, and that would cause me to be more involved in CFP.	Participation in the national organization that has direct impact on food safety regulations.	Yes	Yes
11	6/14/22 8:38:07	6/14/22 9:07:08	anonymous	No	The state does their thing and they vote with which I'm sure is their best choice. However, they did not reach out to us to hold a separate meeting to understand our viewpoints regarding each of the issues from those in our state. Historically, local regulators have only been allowed to attend the state caucus meetings so that a general understanding from all regulators regarding each of the issues could be discerned, especially amongst the state delegates who will be voting. The way it is currently set up, a local regulator has to do their own homework and lobby everyone to get their voice heard.	No	Whenever they decide that its a good time to conduct a training	No	No	I have not heard anyone from the state do so. I'm always clear on the issues because I do a lot of homework before hand and keep up with the actions taken by each of the councils	Ad-hoc	They provide presentation type of training when there is a code change. They are available by email if we have a question.	Yes	I have been involved with CFP for some time. I would love to have the opportunity to serve as a local regulator on the assembly of delegates.	To participate in the issue action discussion and voting process either as a council member or by working with those on the councils to ensure my viewpoints are expressed and provided.	Yes	Yes
12	6/14/22 8:58:05	6/14/22 9:11:55	anonymous	Yes		No	never	No	No	none that i know of	Limited	The state will have or set up meetings when the state wishes to communicate something down the line. Example, if the individuals at the state level thinks the local level may be communicating or doing something the state agency may not approve of, then the state will pass communication down the line letting the local agency know that they object to what is happening even when there was no guidance prior to the state reaching out to the local agency.	No	I do not think I have time to spend / work on issues at the CFP [illegible]	To read about issues other jurisdictions are having and what may be coming down the line.	No	No
13	6/14/22 9:34:17	6/14/22 10:00:54	anonymous	No	The Ohio Department of Health and the Ohio Department of Agriculture represent and advocate for their own best interests and have long been in a "them vs. us" relationship with local health departments. The delegates are their employees and are required to regard the desires of the agencies above all else, including the opinions of what local health departments think they need. This is unlikely to change.	No	Rarely - I can't recall any such meetings. Meetings with the state officials/ state delegates involve meetings where we *may* be permitted to observe - such as the Retail Food Safety Advisory Council (RFSAC) or where they are telling us what is going to happen during Food Safety Meetings. There are opportunities to ask questions, but these are by no means discussions. We are told what will happen and the questions are only in regard to clarification as to how they feel we should be interpreting or responding to situations. Our feedback as local health departments is deemed unnecessary. Feedback can be formally submitted during rule review, but that is only because it is required, not that it is seriously considered. The only way people know about CFP is if they engaged and found out about it on their own. It is not promoted or discussed by our state agencies. They don't want us involved at all.	No	There are none. They dc	No	Never. Have never been contacted or asked and I would be the person to ask at my department.	Limited	Non-existent needs to be an option. The state uses a top down management style. There is little involvement by the locals in what actually happens. There may be some "committees" to make it look like LHDs are involved, but there is little actually taken from them and put to use. They make all the decisions and we deal with them. They do not involve us in CFP related issues at all.	Yes	[illegible] to be more diversified so that more voices can be heard. If it truly is a unanimous decision, it would be the same result anyway wouldn't it? What would it hurt to have more voices? With the voting power only at the top state agencies and their delegates, currently, local health departments have no say, no power, and really no incentive to want to be involved in CFP. I think we need to get the word out that Locals CAN make a difference and CAN play a role in how our codes are made. The state likes to make people think otherwise. This can be a collaborative effort. The state agencies are	It is important to understand how everything fits into the big picture. Even though we are a small part of the puzzle, we each contribute to a greater whole and can influence what happens. If few people care enough to be involved, we all will suffer when decisions are made by limited perspectives. Additional perspectives, can provide insights that we may not have been aware of. That can help us make more informed decisions. What we do keeps our communities and families safe. That is important and a valuable use of time.	Yes	Yes
14	6/14/22 10:28:36	6/14/22 10:32:49	anonymous	No	Our State is not involved in CFP or the FDA Program Standards.	No	Our State is very hands off. Little to no communication about anything. We basically do what we want and govern ourselves.	No	No	State does not discuss.	Limited	State does not do anything to support local efforts.	Yes	We are already heavily involved in CFP through committees and council membership. We just do not get to vote or have any input after that.	To help develop Food Code policy, provide input from actual 'boots on the ground' individuals, and to learn more about food law.	Yes	Yes
15	6/14/22 10:48:25	6/14/22 10:56:25	anonymous	No	In Nevada, there are 4 jurisdictions, three local county health districts that cover environmental health for their respective counties and the State of Nevada that covers all other rural counties within in the state. Each jurisdiction is separate with their own regulations, etc. The state delegation committee does not communicate important retail food issues to our jurisdiction and does not have an understanding of our needs and issues at the local level.	No	Had one meeting prior to the last CFP meeting, but no other outreach from the State Delegates regarding CFP issues.	No	No	So far, just one meeting prior to the 2020/21 CFP.	Limited		No	We already have several staff on committees and have participated on council. We would continue to be involved with CFP regardless of having local voting rights.	Our agency has been active in CFP for several years as we want to be informed of immerging food safety issues that effect our local community.	Yes	Yes
16	6/14/22 12:56:40	6/14/22 13:10:03	anonymous	Yes		Yes	Upon request by either party	No	Yes	The local representation has dialogue and opportunity sharing to come to consensus prior to vote. Ultimately, as is known, the state votes accordingly to what they believe is accurate for the entire state.	Open		No	I'm already actively involved and our delegation of authority is granted by the state.	I agreed to represent the local regulators in the SE on the EB board. It is of service to the profession.	Yes	Yes
17	6/14/22 16:58:44	6/14/22 17:14:19	anonymous	No	In the past we would have meetings and work groups to talk about the issues submitted to the CFP. Last two CFP Annual meetings there was no coordinated meetings or work groups to discuss the presented issues prior the CFP annual meeting.	No	Have not meet for the last few years.	No	No	Only at the CFP regulatory meetings.	Limited	Haven't had meetings regards CFP Issues for a long time.	Yes	We are already pretty involved with CFP but would like to become more involved with local participation.	Being able to be involved on working committees, and councils. Being able to listen to the dialogue of issues being presented to the three councils.	Yes	Yes

18	6/14/22 17:52:38	6/14/22 18:02:35	anonymous	No	Locals represent themselves best and make decisions more efficiently. There is an association that brings all the locals together with the State agency but the State does not make the necessary decisions in a timely manner to allow locals to progress in their decision making.	Yes	These meetings are scheduled once a month. They are not exclusively for CFP related items but if there are any, they would be discussed at this meeting.	No		Yes	As stated above, if they do come up, it would be at the monthly meetings. Our local jurisdiction has multiple members of CFP so we are aware through direct participation.	Ad-hoc	Our State agency does not have the expertise nor the decision making processes in place to lead food safety topics and issues.	Yes	Understanding that our voice could directly be heard, would increase participation. Our large local agency is the most influential food safety agency within the State. The State relies on the locals a lot but does not provide the necessary leadership.	To be part of the discussion in how our industry approaches regulations and the direction food safety programs should be progressing in.	Yes	Yes
19	6/14/22 17:51:28	6/14/22 18:09:33	anonymous	No	There is little to no communication between our jurisdiction and the State Delegate regarding CFP issues.	No	We may run into them at the CFP Biennial Meeting. A "formal" meeting is not scheduled.	No		No	We usually aren't even informed of who the State Delegate is. The State does not reach out to us regarding CFP Issues. Any communication takes place at the Biennial Meeting if we run into each other, such as at the regulator caucus or in the halls at breaks.	Limited	We do not have regularly scheduled meetings or communication with our State.	No	I am sufficiently involve, additional voting rights would not cause me to get more involved.		Yes	Yes
20	6/14/22 15:42:53	6/15/22 14:34:46	anonymous	No	The state does not solicit information/feedback from the counties regularly and the counties often take topics to the state for discussion and receive no feedback or untimely feedback. When the state is engaged on a topic, they often defer to the counties so they are not involved. In addition, the state mostly regulates correctional institutions and behavioral health facilities. The local counties regulate more than 90% of retail food facilities and have the greatest experience.	No	The state attends a monthly meeting with all of the counties but CFP and how the State will vote on CFP items is not a routine agenda item. The state does not engage the counties in discussing issues or proposing issues in advance of the biannual meeting.	No	This dialogue is typically	No	This interaction is infrequent and we may discuss items that end up at CFP but the conversation is not typically geared towards preparing for CFP voting or discussions. The state also lacks in-house expertise of the regulations.	Limited	The counties often approach the state with food safety topics but the response is often to handle it on our own or the state says they will get back with us and it does not happen timely or at all	Yes	Local representation could speed things up for regulators and our stakeholders, but we risk diluting the importance of the states participating in the process.	We have participated in councils to discuss the issues. We have also provided comments on proposed issues.	Yes	Yes
21	6/15/22 14:58:16	6/15/22 15:12:31	anonymous	No	We are very seldom asked or given the opportunity to participate in any meetings determining regulatory activity.	No	Never	No		No	Never	Limited	We are contracted by the state and the state makes all of the decisions.	Yes	I would be able to provide insight to my staff and have a better understanding of how decisions are made regarding regulatory issues.	I wanted to get more involved and have more knowledge of how decisions are made.	No	Yes
22	6/16/22 8:16:09	6/16/22 8:33:03	anonymous	No	Our state delegates do not communicate with the local jurisdictions in our state regarding issues, needs, requests, or CFP involvement.	No	zero	No		No	zero	Ad-hoc	There are no regularly occurring meetings or communication. Conversations are initiated at the local level on an as needed basis. As a home rule state, our state department of health does not have oversight of our program.	Yes	As a local regulator, we are as active as can be in the current structure on councils and committees. We have not observed or participated in a closing session as we have no impact or input at that level.	Changes made to the Food Code and Program Standards have the greatest impact on local jurisdictions. I want to have a voice in the changes that are made that affect food safety. When change is made and passed down to locals, often locals do not embrace these changes and this contributes to the inconsistency of the food safety regulatory structure at all levels across the country.	Yes	Yes
23	6/16/22 12:34:12	6/16/22 12:42:43	anonymous	No	It appears that most of the items passed through the councils or recommendations by the council tend to pass in the assembly and the assembly of delegates is more of a formality but I also don't know who my state delegates are which kind of says to me that there is a barrier there if there is no opportunity to speak to them. I know this may be more possible in our "region" meetings that occur during CFP, but if these states delegates don't attend those meetings, how are we supposed to know who they are or network with them?	No	Leading back to the last question, our jurisdiction may just be getting more involved in these discussions and there are instances when our department works with the state but I'm not sure if there are instances where we meet with the state specifically for this purpose.	No	Not that I know of.	No	Not that I know of.	Limited	Again, I as a local member have not had any insights or guidance on even having a discussion with our state people so maybe I'm just super new but no idea.	Yes	I think people may be more inclined to be involved when they know they are contributing to the decision. Again, I think that being involved in the committees is good enough for me and I haven't seen anything shot down by what the committees are doing by the assembly so I think local regulators do have some power, it may just come down to how that is marketed. Also I get the sense that many local authorities see this as more of a hindrance rather than an opportunity to grow as an employee. My local gov employer has not decided if my involvement is really allowed based on my job title. I tend to clock out during the CFP	I like to give our perspective at the local level in the field to help make decisions on ways to standardize or simplify processes to make it easier for all of us. It's tough when local regulations tend to be different in regions and being able to have these discussions to talk them out may be helpful for everyone involved. I like to be involved in these as it helps me get a whole view sense of the process which I believe helps me become a better inspector.	Yes	Yes
24	6/18/22 10:17:50	6/18/22 10:32:22	anonymous	No	Attendance by my state at the Biennial Meeting has not been consistent over the last decade, and most local inspectors in my state do not understand the function of the CFP, the Biennial Meeting or the way that the Food Code is updated.	No	Rarely, if ever, mostly due to the lack of local involvement in the Biennial Meeting.	No		No	Never	Limited	In my state, experienced food safety employees are retiring and there is a lack of experienced inspectors at both the state and local level. Because my state does not use the Food Code, the mechanism to field train and certify inspectors is dissicult and there is a back-log of new inspectors needing certification.	No	Local inspectors in my state (CT) are responsible for all environmental oversight: wells, septic, salons, pools, housing, etc. and do not have time to get involved in CFP or focus with any debth on food safety.	I used to work for a Tribal Health Dept. and had time to devote to CFP. Since returning to local health during the pandemic, it is not possible do to the huge workload.	Yes	No

25	6/22/22 13:38:08	6/22/22 13:56:09	anonymous	No	As a local regulator in my state highly involved with CFP over the past years I have never had my ST-D reach out to my department and ask for requests to bring up to the CFP. We have also never had information or updates from the CFP in our state.	No	This has never occurred in my state.	No	Yes	There has been no consultation with local jurisdiction.	Ad-hoc	Local jurisdictions contact the state agency only when there is a question, scenario, or new procedure that requires state guidance on.	No	if we start to allow local regulators to have voting rights within CFP there may be the possibility of conflict of interests (many local regulators may be involved/married into families of large industry companies etc. and may start to push for their agendas), disagreements with local regulators and state agencies/delegates, and an opening to undermining future CFP work. I am a local regulator and against having voting rights traditionally held by our state delegates. I do ask for updates from our state delegates about work being done at the CFP	I like to know what is going on at a national level. I like to be involved with committee work and helping contribute to national changes. I enjoy policy-making work and ensure things are carried out with DEI work in mind also.	Yes	Yes

Local Regulatory Committee Survey

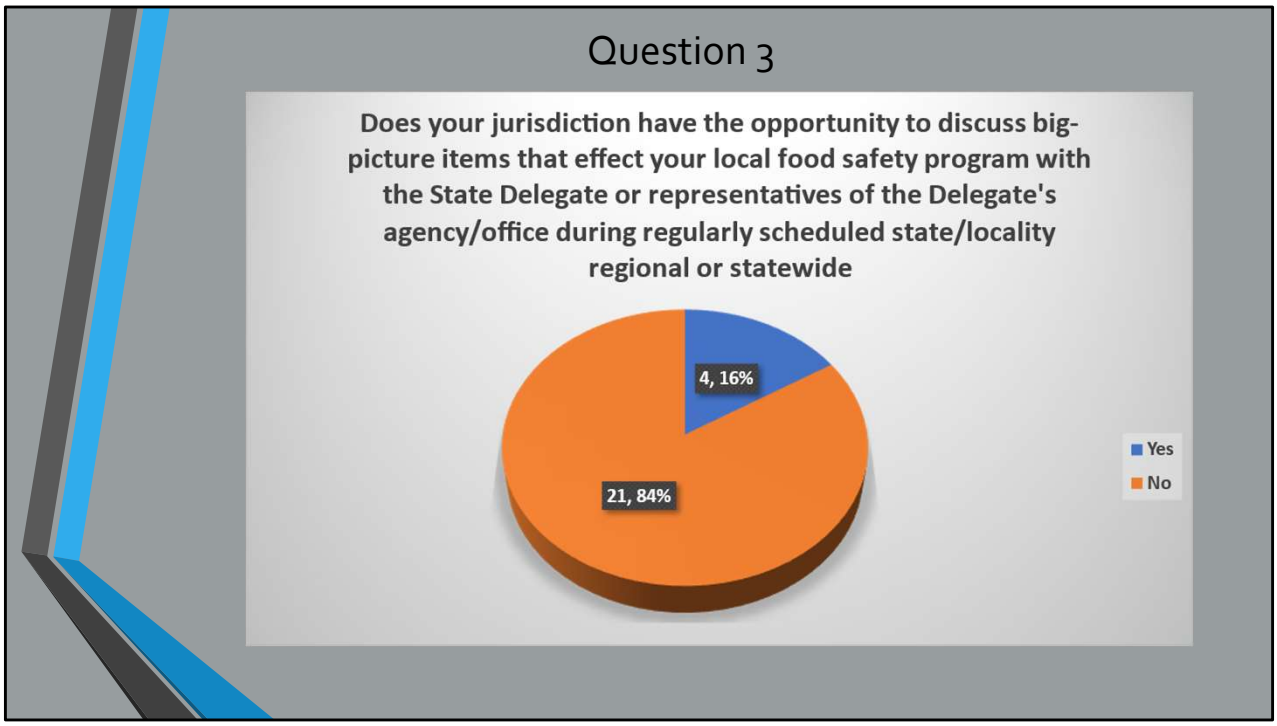
Prepared by Samuel Gaber



Observation: Little to no communication between the states and locals.

Example:

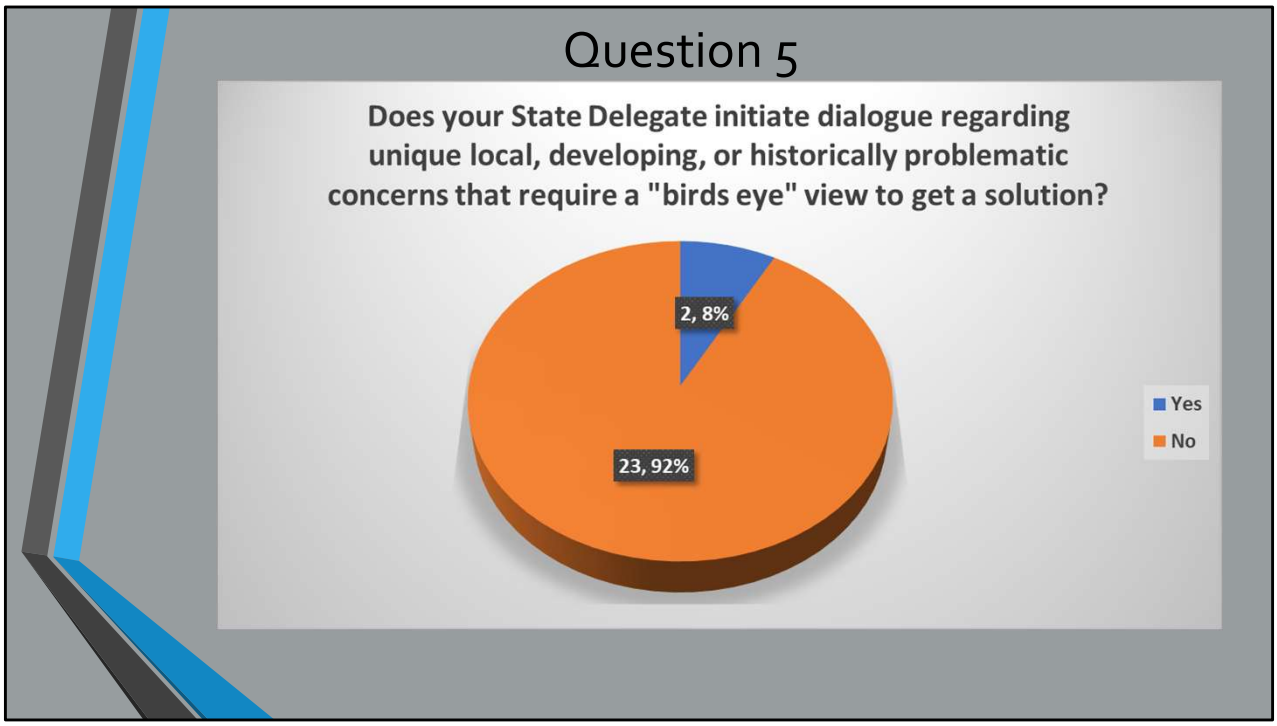
- State does not communicate with local health dept.'s.
- There is little to no communication between our jurisdiction and the State Delegate regarding CFP issues.
- There appears to be some confusion over **who** should be communicating information to the Local Regulators is it the state? The Delegate?



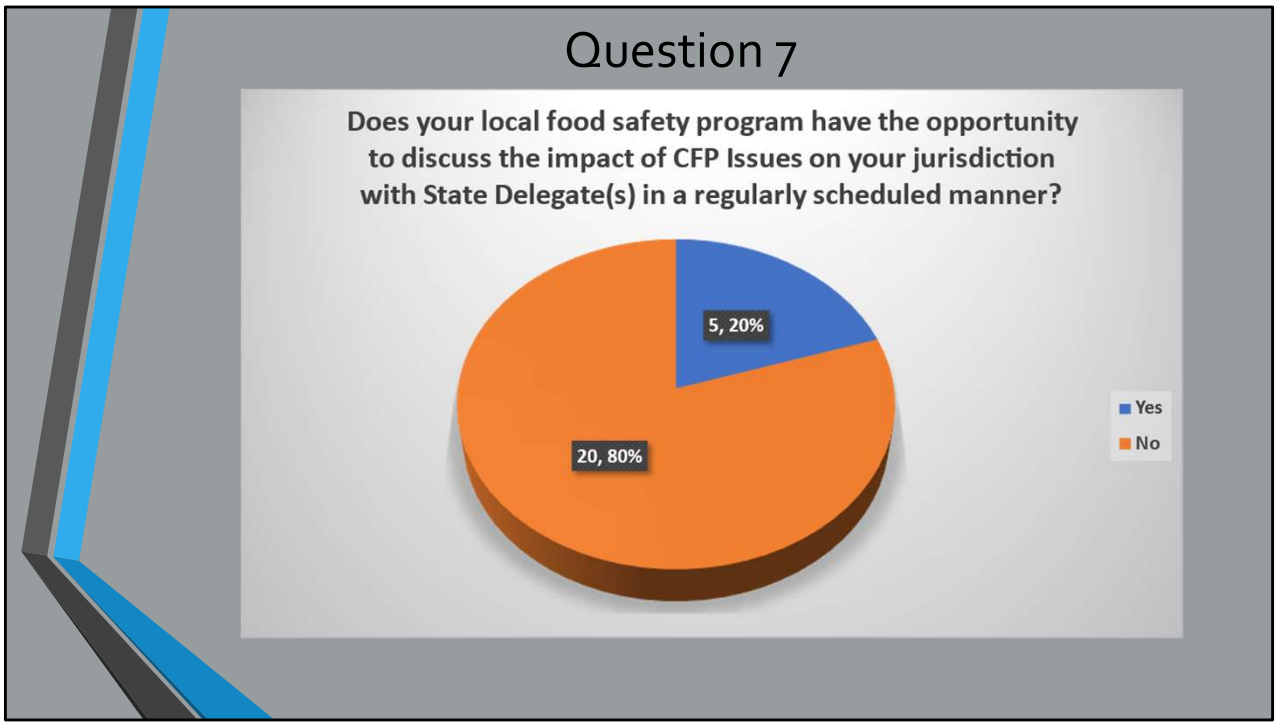
Observation: Official meets are not happening between states and locals.

Example:

- This has never occurred in my state
- We may run into them at the CFP Biennial Meeting. A "formal" meeting is not scheduled.
- We do not. We meet regularly with them but it is always around issues we see in our community, not related to CFP issues
- We have a regularly monthly state conference call on local issues but not exclusively on big picture CFP issues. It would be nice to connect quarterly with our state to bring everyone up to speed on the various committee work within each Council that LHJs may be working on.



Same two as previous question

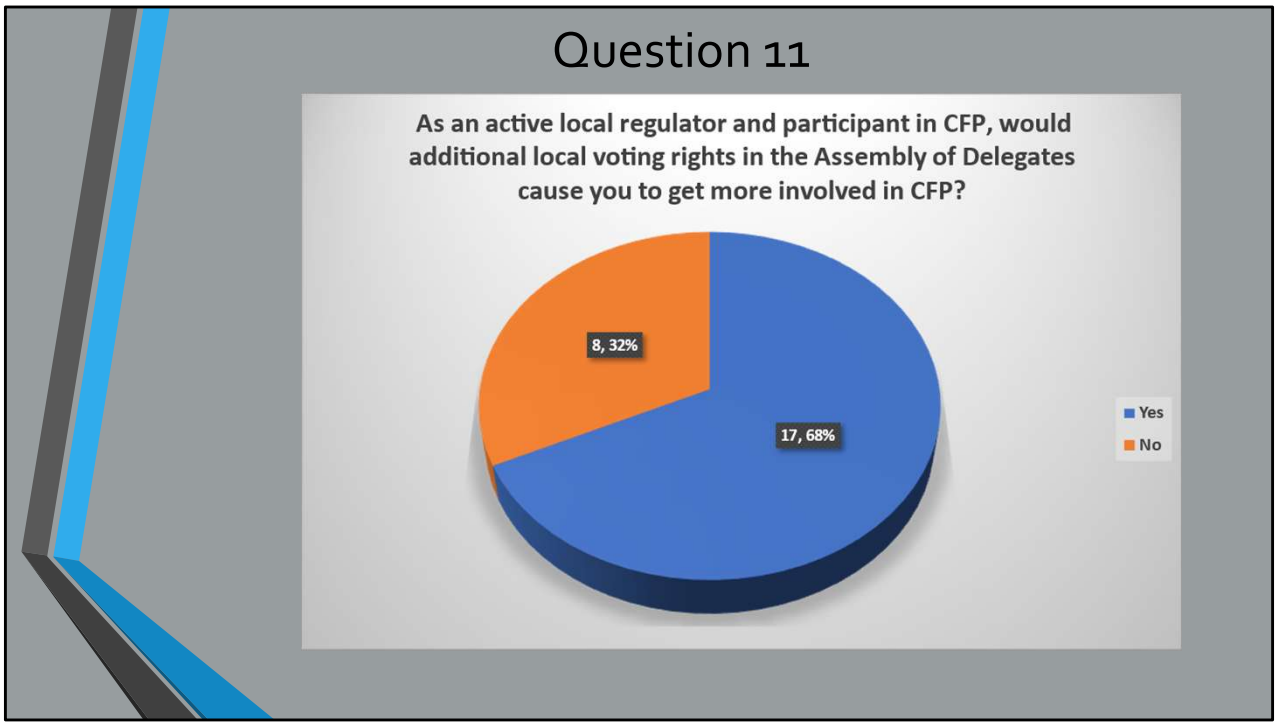


Observation: Little to no communication between the states and locals.

Example:

- There are none. They don't want our opinions or for us to be involved at all.
- Not sure unless you're heavily involved with CFP issues within each Council or following CFP issues?
- Historically, CFP issues haven't been discussed between local and State delegate prior to voting on CFP issues. Mostly clear on CFP issues being discussed & evaluated but think that it would be valuable for state and locals to visit prior to voting to be sure that all things are considered regarding voting outcomes.

General comments reflect a top down approach to any messaging between state and local.

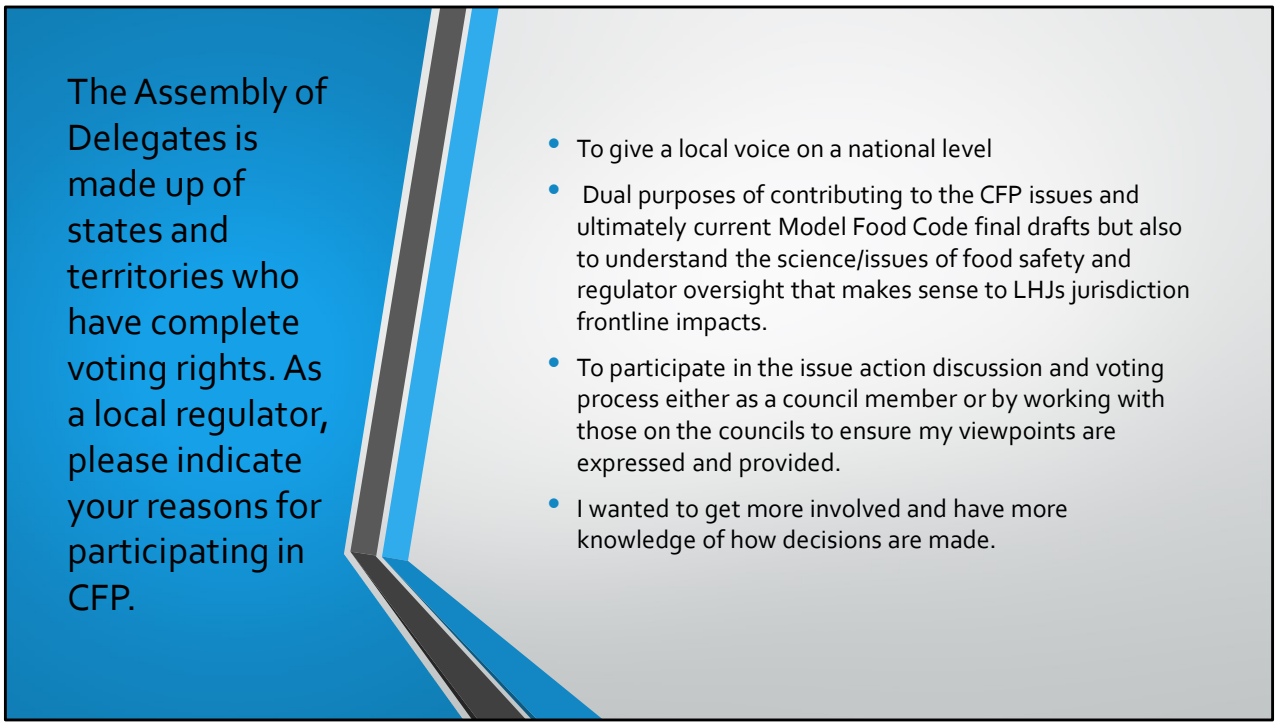


Observations: Locals want to participate
Of those that answered no 7 of them said they were already active and one said they didn't have time.

Example:

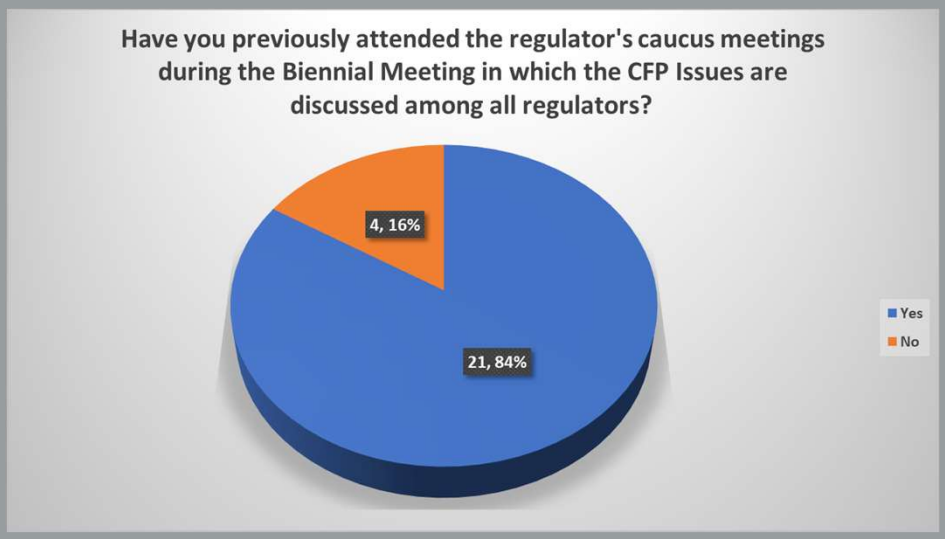
- To give a local voice on a national level
- To participate in the issue action discussion and voting process either as a council member or by working with those on the councils to ensure my viewpoints are expressed and provided.
- But not at the expense of aligning with the State on issues and voting - need to communicate closely. Voting rights does not necessarily mean getting more involved with CFP as time constraints and subject matter expertise of the individual factors in more.
- If we start to allow local regulators to have voting rights within CFP there may be the possibility of conflict of interests (many local regulators may be involved/married into families of large industry companies etc. and may start to push for their agendas), disagreements with local regulators and state agencies/delegates, and an opening to undermining future CFP work. I am a local regulator and against having voting rights traditionally held by our state delegates.

- I do ask for updates from our state delegates about work being done at the CFP level from time-to-time. This should be happening, but is not.



Observations:
The general vein of the answers to this were almost all along the same vein. To be part of the process, to have their voice heard and to have a say in the decisions being made

Question 14


Have you previously attended the regulator's caucus meetings during the Biennial Meeting in which the CFP Issues are discussed among all regulators?
4, 16%
21, 84%
Yes
No

Remarkably, even with communication issues noted the data shows the majority of participants will attend the next biennial conference.

PSC Issue #8 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC8 RPS Standard 2 Trained Staff Instructions and Worksheet for a VA
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC8 RPS 2022 Program Standards 6 Compliance Enforcement Inst and Worksheet for a VA

PSC Issue #9 list of content documents

1. 1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC9 Program Standards 2022 Standard 5 Edits
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC9 Program Standards 2022 Definitions Edits

PSC Issue #9 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC9 & PSC17 Standard 5 FBI and Food Defense Preparedness and Response

2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC9 2022 Program Standards Definitions

PSC Issue #16 list of content documents

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC16 Standard 5 Roadmap draft 10 22
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC16 Standard 5 Data Collection Template

PSC Issue #17 list of content documents

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC17 Program Standards 2022 Standard 2 with Crosswalk added
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC17 Program Standards 2022 Standard 5 with Crosswalk added

PSC Issue #17 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC 4, PSC13 & PSC17 2022 Program Standards 2 Trained Regulatory Staff
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC9 & PSC17 2022 Program Standards 5 FBI and Food Defense Preparedness and Response

PSC Issue #18 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC18 www.foodprotect.org – Crosswalk Screenshot

PSC Issue #19 list of supporting attachments

1. PSC1 Program Standards Committee Report, Attachment title: PSC19 Issue 2020 II-033

PSC Issue #10 list of content documents

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC10 Draft Standard 6 Establishment File Worksheet Food Code Form 3A Based

PSC Issue #11 list of content documents

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC11 Draft Standard 6 Standardized Key Crosswalk to the 2017 FDA Food Code

Clearing House Question STND 6

State Enforcement Policy and Corrective Action

Keywords: STD-06, FDA

Issue Description

Background

As a result of 2019 legislation, our state implemented a new, progressive methodology for enforcement that became effective on January 1, 2020. This protocol takes into consideration not only the severity of the identified violation but also the prevalence of violations observed. The legislation provides for a uniform system to communicate inspection results which is based on an overall point system driven by assigned values of low, medium and high pervasiveness (identified in the attached document "19-09 Requirements for Communicating Inspection Ratings"). This point system establishes the criteria by which resources are to be directed for additional full re-inspections or enforcement activities.

Pervasiveness is the overall evaluation of specific issues observed to determine how prevalent the violation is. Using all available information such as active managerial control, previous inspection records, long term controls, and overall risk/severity of the specific situation, an inspector assigns a violation pervasiveness. This system then classifies routine and re-inspections into one of three ratings ("Pass," "Re-inspection," or "Closed") based on the total cumulative violations/ points. This rating is then used to determine the next required action: no required action (the next routine inspections is scheduled), a full facility re-inspection, or the immediate suspension of a license to operate. Facilities that score less than 50 points pass the inspection and do not have to demonstrate correction of risk factor or intervention violations through re-inspection or other follow-up.

Question/Problem

The current enforcement system in our state focuses on comprehensive compliance with the food code through a points-based rating system. Establishments that achieve a "Pass" rating during an inspection will not be required to show resolution for any out-of-compliance risk factor or intervention violations. Does this enforcement system meet the intent of Standard 6, Compliance and Enforcement?

Rationale

It is possible to have a risk factor violation that was unable to be corrected on-site at a facility that did not receive enough accumulated points to warrant a full re-inspection and actually achieved a "Pass" rating. At the time of the inspection, a "Pass" rating requires no further action by the operator to demonstrate correction of a violation and the next routine inspection will be scheduled. The "Pass" score during a full risk-based inspection has demonstrated that the operator had an overall effective control of the food safety risks. The system in Colorado was designed to allow regulatory resources to be focused on the operators that have significant food safety risks (resulting in a full "Re-inspection" or "Closure" of the facility) and not on those facilities that have their food safety risks under control (resulting in a "Pass" score) and have demonstrated active managerial controls are in place.

The desired outcome is to focus resources to effectively achieve compliance with regulatory requirements at facilities that have a significant lack of control over risk factors and interventions. Point values are reflective of risk factors and interventions and are given more emphasis based on prevalence.

Standard 6 – Criteria 1

1. Compliance and Enforcement Procedure

a) The jurisdiction has written step-by-step compliance and enforcement procedure that describes what actions and tools (i.e. forms, documents, interventions) are to be used to achieve compliance

<u>Clearinghouse Response</u> (11-30-2022)

No. The intent of Standard 6 is to evaluate the effectiveness of a jurisdiction's compliance and enforcement policy. Compliance and enforcement activities should result in follow up actions for out-of-control risk factors and timely correction of code violations. The program must demonstrate credible follow up for each violation noted during an inspection with particular emphasis placed on risk factors that most often contribute to foodborne illness.

PSC Issue #12 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC12 2022 Program Standards 8 Program Support and Resources
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC12 Issue 2020 II-017 Packet

FTE DATA CALCULATION

Calculate productive hours per year for an employee doing 100% food inspections

Information For One Employee		Hours/Year	Hours/Day	Total Hours
Annual FTE Hours Per Year: Industry Standard				2080
	Local Holiday Hours Per Year			0
	Local Vacation Leave Hours Per Year			0
	Local Sick Leave Hours Per Year			0
	Local Family-Personal Leave Hours Per Year			0
Productivity Factoring Per Year				
	Travel Time For Inspection			2080
	Administrative Work (in-office work)			2080
	Break time			2080
	Others			2080
Personal Development Time Per Year				
	Professional Development			2080
	Others			2080
Productive Annual FTE Hours Per Year (FTE Conversion Factor)				**2080**

FOOD SAFETY INSPECTION HOURS PER YEAR

Position Title	Percent of time spent on food inspections	Number of Employees	Total Hours
			0
			0
			0
			0
			0
			0
Total Food Safety Inspection Hours			**0**
Total Current FTE			**0.00**

Actual working days	Actual working weeks
260	52

Alter

STANDARD 8's REQUIRED FTE FOR YOUR JURISDICTION

	Low Risk Establishments	Frequency of Low Risk Est Inspections Per Year
Routine and Permitting		1.00
Follow Up Inspections/Reinspections (Assumes 15% of total)		
Foodborne Illness Complaints (Assumes 1% of total)		
Other (Assumes 10% of total)		
Total Number of Required Inspections		
Hours Spent Per Inspection	0.75	
Total Inspection Time	0	
Total Required FTE		
Standard 8.1 Staffing Level		

Sources
-2017 Subcommittee # 2 - Survey 1 and 2
-2019 Pilot Study

Moderate Risk Establishments	Frequency of Moderate Risk Est Inspections Per Year	High Risk Establishments	Frequency of High Risk Est Inspections Per Year	Total
	2.00		3.00	0
				0
				0
				0
				0
1.25		2.00		
0		0		0
				0.00
				Standard not met

STANDARD 8's REQUIRED FTE FOR YOUR JURISDICTION		
	Very Low Risk Establishments	**Frequency of Very Low Risk Est Inspections Per Year**
Routine and Permitting	0	1.00
Follow Up Inspections/Reinspections (Assumes 15% of total)		
Foodborne Illness Complaints (Assumes 1% of total)		
Other (Assumes 10% of total)		
Total Number of Required Inspections		
Hours Spent Per Inspection	0.75	
Total Inspection Time	0	
Total Required FTE		
Standard 8.1 Staffing Level		

Sources
-2017 Subcommittee # 2 - Survey 1 and 2
-2019 Pilot Study

Low Risk Establishments	Frequency of Low Risk Est Inspections Per Year	Moderate Risk Establishments	Frequency of Moderate Risk Est Inspections Per Year	High Risk Establishments
	2.00		3.00	
1.00		1.25		2.00
0		0		0

Frequency of High Risk Est Inspections Per Year	**Total**
4.00	0
	0
	0
	0
	0
	0
	0.00
	Standard not met

Conference for Food Protection
2020 Issue Form

Issue: 2020 II-018

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

All information above the line is for conference use only.

Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2016 II-020; new or additional information has been included or attached and the recommended solution has been revised.

Title:

PSC Issue #2 New assessment tool for Standard 8 Staffing Level Criteria

Issue you would like the Conference to consider:

The Program Standards Committee has addressed the charges outlined in Issue 2018 II-018: Continue Revision of Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) Standard 8 Staffing Level Criteria. The Committee has proposed a recommendation that the FDA modify the Standard 8 "Staffing Level" criteria by including the proposed model assessment tool as a secondary option to assess compliance based on the findings of the 2018 - 2020 Program Standards Committee, Subcommittee #2.

Public Health Significance:

The VNRFRPS offer a systematic approach to, through a continuous improvement process, enhance retail food regulatory programs. The VNRFRPS define and provide a framework designed to accommodate both traditional and emerging approaches of regulatory programs operating within an integrated food safety system. The Program Standards Committee established a subcommittee to address the specific charges in Issue 2018 II-018. The subcommittee, with support from staff from Harris County Public Health, created a new proposed model assessment tool, ensured it to be statistically sound, and completed a pilot study among 19 jurisdictions to test the proposed model. The information collected provided the means to: (1) Improve the proposed model assessment tool that was initially created by the Standard 8 Subcommittee in Issue # 2016 II-020; (2) Validate the statistical soundness of the proposed model by confirming there was no relationship found between times and frequencies provided by "high" and "low" performing jurisdictions; (3)

Determine if the proposed model assessment tool could be used in the real world setting by conducting a Pilot Study to assess the functionality of the model among varying jurisdictions; and (4) Utilize data from the study to recommend the proposed model assessment tool be included in the Standard 8 "Staffing Level" criteria as an alternative way to determine compliance.

Recommended Solution: The Conference recommends...:

The Conference recommends that a letter be sent to FDA asking them to modify the "Description of Requirements" for "Staffing Level" in Standard 8 by including the proposed model assessment tool as an alternative option to assess compliance for the VNRFRPS.

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Supporting Attachments:

- "PSC Issue #2 list of supporting attachments"

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

PSC Issue #2 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC2 CFP Issue 2020 II-031
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC2 2022 Program Standards 1 Regulatory Foundation

Template approved: 7/13/2021

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COMMITTEE NAME *Food Defense Committee (FDC)*

DATE OF FINAL REPORT: *12/2/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Albert Espinoza and Jennifer Bonsky

COMMITTEE CHARGE(S):

Issue # 2020 II-009

1. *Identify current food defense references to be included in Appendix 2, Section 4.*
2. *Recommend whether an additional knowledge area under 2-102.11(C) relating to Food Defense in food establishments is appropriate.*
3. *Report the committee's findings and recommendations back to the Conference at the next Biennial Meeting*
4. *The Committee would work closely with the FDA Food Defense and Emergency Coordination staff in CFSAN*

Issue # _____

1.
2.
3.

COMMITTEE WORK PLAN AND TIMELINE: CO-CHAIRS CONTINUED TO WORK THE PLAN AND TIMELINE IN ACCORDANCE WITH CHARGES SINCE OCTOBER 2021.

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

1. ***Overview of committee activities:***
   - Initial meeting in November 2021 after committee membership approval.
   - Routine meetings held on: 11/22/21, 12/06/21, 01/18/22, 1/31/22, 02/14/22, 02/28/22, 3/28/22, 4/11/22, 4/25/22, 5/23/22, 6/6/22, 7/18/22, 8/1/22, 8/15,22, 8/29/22, 9/12/22, 9/26/22, 10/10/22, and 10/24 via Teams.
   - Since January 2022 our committee completed two participant surveys. First survey obtained members Yes/No and comments on Charge 2 – whether an additional knowledge area under 2-102.11(C) relating to Food Establishments is appropriate. Second survey, more specific on participant recommended verbiage.
   - With 80% Yes on recommending additional knowledge area, specific to Food Defense and 100% Yes on proposing the FDA definition for Food Defense be added.
   - Charge 1 – FDA and USDA consultants provided their updated website links, participants reviewed and provided comments to update Annex 2, Section 4, will be submitted for Council consideration.
   - Our committee worked on an employee orientation checklist for Food Defense to completion. This document is to be submitted as an issue for Council consideration.
   - Charge 4 – We want to thank our FDA and USDA consultants for being on our virtual sessions, working closely with our committee. The FDA Food Defense and Emergency

Coordination staff, Julia Guenther and Jon Woody attended our meetings, providing input periodically and being available to assist with our drafted issues to be submitted.

Our Charge - that a FDC be reestablished to evaluate ways to improve Food Defense awareness for both operators and regulators in food establishments.

Charges for the committee are:

- Identify current food defense references to be included in Annex 2, Section 4.
- Recommend whether an additional knowledge area under 2-102.11(C) relating to Food Defense in food establishments is appropriate.
- Report the committee's findings and recommendations back to the Conference at the next Biennial Meeting.
- The Committee would work closely with the FDA Food Defense and Emergency Coordination staff in CFSAN.

2. ***Charges COMPLETED and the rationale for each specific recommendation:***

a. Charge 1 - Identify current food defense references to be included in Annex 2, Section 4. This charge is completed with providing Annex 2, Section 4 updated information.

b. Charge 2 - Recommend whether an additional knowledge area under 2-102.11(C) relating to Food Defense in food establishments is appropriate. After discussion, two surveys and a final vote our committee completed this charge. Our participants are in favor of Food Defense awareness by employees be provided by the Person in Charge.
Approved language by vote on 7/18/2022:
ADD- FDA Food Code- 2-102.11 Demonstration (C) Responding correctly to the inspector's questions as they relate to the specific FOOD operation.

18) Explaining steps that are taken to prevent intentional ADULTERATION by CONSUMERS, FOOD EMPLOYEES, or other persons including monitoring operations, ingredients, supplies, and finished products for unusual or suspicious activities, and similar FOOD DEFENSE activities.

ADD- FDA Food Code – 2-103.11 Person in Charge the PERSON IN CHARGE shall ensure that: (Q) EMPLOYEES are aware of food defense, such as signs of intentional acts of ADULTERATION as it relates to their assigned duties and report suspicious activity to the PERSON IN CHARGE.

ADD- FOOD DEFENSE Definition: FOOD DEFENSE is the effort to protect food from acts of intentional ADULTERATION.

c. Charge 3 - Report the committee's findings and recommendations back to the Conference at the next Biennial Meeting.
Our committee co-chairs will submit our findings and approved recommendations as CFP 2023 issue(s), forwarding to our Council II Chair, Vice Chair for comment, then submit to our CFP issue receiver.

d. Charge 4 - The Committee would work closely with the FDA Food Defense and Emergency Coordination staff in CFSAN.

   Our committee wishes to thank our FDA Consultants, some of whom represent the FDA's Food Defense and Emergency Coordination staff in CFSAN. They actively participated in our committee meetings and discussion. USDA was also present for our meetings, provided Annex update and actively participated with input during discussion of our charges.

3. ***Charges INCOMPLETE and to be continued to next biennium:***

   There are no incomplete charges, our committee completed work on the four charges provided by Council II.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

1.

2.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. ***Issue #1: Report – Committee Name:*** **List of content documents submitted with this Issue:**
Committee Member Roster:

☒ ***See attached revised roster PDF*** ☐ ***No changes to previously approved roster***

"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

FDC Membership roster is updated to include alternate members requested by Co-Chairs to participate as voting members. Participants who have resigned from the committee are noted with a strikethrough.

(1) ***Other content documents:***

b. List of supporting attachments: ☒ ***Not applicable***

(b.i.1)

1. ***Committee Issue #2***: Amend Food Code – add Food Defense requirement under 2-102.11(C).
2. ***Committee Issue #3***: Amend FDA Model Food Code Annex 2, Section 4 Food Defense references.
3. ***Committee Issue #4:*** Approval and Posting of Food Defense Guidance Document

Food Defense

Employee Orientation

Establishment Name: _____ **Employee ID#:** _____

Food Employee Name: _____

Employee Awareness Checklist: The purpose of this checklist is to provide a guideline to help raise employee awareness pertaining to Food Defense. This can be used during employee orientation or during routine employee training to help document Food Defense discussions.	**Employee Initials**
Be a responsible employee. Communicate any potential food defense issues to your manager.	
Be aware of your surroundings and pay close attention to customers and employees who are acting suspiciously or are not where they belong	
Limit the number of personal items you bring into your work establishment and keep items secure in a designated area	
Be aware of who is working at a given time and where (in what area) they are supposed to be working.	
Periodically monitor the food display and food service areas (like salad bar, food displays, and other self-service foods.)	
Make sure chemicals are labeled an in their designated storage or sales area. Notify manager if large amounts of chemicals are missing.	
Know your company guidelines and follow them. If you have questions or believe company guidelines are not being followed, request assistance from your manager.	
Take all threats seriously, report any verbal or social media threats made by other employees or customers to your manager.	
If the back door is supposed to be locked and secure, **make sure it is!**	
If something doesn't look normal, **stop** using the product and **notify** your manager **immediately**. For example, if a food product or chemical you use looks different than it usually does	
If an ex-employee or non-employee enters an **"employees only"** area, let them know they have entered an "employee only" area, ask if they need help, escort them out of the employee area. Notify the person in charge or a manager.	
Cooperate in all investigations and notify management or corporate office. This could mean answering questions from the police or other government officials	
Do not talk to the media; refer all questions to your manager, person in charge, or corporate office.	
If you are aware of a hoax, prank, or social media challenge, notify your manager **immediately**.	
CUSTOMER AWARENESS SOP:	
Be aware of any unattended bags or briefcases customers bring into your operation, notify your manager **immediately**.	
If a customer walks into an **"employee only"** area of your operation, ask the customer politely if he or she needs help, then notify a member of management.	
VENDOR AWARENESS SOP:	
Check the identification of any vendor or service person that enters restricted areas of your operation and do not leave him or her unattended. Make sure management is aware of any after-hour vendor services or deliveries.	
Monitor all products received and look for any signs of tampering.	
When a vendor is making a delivery, never accept more items than what is listed on your invoice. If the vendor attempts to give you more items than listed, **notify your manager**.	
When receiving deliveries: **Step 1.** Always ask for identification. **Step 2.** Stay with the delivery person. **Step 3.** Do not allow the person to roam freely throughout your operation. **Step 4**. Delivery vehicle must always be attended or locked when the driver is away delivering products.	
FACILITY AWARENESS SOP:	
Report all equipment, maintenance, and security issues to your manager.	
Document any equipment, maintenance, and security issues.	
Be aware of the inside and outside of your facility, including the dumpster area, and report anything out of the ordinary.	
ESTABLISHMENT SPECIFIC FOOD DEFENSE (OPTIONAL):	

EMPLOYEE SIGNATURE DATE OWNER/MANAGER SIGNATURE DATE

Resourced by: SURE, Food Defense Manager Manual For food service and retail establishments

NEW EMPLOYEE ORIENTATION

1. It is the recommendation that food establishment employees complete this Food Defense Employee Orientation form within 30 days of hire. This includes anyone that serves or sells food, including volunteers, owners, and managers, regardless of whether they have been trained in food safety.

2. The Food Defense Employee Orientation should be completed in its entirety.

3. The food establishment employee should complete the top section which includes Establishment Name, Name of Employee, and the Employee ID Number (if applicable).

4. Food establishment employee should read and initial all the statements listed under each topic.

5. Please make sure that both the owner/manager and food employee sign and date the form.

6. Completed Food Defense Orientation forms should be maintained as part of the food establishment's operating records and kept for two years. You are encouraged to keep the original completed forms for the duration of the employee's employment.

7. This form should be completed only one time by each food establishment employee. If you wish to review this information again in the future with an employee who previously completed the form, follow these steps. Review the information and have the employee sign and date the back of the form.

Committee Name: Food Defense

Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email	
Espinoza	Albert	Co-Chair	Industry - Retail Food	H-E-B	San Antonio	TX	210-8845783	espinoza.albert@heb.com	
Bonsky	Jennifer	Co-Chair	Regulatory - State	Michigan Department of Agriculture & Rural Development	Lansing	MI	517-614-0149	bonskyj@michigan.gov	
Inman	Adam	Member	Regulatory - State	Kansas Dept. of Ag	Manhattan	KS	785-5646764	adam.inman@ks.gov	
Morris	Travis	Member	Regulatory - State	Florida Department of Health	Tallahassee	FL	850-9016498	travismorris10@hotmail.com	
~~Harrison~~	~~Lisa~~	~~Member~~	~~Regulatory - State~~	~~Indiana Department of Health~~	~~Indianapolis~~	~~IN~~	~~317-4122106~~	~~lharriso@isdh.in.gov~~	~~Notified her CC Chairs she accepted another opportunity. Jennifer confirmed her email no longer active.~~
Vauls	Patricia	Member	Regulator - State	Maryland Department of Health	Baltimore	MD	410-7678447	patricia.vauls@maryland.gov	Patricia Vauls accepted position as Regulator -State voting member. 11/17
Bell	Wendy	Member	Regulatory - Local	Mecklenburg County Public Health	Indian Trail	NC	980-257-3999	Wendy.Bell@MecklenburgCountyNC.gov	
Villareal	Rolando	Member	Regulatory - Local	County of Sacramento	Sacramento	CA		surfvillareal@gmail.com	
Baroudi	Dr. Al	Member	Industry - Food Service	The Cheesecake Factory	Thousand Oaks	CA	818-8715890	abaroudi@thecheesecakefactory.com	
Morrison	Laura	Member	Industry - Food Service	Ohio Restaurant Association	Columbus	OH	614-5634495	lmorrison@ohiorestaurant.org	
Waldroop	Hillary	Member	Industry - Retail Food	Publix Super Markets	Lakeland	FL		hillary.waldroop@publix.com	
~~Ciarimboli~~	~~Ellen~~	~~Member~~	~~Industry - Retail Food~~	~~Hy-Vee Inc~~	~~West Des Moines~~	~~IA~~	~~515-7793553~~	~~eciarimboli@hy-vee.com~~	
~~Allen~~	~~Consuelo~~	~~Member~~	~~Industry - Retail Food~~	~~Whole Foods Market~~	~~Austin~~	~~TX~~	~~512-4268709~~	~~consuelo.allen@wholefoods.com~~	
Brown	Bob	Member	Industry - Retail Food	Whole Foods Market	Austin	TX	512-9447405	robert.brown@wholefoods.com	
Summers	Christine	Member	Industry - Vending and Distribution	Compass Group - Cantee	Belmont	NC	425-2816397	christine.summers@compass-usa.com	
Lindholm	Jeffrey	Member	Industry - Support	iCertainty	Chevy Chase	MD	240-9084111	jeff.lindholm@icertainty.com	
Collins	Alicia	Member	Industry - Support	Steritech	Charlotte	NC	707-208-4399	Alicia.Collins@Steritech.com	
~~Baker~~	~~Rance~~	~~Member~~	~~Industry - Support~~	~~NEHA~~	~~Denver~~	~~CO~~	~~303-3241161~~	~~rbaker@neha.org~~	
Kincheloe	James	Member	Consumer	Center for Science in the Public Interest	Washington	DC	707-490-7087	jkincheloe@cspinet.org	

Non-Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email	
Dutilly	Devin	FDA Consultant	Federal	FDA			301-348-1980	Devin.Dutilly@fda.hhs.gov	
Wanucha	Donna	FDA Consultant ALT	Regulatory - Federal	FDA			678-616-5600	Donna.Wanucha@fda.hhs.gov	
Clark	Carrie	USDA Consultant	Regulatory - Federal	USDA-FSIS				carrie.clark@usda.gov	
Hanson	Patricia	Alternate	Regulator - State	FDACS	Tallahassee	FL	850-6669090	patricia.hanson@fdacs.gov	
~~Davis~~	~~Diane~~	~~Alternate~~	~~Regulatory - Local~~	~~Harris County Public Health~~	~~Missouri city~~	~~TX~~	~~713-2746367~~	~~diane.davis@phs.hctx.net~~	
~~English~~	~~Amber~~	~~Alternate~~	~~Regulatory - Local~~	~~Washoe County Health Distric~~	~~Reno~~	~~NV~~		~~aeenglish@washoecounty.us~~	~~Withdrew, 11/1/2021~~
Graham	Julian	Alternate	Industry - Food Service	Centerplate	Lutherville Timonium	MD	407-7120481	julian.graham@me.com	
Millwood	Corey	Member	Industry - Retail Food	Publix	Marietta	GA	678-6728703	corey.millwood@publix.com	
Melichar	Wayne	Alternate	Industry - Vending and Distribution	Feeding America	Elmhurst	IL	312-3995281	WMELICHAR@FEEDINGAMERICA.ORG	
Cammarata	Tara Paster	Alternate	Industry - Support	Paster Training, Inc.	GILBERTSVILLE	PA	484-4318240	tara.paster@pastertraining.com	
Guzzle	Patrick	Alternate	Industry - Support	National Restaurant Association	Boise	ID	208-515-8688	pguzzle@restaurant.org	
Kantrowitz	Sarah	Alternate	Academia	Perkins&Will	Boston	MA	914-5230757	sarah.e.kantrowitz@gmail.com	
Wilson	David	Alternate	Consumer (organizations)	After School Matters	La Grange	IL	708-5820022	d.wilson180@my.chicago.chefs.edu	
Garren	*Donna*	alternate	Processing	Institute	Arlington	VA	703-6630252	dgarren@affi.com	
committee size is standing									

Food Defense

Employee Orientation

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Committee Name: Food Safety Management Systems

Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Sedlak	Mandy	Chair	Industry - Food Service	EcoSure, a Division of Ecolab	Naperville	IL	612-271-4935	mandy.sedlak@ecolab.com
Sylvis	Christine	Co-Chair	Regulatory - Local	Southern Nevada Health District	Las Vegas	NV	7027590507	sylvis@snhd.org
Huffman	Troy	Member	Regulatory - State	Colorado Dept. of Public Health & Environment	Denver	CO	3036923664	troy.huffman@state.co.us
Jackson	Jeff	Member	Regulatory - State	Arkansas Department of Health	Little Rock	AR	8708477619	jeff.jackson@arkansas.gov
Smith	Colleen	Member	Regulator - State	NH DHHS	Concord	NH	16032714858	colleen.smith@dhhs.nh.gov
Sanders	Heather	Member	Regulator - State	Pennsylvania Department of Agriculture	Harrisburg	PA	717-836-2115	hesanders@pa.gov
Pollock	Evelin	Member	Regulatory - Local	Harris County Public Health	Houston	TX	713-248-5691	evelin.pollock@phs.hctx.net
Woods	Yolanda	Member	Regulatory - Local	Shelby County Government	Memphis	TN	19012229190	yolanda.woods@shelbycountytn.gov
Monique	Crawford	Member	Regulator - Local	Harris County Public Healh	Houston	TX	8328402522	monique.crawford@phs.hctx.net
Boyles	Chris	Member	Industry - Support	Steritech	Charlotte	NC	704-968-3822	chris.boyles@steritech.com
Rossow	Todd	Member	Industry - Retail Food	Publix Super Markets, Inc.	Lakeland	FL	8637977659	todd.rossow@publix.com
Edelen	Jeffrey	Member	Industry - Retail Food	Whole Foods Market	Austin	TX	737-932-1143	jeff.edelen@wholefoods.com
Whitlock	Lisa	Member	Industry - Retail Food	Lisa Whitlock Retail Food Safety Consultant	Loma Rica	CA	(530) 770-1953	kitchencooker63@gmail.com
Tew	Dan	Member	Industry - Food Service	Yum! Brands	Prosper	TX	5026193447	daniel.tew@yum.com
Okenu, Ph.D.	Dan	Member	Industry - Food Service	H-E-B Grocery Company	San Antonio	TX	(404)805-2221	okenu.daniel@heb.com
Hsieh	Hsing-Yi	Member	Industry - Retail Food	Skogen's Festival Foods	De Pere	WI	9205405644	hhsieh@festfoods.com
Zaziski	Linda	Member	Industry - Food Service	Little Caesar Enterprises/Blue Line Distribution/Champion Food Service	Detroit	MI	586-243-6932	linda.zaziski@lcecorp.com
Nutt	Elizabeth	Member	Industry - Support	Association of Food and Drug Officials	Tuilsa	OK	9182711420	enutt@afdo.org
Quam	Susan	Member	Industry - Support	Wisconsin Restaurant Association	Madison	WI	6082162875	squam@wirestaurant.org

Non-Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Otto	CRD Jessica	FDA Consultant	Regulatory - Federal	FDA			240-402-1876	Jessica.Otto@fda.hhs.gov
Marcello	John	FDA Alterante	Regulatory - Federal	FDA			480-829-7396 x 2035	john.marcello@fda.hhs.gov
Wittry	Beth	CDC Consultant	Regulatory - Federal	CDC			770-488-7333	Xks5@cdc.gov
Otto	Mark	CDC Consultant Alternate	Regulatory - Federal	CDC			404-498-6400	rwv3@cdc.gov
Smith	Melissa	Alternate	Industry - Food Service	TPC Training - State Food Safety	Buffalo Grove	IL	5037295667	melissa.smith@statefoodsafety
Temke	Laura	Alternate	Industry - Retail Food	Sendik's Food Markets	Milwaukee	WI	4147327585	laura.temke@sendiks.com
Wildey	Laura	Alternate	Industry - Retail Food	National Environmental Health Association (NEHA)	Denver	CO	3026685403	lwildey@neha.org
ZENLEA	JEREMY	Alternate	Industry - Retail Food	EG America	Westboro	MA	6035832506	jzenlea@cumberlandfarms.com
Bussiere	Vanessa	Alternate	Industry - Support	Aspire Food Safety Solutions LLC	Tacoma	WA	253-334-5181	vanessa@aspirefoodsafety.com
Dohnal	Theodore	Alternate	Industry - Support	Huginn Consulting LLC	Big Rapids	MI	231-349-3322	tdohnal@huginnconsultingllc.com
Eisenbeiser	Ashley	Alternate	Industry - Support	FMI	Arlington	VA	2022200689	aeisenbeiser@fmi.org
Flusberg	Martin	Alternate	Industry - support	Powerhouse Dynamics	Newton	MA	617 680 2471	martin@powerhousedynamics.com
Seminara	Mario	Alternate	Industry - Support	Food Safety Works LLC	Lakewood	CO	7206811615	mario@foodsafetyworksll.com
Follett*	Emilee	Alternate	Industry - Support	State Food Safety				efollett@statefoodsafety.com
Wilson	David	Alternate	Consumer (organizations)	After School Matters	La Grange	IL	17085820022	d.wilson180@my.chicago.chefs.edu
Crawford, Ed.D.	Herman	Alternate	Academia	Nutri-Rific LLC	Webster	NY	9728850067	NUTRIRIFIC@GMAIL.COM
Dunleavy	Sean	Alternate	Regulator - State	Michigan Department of Agriculture and Rural Development	Howell, MI 48855	MI	15172438895	dunleavys@michigan.gov
Wallingford	Shelly	Alternate	Industry - Food Service	First Watch Restaurants	Bradenton	FL	(720) 456-5702	swallingford@firstwatch.com

Note: *Minimum council committee size is 11 (as noted above): 1-Chair; 1-Vice Chair; 1-State; 1-Local; 2-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise; 6-Non-voting alternates.*
Maximum council committee size is 23 voting members: 1-Chair; 1-Vice Chair; 4-State; 4-Local; 8-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise; 18-Non-voting alternates.
Membership on standing committees is defined by the Executive Board. On all CFP committees, the committee chair, co-chair(s), and vice chair(s) all count towards constituency balance.

*added at the direction of Conference Chair and not eligible as a voting member until approved by the Executive Board

Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

The Conference Chair, Executive Director, Council Chair, or Issue Chair may return committee reports, Issues, or attached documents requesting edits to improve clarity or understanding, or to include missing information.

Committee-submitted documents may impact the image, credibility, and integrity of the Conference as an organization. With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME: Food Safety Management Systems (FSMS) Committee

DATE OF FINAL REPORT: December 2, 2022

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Mandy Sedlak, Committee Co-Chair Industry
Christine Sylvis, Committee Co-Chair Regulatory

COMMITTEE CHARGE(S):

Issue: 2020 II-030

1.Identifying barriers to the universal *voluntary* development and implementation of documented FSMSs consistent with Annex 4 of the Food Code.

2.Identifying solutions for overcoming the identified barriers in #1 and provide recommendations for how to promote the solutions.

3.Conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code. In the assessment, the committee should consider providing feedback on:

a) the hurdles/challenges involved in such a requirement; and

b) recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries. The committee should also consider a gap analysis of § 2-103.11 as a starting point.

4.Developing recommendations on next steps to promote universal development and implementation of documented FSMSs consistent with Annex 4.

5.The committee should report its findings and recommendations at the next Biennial Meeting of the Conference for Food Protection. While FDA's efforts will be ongoing during this time, the findings and recommendations will continue to be useful to the agency as it continues to implement its blueprint on retail modernization.

COMMITTEE WORK PLAN AND TIMELINE:

The committee met monthly from November 2021 through November 2022. Workgroup documents were shared via FoodSHIELD, CFP Microsoft Teams/SharePoint, and attached to calendar invitations. Microsoft Teams was used for monthly meetings and for the working document. The following milestones were established: identifying barriers to the universal *voluntary* development and implementation of documented FSMSs consistent with Annex 4 of the Food Code by January 2022; identifying solutions for overcoming the identified barriers and provide recommendations for how to promote the solutions by August 2022; conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs in a future edition of the Food Code by September 2022; and developing recommendations on next steps to promote universal development and implementation of documented FSMSs by October 2022. Periodic reports were prepared and submitted in October 2021, March 2022, July 2022, and November 2022, in accordance with the CFP master calendar.

COMMITTEE ACTIVITIES:

1. Overview of committee activities:

Council II Vice Chair Drafted initial proposed membership roster which was approved by the Board.

Dates of committee meetings or conference calls: The committee has met on November 16, 2021, December 14, 2021, January 18, 2022, February 14, 2022, April 19, 2022, May 17, 2022, June 24, 2022, July 26, 2022, October 18, 2022, and November 15, 2022, November 18, 2022. A subcommittee was created to organize identified barriers into subcategories and consolidate and edit the barriers. Additional subcommittees were created to review the solutions submitted by barrier subcategory (economic, people, and training), and to identify pros and cons.

The initial meeting November 16, 2021, included committee member introductions, a review the committee charges, a timeline for addressing the charges was agreed upon, and it was decided that FoodSHIELD will be used for document sharing.

During the meeting December 14, 2022, work being conducted on FSMSs by other groups such as the food safety management survey that the Association of Food and Drug Officials (AFDO) in conjunction with the FDA Retail Food

Safety Regulatory Collaborative was discussed, an overview of FoodSHIELD and the working document was provided, and committee members were encouraged to submit new barriers and barriers submitted.

During the meeting January 18, 2022, the categories to organize barriers (economics, training, processes, accountability, people) were discussed and an overview of the AFDO food safety management industry survey was provided.

During the meeting February 14, 2022, the barriers listing, as organized by the subcommittee, were reviewed. The committee determined that the terms in Annex 4 of the Food Code (Food Safety Culture, Food Safety Management Systems (FSMS), and Active Managerial Control (AMC)) needed to be clarified and defined prior to moving forward with solutions.

During the meeting April 19, 2022, a definition for AMC was decided upon and work on a definition for FSMS was commenced.

During the meeting May 17, the format for the solutions listing was decided upon and three subcommittees, with leads for each of the related barrier categories were created (economic, people, training). Work on a definition for FSMS continued.

During the meeting June 24, 2022, the definition for FSMS was completed and an example of how to implement a FSMS was discussed. Review of solutions to economic and people barriers were complete. The co-chairs met with FDA Advisor, John Marcello, on June 24, 2022, to discuss the direction of the Committee and future actions/charges of the FSMS. The co-chairs met with Council II Chair and Vice-Chair, Courtney Halbrook, and Wendy Bell, on July 13, 2022, to discuss the progress of the Committee and recap the discussion with the FDA Advisor to ensure it aligned with the charges of the Committee.

During the meeting July 26, 2022, a quorum was not established so the definition of FSMS could not be voted upon. Options for the future direction of the Committee was discussed and work on Charge #3 commenced.

During the meeting September 20, 2022, the committee discussed and voted on changes to the roster. The roster changes were necessary to form a quorum to vote in future meetings as a result of non-attendance and individual requests. The roster update consisted of removing voting members Mark Speltz (Regulator – Sate) and Naomi Macias (Regulator – Local) who respectfully asked to be removed from the committee due to a new job responsibility. Moved voting members Sean Dunleavy (Regulator – State) and Shelly Wallingford (Industry- Food Service) to non-voting members due to missing at least three consecutive meetings and not responding to an email regarding future participation. Transferred Troy Huffman and Hsing Yi from non-voting members to voting members to replace those listed in 1 and 2 above. Transferred Evelyn Pollak to an alternative voting member. The committee also voted/approved the proposed FSMS definition. The committee also established a special meeting on September 29, 2022, to finalize pros and cons. A reminder was made that the committee would vote on accepting the proposed solutions and barriers on the October 18, 2022, meeting. There was also discussion around the future of the FSMS committee.

During the October 18, 2022, meeting, a quorum was established, and the committee voted and approved the proposed barriers and solutions. The committee discussed the development of prospective Committee Issues to present to Council II Chair and Vice Chair by November 18, 2022. The committee also discussed consideration for recreating the FSMS Committee with proposed committee charges and the idea presented by Eric Moore and Ben Chapman, Digital Food Safety Systems (DFSS) Committee Co-Chairs, about submitting an Issue to establish a joint Standing Committee to encompass the work of the FSMS and DFSS Committees. Next steps, co-chairs met with stakeholders for considering recreating with the DFSS committee. Committee co-chairs Mandy Sedlak and Christine Sylvis will draft charges report and issues for review by the FSMS committee before the November 15, 2022, meeting.

During the November 15, 2022, meeting, the committee voted/approved to accept the Pros/Con report as written to be included in final report submission. The next discussion was around developing recommendations on how to promote universal development and implementation of documented FSMSs consistent with Annex 4. The committee started with 2 options. 1. Consider recreating FSMS Committee – creating committee charges using the Barrier's list as a starting point. 2. Consider idea presented by Eric Moore and Ben Chapman, Digital Food Safety Systems (DFSS) Committee Co-Chairs, submitting an Issue to establish a Standing Committee to encompass the work of the FSMS and DFSS Committees. The will of the FSMS committee was to request a standing committee (w/o digital committee). A motion was made to recreate the committee as council committee w/chargers and to create a separate issue to change from a council committee to a standing committee w/duty as stated by constitution and bylaws. Motion passed. The final discussion of the meeting was around the charges for FSMS Committee during 2023-2025 biennium. The considerations for charges were:

- Risk Factor for PIC provision
- Cost benefit analysis (NACCHO/collaborative)
- Develop a toolbox, develop verbiage to outline prerequisites (SOPs) that are not covered. Review results of EHS-Net/CDC collaboration and incorporate into toolbox
    - Focus on Employee Health, Healthy people
    - Use the school USDA/HACCP SOPs as a possible guide/tool; consider reviewing #4 "Guidance for School Food Authorities, "Developing a Food Safety Program based on the process approach to

HACCP Principles" Consider having CDC provide an overview of project and what tools may come out of this down the road.
    - CONSIDER: Piloting a FSMS for Employee Health program to see how it might work. Find industry volunteer to develop FSMS; site visits to support and verify effectiveness. Industry/Regulatory Partner. Note this is something that CDC is already using this approach/project. Initialed via EHS-Net
    - Get understanding of EHS-Net project as how it relates to FSMS committee work and consider collaboration and providing guidance based on the results of the study.
    - The overarching thread of these suggestions is that we need to increase awareness, communication and idea sharing with initiatives already underway. A committee may not be well suited to do a pilot study themselves but give the results they could give guidance.
- Reviewing the previously identified pros and cons to barriers to the universal voluntary development and implementation of documented FSMS and provide additional remedies
- Items not covered in our current charges
- Complete gap analysis of PIC Provision
- Committee Charge to fill in the gaps between all areas working on aspects of employee health and all aspects of collaboration/projects currently being done.

During the November 18, 2022, meeting, the committee discussed how to and where to suggest the addition of the approved FSMS definition into the Food Code. After much discussion, the committee proposed that it be added in the public health significance section. (The Definition be incorporated into chapter 1, and that FSMS and its definition be incorporated into to AMC.) The committee voted to include FSMS, AMC into code w/voluntary use terminology, the motion passed. Mandy and Christine edited the draft issues to improve clarity and style as discussed and shared the issues with all members. The final report was submitted to Council II Chair and Vice Chair on November 18, 2022

In addition to monthly meetings additional Subgroup Meetings took place on the following dates:

- 01-11-2022
- 02-02-2022
- 02-08-2022
- 02-28-2022
- 03-22-2022
- 04-14-2022
- 05-13-2022
- 07-13-2022
- 08-25-2022
- 9-29-2022
- 10-31-2022
- 11-02-2022

Collaborative Meetings:

- 09-13-2022
- 11-04-2022

2. Charges <u>COMPLETED</u> and the rationale for each specific recommendation:

a. (Charge 1) Identifying barriers to the universal *voluntary* development and implementation of documented FSMSs consistent with Annex 4 of the Food Code.
    i. The Committee met on several occasions including subcommittee work to identify barriers to the universal voluntary development and implementation of documented FSMSs. The barriers are documented in the Committee Findings Report.

b. (Charge 2) Identifying solutions for overcoming the identified barriers in #1 and provide recommendations for how to promote the solutions.
    i. The Committee met on several occasions including subcommittee work to identify solutions for

overcoming the identified barriers in #1 and provide recommendations for how to promote the solutions. The solutions are documented in the Committee Findings Report.

c. (Charge 3) Conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code. In the assessment, the committee should consider providing feedback on: a) the hurdles/challenges involved in such a requirement; and b) recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries. The committee should also consider a gap analysis of § 2-103.11 as a starting point.
    i. The Committee met on several occasions including subcommittee work to identify pros/cons assessment of including a requirement for the development and implementation of documented FSMSs in a future edition of the Food Code. The pros and cons are documented in the Committee Findings Report.

d. (Charge 4) Developing recommendations on next steps to promote universal development and implementation of documented FSMSs consistent with Annex 4.
    i. The Committee met on several occasions including subcommittee work to develop recommendations on next steps to promote universal development and implementation of documented FSMSs consistent with Annex 4. The Committee is submitting an Issue for the 2023 CFP Biennial Meeting to include the definitions of Active Managerial Control and Food Safety Management Systems into Chapter 1 of the Food Code and incorporate these systems into Chapter 2 of the Food Code in § 2-103.11. It is also being recommended that the future FSMS Committee continue to develop recommendations on additional steps to promote universal development and implementation of documented FSMSs.is

e. (Charge 5) The committee should report its findings and recommendations at the next Biennial Meeting of the Conference for Food Protection. While FDA's efforts will be ongoing during this time, the findings and recommendations will continue to be useful to the agency as it continues to implement its blueprint on retail modernization.
    i. The Committee is submitting an Issue for the 2023 CFP Biennial Meeting to acknowledge this final report with attachments containing meeting minutes and the Committee Findings Report which includes the findings and recommendations.

3. Charges <u>INCOMPLETE</u> and to be continued to next biennium:

All charges are complete, however continued work is needed to promote universal development and implementation of documented FSMSs.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***
☐ ***Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.***

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. ***Issue #1:*** **Report – Food Safety Management System (FSMS) Committee**

List of content documents submitted with this Issue:

- 2021-2023 FSMS Committee Roster
- 2021-2023 FSMS Committee Final Report
- FSMS Findings Report

Committee Member Roster:

☐ ***See attached revised roster PDF*** ☒ ***No changes to previously approved roster***
"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) ***Other content documents:***

a. List of supporting attachments: ☐ ***Not applicable***

- 2021-2023 FSMS Committee Meeting Minutes
- 2021-2023 FSMS Committee Attendance Log

2. ***Committee Issue #2***: Re-create – FSMS Committee

3. ***Committee Issue #3***: Create FSMS Committee as Standing Committee

4. ***Committee Issue #4:*** Amend Food Code – Include Active Managerial Control and FSMS

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ISSUE 2020-II-030

Title: **Creation of a Food Safety Management System (FSMS) Committee**

Committee Recommended Solution: The Conference recommends...:

a Food Safety Management System (FSMS) Committee be created and work with stakeholders such as but not limited to the Retail Food Safety Regulatory Association Collaborative to identify recommendations for developing and implementing documented, HACCP principles-based Food Safety Management Systems (FSMSs) in all food establishments to support FDA's blueprint for a New Era of Smarter Food Safety. The FSMS Committee should consider:

1. Identifying barriers to the universal voluntary development and implementation of documented FSMSs consistent with Annex 4 of the Food Code.
2. Identifying solutions for overcoming the identified barriers in #1 and provide recommendations for how to promote the solutions.
3. Conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code. In the assessment, the committee should consider providing feedback on:
   a) Hurdles/challenges involved in such a requirement; and
   b) Recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries. The committee should also consider a gap analysis of § 2-103.11 as a starting point.
4. Developing recommendations on next steps to promote universal development and implementation of documented FSMSs consistent with Annex 4.
5. The committee should report its findings and recommendations at the next Biennial Meeting of the Conference for Food Protection. While FDA's efforts will be ongoing during this time, the findings and recommendations will continue to be useful to the agency as it continues to implement its blueprint on retail modernization.

CHARGE 1: BARRIERS

Economic Barriers

Economic related barriers to the universal voluntary development and implementation of documented FSMSs consistent with Annex 4 of the Food Code.

1. **Resource Barriers**
    a. Insufficient supervision/oversight of staff (such as a Certified Food Protection Manager (CFPM)) during all hours of operation.
    b. Lack of resources (time, personnel) to develop and implement SOPs and train on FSMSs.
    c. Implementing FSMSs is costly and difficult.
    d. Lack of expertise and direction by staff to create FSMSs.
    e. Costs associated with technology upgrades (electronic monitoring on refrigeration, electronic logs/recordkeeping, databases) to capture data and report findings.
2. **Time Barriers**
    a. Staff and management do not have enough time dedicated for monitoring and recordkeeping.
    b. Lack of time for development, implementation/training, maintenance, and continuous improvement.
    c. FSMSs are not addressed during the plan review process. Regulators place emphasis on physical facilities over operational elements (AMC and FSMS) during plan review
3. **Cost Barriers**
    a. Concern that FSMSs will increase costs due to an increase in corrective actions.
        i. Training costs associated/especially with high turnover and staff shortage.
        ii. Costs for development, implementation/training, maintenance, and continuous improvement (Labor, Materials, Support, Training).
        iii. Cost/benefit (return on investment) of FSMSs is hard to quantify.
    b. Cost of foundational prerequisite programs (i.e., facility, equipment, pest management, cleaning).

People Barriers

People related barriers to the universal voluntary development and implementation of documented FSMSs consistent with Annex 4 of the Food Code.

1. **Buy-in Barriers**
    a. Resistance to change.
    b. Disconnect between food safety behaviors and the occurrence of foodborne illness.
    c. Lack of knowledge of the “why” for food safety related to business case.
    d. Food safety is behavioral so getting staff (leadership and front-line) to buy in to it is difficult.
    e. Lack of operator motivation to implement and maintain more processes. FSMSs are perceived as extra work.
    f. Voluntary FSMSs without tangible incentives will probably not be followed. Voluntary perceived as not important or necessary.

g. Development of a FSMS will vary for different types of food establishments (chain/independent, quick service/full service, process 1/2/3, etc.). Although the principles are the same, model templates may not apply to all types of food establishments.
h. Resistance of leadership to invest in FSMSs, people, and processes to help maintain food safety.

2. Leadership/Accountability Barriers

a. Lack of management commitment.
b. Competing priorities.
c. Lack of management setting expectations and holding people accountable.
d. Lack of a champion.

3. Values Barriers

a. Lack of trust and understanding between industry and regulatory folks.

4. Cultural/Ethnicity Barriers

a. Language and literacy barriers (spoken and written).
b. Lack of belief in the science and causes of foodborne illness.

Training Barriers

Training related barriers to the universal voluntary development and implementation of documented FSMSs consistent with Annex 4 of the Food Code

1. Training Barriers

a. Lack of training/time for regulatory time to coach, offer guidance to industry
b. Lack of dedicated time to develop procedures that are prerequisites of FSMSs, train food handlers on procedures, review their level of understanding, monitoring, and coaching to improve
c. Lack of training for industry on understanding, developing, and implementing a FSMS.
d. FSMS is not a defined or universally understood/consistent term. Inconsistent use of Food Safety Culture, Food Safety Management Systems, and Active Managerial Control.

2. Knowledge Barriers

a. Lack of knowledge of hazards, risk factors, interventions, and corrective actions.
b. Lack of understanding of the science and causes of foodborne illness.
c. Perception that they “have it covered”.
d. Lack of technical ability to create a FSMS.
e. Upper management may not be clear on the importance of food safety and current food safety conditions.

3. Processes Barriers

a. Some food establishments currently have an unstable foundation of prerequisites (pest control, sanitation, crisis management, etc.) and are not set up for success for developing and implementing FSMSs.
b. Businesses are different, significant process variability. Not a one-size fits all approach.
    i. Type of Operation (Retail food, Sit down Restaurants, Quick serve Restaurants, Convenience Stores)
    ii. Size of operation (# of locations, Franchise operation, Regional vs. national company)

c. Who oversees and manages food safety? Managed at Corporate level vs at the restaurant/store location

4. **System Development/SOPs Barriers**
    a. Lack of standardized processes (across multiple stores, regional, company locations (decentralized management)).
    b. Lack of resources (implementation guides, creation examples, messaging, templates, sample SOPs, guidance documents and tools) to get a FSMS program started.
    c. Annex 4 is not an 'easy-read.' Terminology needs to be defined and used consistently between courses (FD215, FD218), the Food Code, and other materials. There have been significant advancements in the availability of tools since it was drafted.
    d. Lack of capturing and monitoring key food safety data points then using the data to maintain and improve food safety and quality
5. **Code Differences Barriers**
    a. Inconsistent terminology used with industry vs. regulatory.
    b. Many states don't adopt Food Code Annexes.
    c. Alignment between Federal, State, and local authorities.

CHARGE 2: SOLUTIONS

Economic Solutions

1. **Lack of resources (e.g., time, personnel, expertise) to develop procedures, implement and train procedures, and monitor ongoing implementation of procedures.**
    a. Provide tools for regulators to educate and assist operators. Provide guidance to regulators on how an inspection might differ for locations that have implemented voluntary a FSMS. Encourage regulatory agencies to schedule visits with operators to promote the adoption of voluntary FSMSs.
    b. Update FDA Food Code Annex to clarify what a FSMS is, how operators can implement them effectively, and how regulators can support them during visits.
    c. Create a starter kit that regulators can provide to operators (such as at the time of initial permitting.) Where appropriate, leverage existing FDA materials, posters, and videos for educating frontline workers. Include:
        i. Education on the basic concepts of FSMSs.
        ii. Examples of procedures, training and monitoring specific to each industry segment (restaurant, grocery, convenience store, etc.)
        iii. Examples of signage and job aids
        iv. Templates for logs
    d. Information on types of technology that can support FSMSs (electronic monitoring for refrigeration, electronic logs/recordkeeping, digital task management, etc.)
    e. Develop an industry-focused marketing campaign to promote FSMSs. Leverage resources and communication channels through the Retail Food Safety Collaborative. Include:
        i. Purpose and value of FSMSs, including cost benefit analyses with case studies and examples.
    f. Available tools and templates for FSMS components.

g. Develop a regulatory-focused marketing campaign to promote FSMSs. Leverage resources and communication channels through the Retail Food Safety Collaborative. Include:
    i. How to communicate the purpose and value of FSMSs.
    ii. Available tools and templates for operators.
    iii. Guidance for how to encourage the voluntary adoption of a FSMS.

2. **Perception that implementing FSMSs is costly and difficult.**
    a. Update ANSI CFPM requirements to include training on FSMSs to promote a more universal understanding of basic FSMS processes and how voluntary adoption improves food safety.
3. **Facilities are not designed to support FSMSs.**
    a. Provide support and training for regulators conducting the plan review process so that they can guide operators toward plans and specifications support voluntary FSMSs now and in the future.
    b. Provide training and materials for regulators conducting the plan review process, such as charts that illustrate FSMSs and encourage forward thinking about how preparation procedures, facility layout, and equipment choices provide a foundation for voluntary FSMSs.
4. **It is difficult to quantify the return on investment for a FSMS and demonstrate that the cost justifies the benefit.**
    a. Create a guidance document that operators can use to design, implement, and evaluate a Case Study to justify the cost effectiveness of FSMSs. Create specific versions for industry segments where appropriate.
        i. How do you create an effective study design?
        ii. What are the costs?
        iii. How do you quantify the benefit for employees, customers, the company?
        iv. How can results from recent FDA Risk Factor Studies be leveraged, e.g., over 60% fewer high-risk issues when managers had strong knowledge of their FSMS?
    b. What is the value proposition in terms of risk mitigation? In terms of quality?
        i. The cost avoidance of prevented foodborne illness outbreaks due to implemented FSMSs.
    c. Create a cost benefit analysis example to educate operators on the benefits of implementing FSMSs. Leverage the Retail Food Safety Regulatory Association Collaborative's "Active Managerial Control Incentive Programs Assessment Report" as a model. (Possibly engage the Collaborative to conduct this work.)
    d. Fund pilot programs to study and quantify the impact of implementation of FSMSs in the real world. Then publish results as detailed cases studies with costs, benefits, and lessons learned.
    e. Leverage the cost benefit analysis to organize and sponsor a collaborative marketing campaign aimed at operators around the cost benefit analysis to encourage voluntary adoption. Publicize through Collaborative and Industry organizations to ensure broad communication across stakeholders.
    f. Provide tools to educate regulatory food inspectors on how to leverage the cost benefit analysis when working with operators to encourage voluntary adoption of FSMSs.

People Solutions

1. Buy-in Barriers

a. For regulatory agencies and industry trade organizations to conduct a general cost benefit analysis for Code Compliance inspections and inspections focused on Risk Based incorporating FSMSs. Identify the return on investment for each type of inspection:
    i. Include stories and case studies of actual foodborne illnesses.
    ii. Create a sample business case that includes benefits to employees, customers, organization, quality, risk mitigation and costs, etc.
    iii. Reframe the role of FSMSs as a good practice that supports other elements of an operation, such as employee retention, training, cost controls to support and market FSMSs.
    iv. To conduct a study of actual costs of implementing FSMSs by the industry with impact changes.
    v. To conduct a study of actual costs of implementing FSMSs training and policy by the regulatory agencies doing risk- based inspections with impact changes as compared to Code Compliance inspection costs.
    vi. Develop simple communication messages that can be used to influence upper leadership. Communicate previous situations where companies did not invest and the negative effects. Several well-known examples exist. The use of facts and statistics can support the messages and can be used as a persuasion tool to increase interest in and creation of a FSMS.
    vii. Use the cost benefit analysis to educate the operator on reasons why they can't afford not to implement a comprehensive FSMSs designed to control hazards associated with foodborne illness risk factors in their businesses.
    viii. For regulatory authorities and industry members to build relationships focused on risk factors and FSMSs via networking meetings, new business start-up kits, virtual meetings, advisory group meetings…coffee with your health department, etc.
b. Identify individuals or groups of individuals within a food facility of industry and/or regulatory community that are food safety ambassadors and advocate for safe food handling practices and procedures that support FSMSs across the industry.
c. Increase in industry member awareness and participation in food safety as it relates to their job.
d. Recommend industry training of front-line workers incorporate the "FDA Retail Food Protection Industry Education Materials -Posters and Videos" into their new hire training plan or use similar training material that illustrate the consequences of poor behavioral food safety practices along with traditional training that describes how to do the procedure correctly.
e. Encourage regulatory agencies to conduct risk factor studies that use Food Code critical limits as part of the study of regulated businesses on a routine basis in partnership with the industry. Identify risk factors in need of priority attention, develop intervention strategies designed to control those problematic risk factors and publicize the initiative and results within the community.
f. Encourage regulatory agencies to implement the criteria in the FDA Voluntary National Retail Food Program Standards for improving their food programs.

g. Regulatory partners should provide outstanding customer service by being helpful and providing appropriate resources to the industry that support the implementation of a FSMS as part of their permit in a consistent and dependable manner.
h. Food safety regulators should tell stories of actual foodborne illness cases studies during their inspections to encourage industry member buy-in of implementing FSMSs. Use social media and commercials to increase industry and consumer awareness about the correlation between FSMSs and compliance of risk factors and how implementation of FSMSs can make a difference. Get statistics to support this message from FDA, CDC, Olmstead County, MN, and other agencies.
i. Consider the use of incentive programs or other systems that motivate good food safety practices. These motivators could include, but may not be limited to: public recognition, certificates/awards for achievement, positive feedback on inspection reports, etc. Examples:
    i. Inspector following up every month or so for first 6 months to a year to support Risk Control Plan for FSMS implementation.
    ii. Incentive programs for AMC of risk factors that includes model templates and examples which are easily accessible by industry members and regulatory authorities. The Retail Food Safety Regulatory Association Collaborative has examples at these links:
    https://ActiveManagerialControlincentiveProgramsAssessmentReport-RetailFoodSafetyCollaborative
    https://www.retailfoodsafetycollaborative.org/tools/active-managerial-control-incentive-programs-examples-from-jurisdictions-leading-the-way
j. Regulatory agencies recognize industry efforts who implement FSMSs successfully in their businesses. For example, regulatory agency could develop web-based public recognition of the business so it pops up whenever someone electronically searches for that business which can be removed by the regulatory agency as necessary. Another example -industry who implements FSMSs and control all hazards associated with foodborne illness risk factors that are in compliance at the time of regulatory inspections might get a permit fee reduction or inspected less frequently if they are routinely in compliance.
    i. Identify incentives for regulatory agency using FSMSs. For example -Inspectors who routinely provide training on FSMSs during inspections might get recognition from their Agency, especially if they are making a difference in their district.
    ii. Include FSMSs component in the application for the Crumbine Award and other state/national awards to recognize regulatory agency efforts in promoting the implementation of FSMSs by the regulated industry and getting improved long-term compliance of risk factors

2. Leadership/Accountability Solutions

a. Provide free guidance and resources through multiple collaborations (FoodSHIELD, Retail Food Safety Collaborative, FMI, NRA, etc.)
b. Encourage both bottom-up and top-down approaches to training, education, and communication on the importance of FSMSs. Create accountability at all levels for well-developed and executed FSMSs.
c. Food service establishments may consider hiring a consultant with expertise in FSMSs to assist in the development, execution, and improvement of the facility FSMS.

d. Define routine corporate level food safety reporting to the Corporate Suite along with recommendations for improvement.
e. Regulatory inspections can support industry efforts in implementing their FSMS by assessing compliance of hazards associated with foodborne illness risk factors at the time of inspection as priority over good retail practices in their limited time

3. Values Solutions

a. Build relationships between regulatory authorities and industry members so they:
    i. Share a common goal to focus on AMC of risk factors and FSMSs.
    ii. Educate on what a FSMS is and how to build/apply/improve.
    iii. Work collaboratively on solving problems around the control of hazards.
b. Regulatory inspectors can support industry efforts in implementing their FSMS by assessing compliance of hazards associated with foodborne illness risk factors at the time of inspection as priority over good retail practices in their limited time.
c. During and after Plan Review:
    i. Recommend industry use preoperational plans and/or inspections as a time to discuss FSMSs with the regulatory authority. Include a review of facility construction and design; menu items and food preparation process based upon how many times a menu item moves through the temperature danger zone, which is between 41 F and 135 F; food handling practices and behavior that may affect equipment needs and facility layout; training and education provided by whom; and current SOPs to support a comprehensive FSMS.
    ii. Operators are encouraged to work with their inspector to identify alternative food safety practices and behaviors to control hazards associated with foodborne illness risk factors after opening day as necessary. Such as, changing from a complex food process that involves cooling and reheating to same day service process that shouldn't require as much refrigeration or facility space.
d. Encourage food safety regulators to engage with food handlers and managers during inspections to explain the importance of food safety concepts using relatable language and storytelling, to foster understanding and buy-in of FSMSs.
e. Recommend regulatory authorities provide classroom and/or field training during onsite inspections that includes education for the industry using the "FDA Retail Food Protection Industry Educational Materials -Posters and Videos" or similar training materials that illustrate the consequences of poor behavioral food safety practices along with traditional training that describes how to do the procedure correctly. Additional option is to conduct/offer virtual training sessions/solution meetings" (This would allow for individualized interaction/topic specific training tailored for the operators needs/deficiencies. While still building the positive relationship between regulatory and business) - may also be a helpful tool to accommodate businesses who operate on second and third shifts.
f. For regulatory agencies to update their inspection reports and standardization procedures to include the assessment of FSMSs. For example, Olmstead County, MN developed a PTV Package (Discussion and Observation Guide and information poster showcasing the results of two in-depth studies) that they use, make appointments with the manager to sit down and have a discussion about food safety during non-busy time. They first began developing

their program in the late 1990's. Another example is FDA FSMSs assessment of foodborne illness risk factor areas to identify correlations between PTM and compliance of risk factors during their most recent risk factor studies.

g. Regulatory to look at incorporating/developing a separate consultative service who work exclusively with industry to assess/develop FSMSs. This division would operate separate from enforcement. OSHA and State OSH programs utilize this concept very effectively for workplace safety -examples: https://www.osha.gov/consultation, http://169.62.82.230/documents/dleg/.wsh_cet0165_216929_7.pdf. MIOSHA for example also utilizes an Alliance program to partner with organizations/businesses to promote/reward safety practices. http://www.agcmichigan.org/uploads/.1/0/6/5/106585507/infosheet_onsite_consultation_services_guideline.pdf. For the alliance, Associations like ASSP (American Society of Safety Professionals) has local chapters that will partner/sign an alliance with MIOSHA to promote and provide community-based services to members/nonmembers and community. This concept could be used/developed to promote effective FSMSs.

4. Cultural/Ethnicity Barrier Solutions

a. Encourage the use of translation services and/or storyboards to effectively communicate messages in multiple languages. The storyboards should illustrate the consequences of the improper food safety practices behavior as well as the desired food safety practices behavior. As an example, the FDA worked collaboratively with many regulatory agencies and industry members to develop storyboards in multiple languages for foodborne illness risk factors.

b. Seek feedback for solutions from other industry peers, food associations, your HR department, Risk Management, and Insurance Providers (as both of these divisions have enormous amounts of data, statistics, program assessments, stories, etc.) etc.

Training Solutions

1. Training Solutions

a. Provide training materials
   i. Assess current FSMSs implementation and focus on vulnerabilities/gaps
   ii. Illustrate the consequences of poor behavioral food safety practices
   iii. Traditional training materials for front line employees based on their job responsibilities

b. Recommend regulatory agencies
   i. Be trained in FSMSs process to be a valuable resource and provide support to the industry for training, materials, consultations, etc.
   ii. Promote incentive programs to facilities with FSMSs leading to decreased inspection frequency
   iii. Evaluate FSMSs during the plan review process
   iv. Assess the uniformity of FSMSs based on the operations and food processes
   v. Include FSMSs in risk classification, potentially leading to less frequent inspections for well-managed locations.

c. Update FDA OTED courses (FD215, FD218, FD312) as necessary to include what a FSMS is, how to verify during routine inspections, and how retail food inspectors can provide guidance on FSMSs to the operator based on inspectional findings.

d. Update CFP Field Training Manual to include verifying knowledge of FSMSs on the Training Plan and evaluate understanding on the Training Worksheet.
e. Update FDA Standardization Procedures to include verification that the candidate has an understating of FSMSs as a performance area.
f. Request SME when reviewing the job task analysis for the CFPM exam to determine if knowledge development of FSMSs should be expected of every CFPM/PIC

2. Knowledge Solutions

a. Increase awareness of the need for FSMSs through a marketing campaign including:
    i. Major causes of foodborne illness in retail
    ii. Control of hazards associated with foodborne illness risk factors
    iii. Use of case studies
    iv. What success looks like in different types of businesses/sizes (risk factor PTM data)
    v. Promote continuous improvement of food safety programs

3. System Development/SOP Solutions

a. Develop an operational toolbox
    i. Create a FSMS Team and assign roles/establish ownership and accountability
    ii. Implementation guidance document (promote parallel development of FSMSs during startup of retail food businesses),
    iii. User friendly/easily implemented training aids,
    iv. Templates,
    v. Coaching and communication, accountability ideas, reinforcement approaches
    vi. Create a tiered system of tools based on establishment processes (considering independents/small chains to large corporate/franchisee)
b. Include ""Managing Food Safety -A Manual for the Voluntary use of HACCP Principles for Operators of Food Service and Retail Establishments"" as a resource
c. Use available resources such as: state/local regulatory authority websites, CFP, universities (i.e., NC State, University of FL, University of GA), professional organizations (IAFP, NEHA, AFDO, NACCHO), Key service providers, Business associations (FMI, NRA, etc.)
d. Review, update and streamline info in Annex 4.
    i. Focus on process with flexible approach rather than prescriptive
    ii. Define elements of FSMSs
    iii. Explain what is foundational vs. best practices
    iv. Explain how to apply principles
    v. Link FSMSs to Inspections

CHARGE 3: PROS/CONS ASSESSMENT SOLUTIONS

PROS of including a requirement for the development and implementation of documented FSMSs in a future edition of the Food Code.

1. FSMSs are very beneficial because research documenting a PIC's strong working knowledge of their FSMS correlates to fewer occurrences of foodborne illness risk factor violations during an inspection. These findings were highlighted in various studies including but not limited to FDA Risk Factor Studies.

2. Operators understand the food safety hazards in their processes and how to control them which would advance AMC and reduce risk factor violation occurrence and prevent foodborne illness.
3. Having all operators and regulatory agencies working toward this common goal of voluntary FSMS implementation could encourage collaboration across the industry and regulatory community. A minimum expectation of FSMSs that control risk factor occurrence can be identified with specific goals for respective partners.
4. Developed and implemented FSMSs have the potential to make onboarding and training new employees easier for industry and regulatory staff.
5. Requiring FSMSs would allow for review of operational components and evaluation during plan review providing regulators and operators with earlier intervention and educational opportunities.
6. Flexible FSMSs could foster an effective food safety culture.

CONS of including a requirement for the development and implementation of documented FSMSs in a future edition of the Food Code.

1. FSMSs are an emerging topic in retail food not widely understood. There is a need for training of regulators and industry on the concept of developing, evaluating, and assessing FSMSs with an emphasis on how FSMSs may differ to address the differences in corporate infrastructure and diversity within the retail and food service industries prior to including a requirement for the development and implementation of documented FSMSs in a future edition of the Food Code.
2. The requirement for the development and implementation of documented FSMSs in a future edition of the Food Code would be difficult for many. Some reasons include:
    a. Small businesses just starting out, or businesses with English as second language to may have limited resources to develop FSMSs.
    b. One size does not fit all types of operations that are regulated under the Food Code.
    c. Extra resources to ensure fairness and equity among types of food establishments would be needed.
    d. It will be a challenge to write the requirement in such a way that all types of operations (large national corporations, to non-English owner operator facilities) will be able to comply with the requirements.
    e. If implemented FSMSs are too simple, it may not achieve the outcome of a well written plan that results in active managerial control.
3. Regulators would need the training and experience and program infrastructure to evaluate/assess the customized and individual FSMSs. In addition, there would need to be an agreement/understanding that format and content is operationally specific and would not have to exactly match a model template or Annex 4.
4. Crafting the verbiage to allow enforceable language may be difficult.
5. This could add time or cost to health departments food programs, and create industry push back/variance requests, etc.
6. It is a large project for any company or location. Many people are likely unfamiliar with the term, so making it "required" will be a large step. This is especially true if the requirement includes that FSMSs be documented. Industry may view this as overregulation even though many are already doing it. If it starts as voluntary, large organizations might pave the way and

create example systems that smaller operators can use as templates. Perhaps industry groups could be leveraged to facilitate this process and openly share examples.

7. The cost to industry to develop FSMSs and the cost to regulators to review industry FSMSs for compliance.
8. Jurisdictions that adopt the food code could exclude or modify this provision, resulting in inconsistencies.
9. Brands may not want proprietary documents and components of their customized FSMS shared in a public document such as a plan review.

2021-2023 CFP
Food Safety Management System (FSMS) Committee

Meeting Number: 1
DATE: November 16, 2021
TIME: 3:00 EST

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisors: Jessica Otto and John Marcello
CDC Advisor: Beth Wittry and Mark Otto
Scribe: Christine Sylvis

Agenda

	AGENDA ITEM	PRESENTER	
1.	Welcome, Call to Order	Christine Sylvis and Mandy Sedlak	
2.	Rollcall	Christine Sylvis	
3.	Conference for Food Protection, Inc. Antitrust Statement	Mandy Sedlak	
4.	Food Safety Management Systems Definition	Christine Sylvis	
5.	Review of Committee Charges	Christine Sylvis	
6.	Review CFP Timeline for Committee Work:	Mandy Sedlak	
7.	Suggested Schedule	Mandy Sedlak	
8.	Overview of Committee Working Plan	Mandy Sedlak & Christine Sylvis	
9.	Action Items	Christine Sylvis	
10.	Next meeting date	December 14, 2021	

MEETING MINUTES:

1. **Meeting Called to Order:**
   - Sylvis FSMS Committee meeting called to order at (time),

2. **Roll Call FSMS Committee:**
   - Roll Call Conducted by Christine Sylvis
     - Co-chair introduction
     - Voting Member introduction
     - FDA Consultant and Alternate introduction
     - CDC Consultant and Alternate introduction
     - Non-Voting Member introduction
   - *See attendance spreadsheet*

3. **Conference for Food Protection, Inc. Antitrust Statement**
   - Read by Mandy Sedlak
     - Moving forward, statement will just be referenced
     - PowerPoint will be kept so statement can be referenced at any time. A copy will also be placed in FoodShield.

4. ***Food Safety Management Systems***
   - Definition of FSMS along with resources
   - References to what committee will be discussing in the next year

5. **Review of Committee Charges:**
   - 5 charges

        - First charge tentatively due January 2022
    - First charge: Identifying barriers to the universal *voluntary* development and implementation of documented FSMSs consistent with Annex 4 of the Food Code.

6. **Review CFP Committee Work Timeline/Calendar:**
    - March 2022
        - Reports for Executive Board Meeting due to ED
    - July 2022
        - Reports for Executive Board Meeting due to ED
    - November 2022
        - Final Committee Reports and prospective Committee Issues due to Council Chairs for preliminary review
        - Revised Final Committee Reports and Issues submitted to Issue Chairs for preliminary review and comment
    - December 2022
        - Issue Submission for 2023 Biennial Meeting opens online for 30 days

7. **Suggested Schedule**
    - Deadline is November 2022 for 2023 Council Meeting
    - Exactly a year to get 5 charges completed
    - Tentative/Suggested Schedule
        - First Charge complete by January 2022
        - Second Charge Complete by April 2022
        - Third Charge Complete by July 2022
        - Fourth Charge Complete by October 2022
        - Final Committee Report Due November 2022

8. **Overview of Committee Working Plan/Administration/Meetings:**
    - Monthly Schedule; 2:00 pm CST every third Tuesday
    - Meeting Frequency?
        - starting out monthly and adjusting as needed
    - Each charge might have separate meeting
    - Meeting Platform?
        - Teams Meeting acceptable
    - Shared Documents?
        - Set up FoodSHIELD group and invite team members

9. **Action Items/Next Steps**:
    - Verify that FoodSHIELD works.
    - Send out Teams invitation for December 14, 2021 with a backup link
    - Identifying barriers – first committee charge before talking about hurdles to overcome them (second charge).
    - Put a live document on FoodSHIELD to add in barriers for first charge.
    - Feedback by December 13, 2021 for next meeting on December 14, 2021.

10. **Next Meeting Date**:
    - December 14, 2021

2021-2023 CFP
Food Safety Management System (FSMS) Committee

11. Identify a Scribe for 12/14/21 meeting:
- Todd Rossow

Meeting Number: 2
DATE: December 14, 2021
TIME: 3:00 – 4:00 pm EST

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisors: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Todd Rossow

Agenda

11. Welcome, Call to Order		
12. Rollcall,	Christine Sylvis	
13. Conference for Food Protection, Inc. Antitrust Statement	Mandy Sedlak	
14. Identify a Committee Scribe:	Todd Rossow	
15. Review CFP Timeline for Committee Work:	Mandy Sedlak	
16. Review of Committee Charges:	Mandy Sedlak	
17. Overview of Committee Plan of work:	Mandy Sedlak and Christine Sylvis	
18. Action Items:	Christine Sylvis	
19. Determine next meeting date:	January 18, 2023	

MEETING MINUTES:

1. **Meeting Called to Order:**
   a. Second FSMS Committee meeting called to order at (time),
      i. Motion accepted (identify members). Todd motioned to open the meeting with a Second by Mark
2. **Roll Call:**
   a. Roll Call Conducted by Christine - She has a maintained spreadsheet of the voting and (alternate) non-voting committee members
3. **Conference for Food Protection, Inc. Antitrust Statement**
   a. Mandy referred to this document and that it is posted to our FoodSHIELD site.
4. **Identify a Committee Scribe:**
   a. Todd was identified as the scribe for this call.
5. **Review CFP Committee Work Timeline:**
   a. Mandy reviewed the Suggested Schedule from the 20211116 presentation
   b. We are currently reviewing Charges 1 to the Barriers to the universal development and implementation of documented FSMSs consistent with Annex 4 of the Food Code. – January 2022
   c. We also reviewed the expected deliverables from the Charge on April 2022, and those due on July 2022, Oct 2022, and the final report due November 2022.
   d. Meeting invites are to be sent out to all with the defined schedules
   e. Meeting was requested to be recorded
6. **Review of Committee Charges:**
7. **Overview of Committee Working Plan:**

a. We will maintain the original direction to hold monthly calls and follow the Schedule to address the Charges.
b. We discussed the AFDO Food Safety Management Survey worked on in conjunction with the FDA Retail Food Safety Regulatory Collaborative
    i. Elisabeth Nutt and John Marcello shared some highlights of the survey.
    ii. The survey was constructed by an AFDO cross-functional working group.
    iii. It has 2 Parts – Part 1 (Food Safety Culture and Employee Health Policy) and Part 2 (Active Manager Control and Food Safety Management Systems).
    iv. The last part of the survey was sent out Dec 1 and will close out at the end of 2021.
    v. Survey was sent to industry and key associations (National Restaurant Assoc, National Association of Chain Restaurants, FMI, Grocers Assoc, etc.) These associations relayed the survey out to their member.
        1. Comment – AFDO should consider sending the survey to State associations too.
    vi. The survey was also sent to key food industries (grocery, C-stores, restaurants, etc., both large and small).
    vii. The survey results will be used to find best practices, what is the industry doing and what are they not doing around these four topics.
    viii. Data to be available at the end of March 2022.
    ix. The FDA Retail Food Safety Regulatory Collaborative objectives will be shared with the CFP FSMS committee. These results of the survey will help support the New Era of Smarter Food Safety as part of FDAs initiative.
    x. Part of the Retail Collaborative Grant is to pursue FSMS and AMC.
    xi. There are no direct connections of the survey questions to the CFP FSMS committee. The Committee can look at the questions and which may best serve the CFP FSMS committee. Elisabeth Nutt will share with the committee the survey questions.
    xii. Again, the results from the survey will be back in the spring of 2022 and will be shared with the CFP FSMS committee.
c. Submit the barrios and solutions, not all members submitted. The summitted comments shared so far were reviewed.
d. Food Shield Overview to see the submitted – Foodsheild.org
e. Go to Groups and see the groups you are part
f. Christine reviewed the committee's folder and where out documents are located
g. There are still some that can't gain access to FoodSHIELD. Email Christine if you are having issues gaining access.
h. John Marcello – He shared some about the AFDO survey on behave of the Retail Collaborative. The survey data collection will be completed by the end of Dec and will have some results to be shared at the January meeting, primarily about Best Practices.
i. The committee members were asked to review the barriers submitted.
j. We need to consider a White Board to collect some common ideas to Barriers.

8. Action Items:

a. Set up a small subgroup to review the Barriers and Solutions comments and help bucket for best organizations. The following volunteered to help. (Venessa B and Jeff J). Others interested should connect with Mandy and Christine. **Christine and Mandy** will set up a call to review these items for consolidation.
b. **Christine** will get the excel sheet with the committee members recorded Barriers and Solutions posted to FoodSHIELD. Each week she will update with additional feedback.

c. **All committee members** should review the Charges, go to FoodSHIELD and review the recorded Barriers and Solutions and be prepared to contribute to the conversation on the January call.
d. **Elisabeth Nutt** will share with the committee the AFDO survey questions.

9. **Motion to adjourn** – Troy H made a motion and second by Mark S.
10. **Next Meeting Date**:
    a. January 18, 2022.
    b. Linda Z will be the scribe for this coming meeting in January (Venessa B also stepped up to help, if needed (via Chat)

Meeting Number: 3
DATE: January 18, 2022
TIME: 3:00 EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisors: Jessica Otto
CDC Advisor: Beth Wittry (Jona Johnson filling in while Beth Wittry on leave)
Scribe: Linda Zaziski

Agenda

20. Welcome, Call to Order	Christine Sylvis	
21. Rollcall	Sylvis/Sedlak	
22. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis	
23. Review barriers identified	Mandy Sedlak	
24. AFDO Industry Survey Overview	Mandy Sedlak	
25. Action Items:	Mandy Sedlak and Christine Sylvis	
26. Next meeting date: February 15, 2021 3:00pm EST	Christine Sylvis	

MEETING MINUTES:

1. **Meeting Called to Order:**
    a. Third FSMS Committee meeting called to order at 3:01pm EST
2. **Roll Call:**
    a. Roll Call Conducted by Christine Sylvis, documented by Mandy Sedlak
3. **Conference for Food Protection, Inc. Antitrust Statement**
    a. Reminder by Christine Sylvis
4. **Review barriers to the universal voluntary development and implementation of documented FSMSs identified**
    a. Subgroup met to identify "categories" of barriers and are working on grouping
        i. 97 barriers have been initially identified
        ii. Categories for barriers identified: economics, training, processes, accountability, people
            1. Sub-committee Divided document into 3 main buckets to assist in consolidation/analyzing/organizing
                a. **Economics** (resources, cost, time, equipment)
                b. **People** (buy-in, staffing, cultural)

                Training (Knowledge of Regulators and Industry) System Development, SOPs Accountability (leadership)
    b. Next Steps:

i. Review barriers Get through barriers by end of January 2022
ii. Address Solutions component: Target Date: April 2022

5. **AFDO Industry Survey overview:**
   a. Presented by Elizabeth Nutt
      i. Background:
         1. Task for collaborative to look at food safety culture
         2. Help industry and regulatory what is active managerial control and what is needed for a good food safety system.
         3. Mick Micklos; NRA, FMI, NCS, NCRS. Industry input 4-part survey management systems, employee heath, food safety systems, food safety culture.
         4. Roll-out done in 2 installments. (Early Nov/2nd Part just closed 1/10)
         5. Iowa State validating survey, looking at how and which data can be used/comparisons
         6. Survey taken by – IAFP, Industry Trade Organizations, AFDO
      ii. Types of Questions
         1. Questions shared with the group
         2. Surveys to be posted to Food Shield. – for committee use.
      iii. TBD – how to use data: actionable, best practice
      iv. Looking to distribution to regional facilities or single operators. To get a good cross functional look to see where these groups are at.
      v. TBD: Findings Report-out. Collaborative wants to convene face-to-face meeting w/industry leaders to share findings/work groups, publication to follow.
      vi. Information may be useful for charges of this committee. – independent research and initiatives can add value to each other
6. **Action Items**:
   a. Subgroup to group barriers and review to consolidate
   b. Committee to review barriers and solutions by next meeting. Provide suggestion to edits/additions
   c. Entire Group - To review barriers before meeting
7. **Next Meeting Date**:
   a. February 15, 2021, 3:00pm EST
   b. Identify a Committee Scribe: Linda Zaziski
   c. Meeting ended 3:25pm; Subgroup stayed on to work on barrier consolidation

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Meeting Number: 4
DATE: February 14, 2022
TIME: 3:00 EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak
FDA Advisors: Jessica Otto
CDC Advisor: Beth Wittry/Jen Otto
Scribe: Linda Zaziski

Agenda

27. Welcome, Call to Order	Mandy Sedlak	
28. Rollcall	Mandy Sedlak	
29. Conference for Food Protection, Inc. Antitrust Statement	Mandy Sedlak	
30. Review CFP FSMS Solutions Pro/Cons Next Steps 20220209	Mandy Sedlak	

31. Comments/Discussion/Formatting; Solution Considerations Next Steps	Mandy Sedlak	
32. Action Items: See minutes	Mandy Sedlak	
33. Next meeting date: March 15, 2021 3:00pm EST	Mandy Sedlak	

MEETING MINUTES:

1. **Meeting Called to Order:**
    a. Forth FSMS Committee meeting called to order at 3:04pm EST
2. **Roll Call:**
    a. Roll Call Conducted/Documented by Mandy Sedlak
    b. Christine is on vacation
3. **Conference for Food Protection, Inc. Antitrust Statement**
    a. Reminder by Mandy Sedlak
4. **Review Committee prepared excel: CFP FSMS Solutions Pros/Cons Next Steps 20220209**
    a. Woot! Woot! Shoutout to the participants of the subcommittee
        i. **Feedback regarding the solutions pro/con next step document**
            1. Concern: Under training barriers: FSMS is currently not clearly defined as a universal term consider prioritizing as most important
                a. Jessica Otto to provide terminology used in the recent surveys.
                b. Elizabeth – Risk factor 'pillars of risk factors" Policy/Procedures in writing, training and Follow-up Accountability
                c. Important not to confuse performance systems reactive control/active managerial control. Active managerial definition is laid out in Annex 4.
                d. Some confusion has been noted regarding Annex 4; culture, food safety management systems and active managerial control
                e. **ACTION: First Priority of Next Working Group**- Better define/Clarify definitions in Annex 4 (Food Safety Culture, Food Safety Management Systems and Active Managerial Control)
                    i. Question are we taking a regulatory approach or an industry approach. Looking at 2 different approaches to the same thing. Voluntary vs Regulatory how is supporting industries efforts to develop a food safety management system.
                    ii. Picture may become clearer once definitions are clarified – differences and similarities between food safety culture, management systems and active managerial control.
                    iii. What are action items that industry can do? What can regulatory do to support? Within the Deli Study as an example: There were 2 steps that were leaned in on: one for industry and one to regulators.
                    iv. Elizabeth Nutt – Update: Industry survey has been closed, sent to Iowa University for assessment. Information to be shared with group as it becomes available.
                    v. Focus on how industry defines
                    vi. Volunteers sought for working group. Suggested meeting date March 1 3:00pm EST
        ii. **Formatting**
            1. Some struggles: Some of the items crossed over to multiple buckets (People, Training, Economics)
            2. Still open for formatting comments, suggestions

iii. **Solutions**
1. **ACTION** – send solution suggestions over to Mandy and Christine to capture in master document.
   a. Review barriers and how they are classified
   b. Can put solution suggestions next to the barrier or in format that is easiest for you.

b. **Next Steps:**
i. **Sub Committee to work on/develop definitions from Annex 4 – Mandy to set up meeting**
ii. Review barriers submit solutions for capturing in the master documents.
iii. Continue to Address Solutions component: Target Date: April 2022

5. **Action Items**:
   a. **Definition Subgroup–** Mandy to set up; March 1, 2022, at 3pm EST
   b. **Entire Group** to review barriers document. Submit solutions to Mandy/Christine by next meeting

6. **Next Meeting Date**:
   a. March 15, 2021, 3:00pm EST
   b. Identify a Committee Scribe: Linda Zaziski
   c. Meeting ended 3:40pm

Meeting Number: 5
DATE: April 19, 2022
TIME: 3:00pm EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisors: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Linda Zaziski

Agenda

1. Welcome, Call to Order	Christine Sylvis	
2. Rollcall,	Christine Sylvis	
3. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis	
4. CFPM and AMC Definitions	Christine Sylvis	
5. Action Items:	Christine Sylvis	
6. Next meeting date: May 17, 2022, 3:00pm EST	Christine Sylvis	

MEETING MINUTES:

1. **Meeting to Order:**
   - Sixth FSMS Committee meeting called to order at (3:02pm),

2. **Roll Call:**
   - Roll Call Conducted by Christine Sylvis
   - Mandy Sedlak not able to attend. Kudos given to Alternates for participating/attending 😊
   - 8 voting members present. No Votes anticipated

3. **Conference for Food Protection, Inc. Antitrust Statement**
   - Reminder by Christine Sylvis

4. FSMS and AMC Definitions

- Review FSMS and AMC Definitions from workgroup 4/14/21
  - Definition documents sent to group. Document is available on the CFP team site for FSMS
  - Committee agreed the CFP AMC definition was a good definition.
  - Some additional sources with additional information – subcommittee, comments, FDA and some references to risk factor studies in delis and other references w/links that have other documents that have similar information in them. Marking instruction on procedures training and monitoring.
  - Definition of FSMS and Procedure (oral/written) w/ examples, Training/Monitoring to follow same example. Notes/Thoughts can be found on document – not full sentences, just thoughts/work in process (so concepts and ideas did not get lost.
  - Consider have one-line definitions with examples listed below and have an example that would show steps from procedure to monitoring/training.
  - Floor opened for discussion:
    - Question asked: Written/verbal – do we need to include these for monitoring
    - Group left off - with training.
    - Monitoring was next bucket to be looked at. Definition was taken from the risk factor study. Has not been word-smithed yet.
    - Suggestion: Use similar language under procedures for monitoring (for consistency purposes) Example could be digital thermometers to tie monitoring piece into paragraph.
    - Monitoring may be more visual then oral.
    - Monitoring – assess knowledge of person; are they following the concept. Can we incorporate 'assessing knowledge'
    - All for ease of system, monitoring just an oral/visual process or is it recorded to ensure that it is being completed. Or are we placing that at the AMC level?
    - FSMS – continuously improved, wrapped up to include continuous improvement process.
    - Monitor and verify. If do not record will be difficult to get to improvement part. Feel recording should be included. Hard to prove or demonstrate corrective action effectiveness w/o proof.
    - Go back to written procedure that monitoring would meet the intent. What's going to differentiate accidental vs purposeful. Procedures like training could be stepped not necessary as an essay in paragraphs.
    - Wall charts and job aids can be part of training
    - Looking at definition – training procedures and monitoring. Putting it into a procedure basics then put into next steps of training, monitoring and improvement. Current definition is a bit confusing.
    - Can have written procedure or can have an oral procedure - i.e. this is how you wash your hands (opposed to written) but would have either demo by PIC or posted job aides/posters. Training how you give information to food employees.
    - Group thinks that oral should be taken out… not sure how to monitor oral
    - Would be challenging for manager to document handwashing; so visual would be a good way to assess/monitor. Lends flexibility
    - Perhaps general statement conducted visually; records of monitoring are the best way to verify completion/compliance.
    - Couldn't record be just a yes or no; wouldn't that be an acceptable record?
      - Depends on how specific the group wants to get
      - Applicable as we can get to put into action in establishment
    - Example from Mark (from chat box) was dropped into Christine's working documents.

- Question: Are we trying to move beyond oral procedures? Ideal or goal would be to have written but oral procedures would be acceptable – this would impact all food establishments, not just restaurants.
- Really looking at how process would be applied.
- Suggestion: Monitoring example for digital temperature where logs, review process by PIC during their shift may be a good place to include these concepts.
- Caution: The more we include - written records, may lose those who truly work in an oral culture. Documented is stronger, but oral is a FSMS. Does not seem like the message we want to say. A well-developed written FSMS is one thing; but oral culture can be a FSMS
- Isn't this in fact one of the barriers that we need to overcome and work through
- For FDA to develop a system that can be used by everybody. Maybe we need to encourage that next level of FSMS.
    - Some mom/pop shops struggle. The monitoring piece is crucial and makes a difference. Know what they are supposed to be doing, but monitoring is not happen. Agree with some of written, some of monitoring should be written. Not necessarily one size fits all. Some may allow documenting others may not (i.e., air monitoring). Is there a way to say that? Written procedure on how something is monitored.
    - Would have something to verify against.
- Is next level having a written process? Is that our charge? Yes, charge does say written FSMS.
- May be conducted visually, monitored with a goal of having a well-documented FSMS program. (i.e., tying in hand washing poster with steps as an example)
- Combination of things – regulatory remember history. Elements of good FSMS and HACCP, inroads of concepts to incorporate. All or nothing. Developing the tools to do root cause analysis. Businesses along process – where are they will be based on how you ask the questions. I.e. some may have written/training may need emphasis on monitoring. Elements can assist in incrementally improving FSMS
- Visual and recording. Procedures and Training then implement more visually. Routine/process then institutionalize and introduce charts/systems that work for the operation. Validation doing process reaches the validated method to ensure the process works and works for the operation.
- Consider using terminology "move towards' opposed to 'have'
- Incorporate the goal, complete and consistent primarily written.
- Examples provided – do we like list? edits, removal, additions?

5. **Overview of Committee Working Plan:**
    - Button up definitions, send out to group for review
    - Christine/Mandy to send out email requesting participation/meeting dates to continue work on solutions to barriers.

6. **Action Items**:
    - Next Steps:
        - Christine to massage examples make sure everything matches; will send updated document out to group.
        - Heads up – We are coming up to our deadline to review 'solutions' for FSMS
        - Completed first set of barriers, next step to work on solutions then move on to pros/cons;

- Additional dates/sub-committee meetings may be established/sent out to begin this work prior to the next formal meeting. All are welcomed to join/participate.

7. **Next Meeting Date**:
   - May 17, 2022, 3:00pm EST
8. **Adjourned at 4:02pm EST**

Meeting Number: 6
DATE: May 17, 2022
TIME: 3:00 EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisor: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Linda Zaziski

Agenda

1. Welcome, Call to Order	Mandy Sedlak and Christine Sylvis	
2. Rollcall	Mandy Sedlak and Christine Sylvis	
3. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis	
4. Review work completed by working group on Solutions/Next Steps	Mandy Sedlak	
5. Review Final Definition of Food Safety Management System	Mandy Sedlak	
6. Review of Committee Charges	Mandy/Christine	
7. Overview of Committee Plan of work	Mandy	
8. Action Items	Mandy	
9. Next meeting date:	Christine/Mandy	

MEETING MINUTES:

1. **Meeting Called to Order:**
   - 7th FSMS Committee meeting called to order at 3:02pm
2. **Roll Call:**
   - Roll Call Conducted by Christine Sylvis, documented by Mandy Sedlak
3. **Conference for Food Protection, Inc. Antitrust Statement**
   - Reminder by Christine Sylvis
4. **Review work completed by working group on Solutions:**
   - Meeting 5/13/22
   - New sheet “Solutions full list” on working Excel document. Updated version in Food Shield 2022-0516.
   - Decided on format of “Solutions” - Assign solutions into 3 barriers “buckets” (color coded)
     - Economic (blue)
     - People (yellow)
     - Training (green)
   - Visual representation shared with attendees on meeting. Various workbooks on workbook.
     - Created new page. Decide How to propose the solutions
     - Using the 3 lists Barriers, People and Training have one list for each set of solutions for these barriers

Solutions next steps:

- Divide into 3 groups to work on solutions, one group per bucket. To locate document: Working, Barriers, Solutions Workbook – go to versions and download. 2.0 version; most current version will have all columns filled out.
- Group Leads: Chris Boyles – Economic; Lisa Whitlock – People; Mandy – Training
- Working groups for each bucket – attached below.

Economic		Training		People	
Chris	Boyles	Elizabeth	Nutt	Mark	Speltz
Sean	Dunleavy	Dan	Okenu, Ph.D.	Dan	Tew
Jeffrey	Edelen	Susan	Quam	Shelly	Wallingford
Jeff	Jackson	Todd	Rossow	Lisa	Whitlock
Naomi	Macias	Heather	Sanders	Yolanda	Woods
Monique	Crawford	Colleen	Smith	Linda	Zaziski
Vanessa	Bussiere	Martin	Flusberg	Melissa	Smith
Herman	Crawford, Ed.D.	Hsing-Yi	Hsieh	Laura	Temke
Theodore	Dohnal	Troy	Huffman	Laura	Wildey
Ashley	Eisenbeiser	Evelin	Pollock	David	Wilson
		Mario	Seminara	JEREMY	ZENLEA

- Review Solutions, decide if appropriate, combine like Solutions, wordsmith as needed
- Original milestone to have Solutions completed: April 2022 (Note: We are a bit behind to work on definition of food safety management systems)
- Goal: Complete Solutions lists by May 31, 2022 and return to Mandy Sedlak and Christine Sylvis.
    - An updated version will be sent to the full committee for review.
    - Mandy Sedlak and Christine Sylvis are available to schedule and join meetings.

5. Review the Definition of Food Safety Management System

- References for definition development
- April 14th version – Almost complete w/FDA feedback
- Documented 4/20 – Review
    - Procedures for Procedures, Training and Monitoring.
    - Final Version reviewed as group
        - Change maintain to ‘follow’
        - Under monitoring, include technology (monitoring/automatic) systems.
        - A written FSMS indicated better compliance. Under procedures, “oral’ can you document. Concern the word oral waters down the intent
            - Careful not to get bogged down, some of industry may not be able to do everything, may have procedures of culture, even though the system is primarily oral. Group goal is to help move bar. Delicate balance to consider diversity, and open to other approaches that are out there.
            - Something written does not need to be complicated reference to manual of dishwasher, fact sheet from local HD/written. Something written not huge/beautiful but right direction.
            - If we want to make progress take into account, there are several ways to do things. Which would include oral. Not everything written down; less prescriptive.

- Have had extensive conversations lending to the definition listings allowing oral, written, job aids, posters w/steps, SOP etc… last sentence – Ultimate goal is – while not discounting the other types of methods/modalities.

- Training – discussion on verbiage; add goal is to…
  - Add specific/assigned to the employee's job duty (what they do).
  - Consider not singling out.
  - Add including allergen and awareness
  - Shouldn't this be more general then specific?
  - PIC needs to know all so they can monitor and ensure that all employees are doing what they need to. But specific employees only need to know what their specific job duties would require. (ie dishwasher would not necessarily know temperature to cook food)
  - Concern raised regarding others doing multiple jobs
  - Broader the more encompassing. Broad brush approach allows industry operator to put together a system to effectively train their employees.
  - Job duties is broad, that employee needs to be trained in all duties they are responsible for.
  - Consider using Jessica's verbiage; consider including the word document/documenting. (being the ultimate goal)
  - Refresher and frequency important to include.
  - Straw poll – 'All' was the most preferred verbiage

6. **Review Committee Charges**
7. **Overview of Committee Working Plan:**
   - Next milestone, July 2022: Conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code. In the assessment, the committee should consider providing feedback on:
     a) the hurdles/challenges involved in such a requirement; and
     b) recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries.
     The committee should also consider a gap analysis of § 2-103.11 as a starting point.
8. **Action Items:**
   - Subgroups meet and complete Solutions Lists, return to Mandy Sedlak and Christine Sylvis by May 31, 2022.
   - Review updated Solutions List for the three buckets of Barriers sent out after June 1, 2022 to discuss at the June 21, 2022 meeting.
   - ACTION For all Members– Review definition and review the barrier buckets/solutions
9. **Next Meeting Date: June 21, 2022, 3:00 EST**
10. **Meeting Adjourned 4:00pm EST**

Meeting Number: 7
DATE: June 23, 2022
TIME: 10:00AM EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisor: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Linda Zaziski

Agenda

1. Welcome, Call to Order	Mandy Sedlak and Christine Sylvis	

2. Roll Call	Mandy Sedlak and Christine Sylvis	
3. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis	
4. Review work completed by working groups on Solutions/Next Steps	Mandy Sedlak	
5. Review of Committee Work Plan	Mandy Sedlak	
6. Action Items	Mandy Sedlak	
7. Next meeting date: July 19, 2022	Christine/Mandy	

MEETING MINUTES:

1. **Meeting Called to Order:**
   - 7th FSMS Committee meeting called to order at 10:04am
2. **Roll Call:**
   - Roll Call Conducted by Christine Sylvis, documented by Mandy Sedlak
3. **Conference for Food Protection, Inc. Antitrust Statement**
   - Reminder by Christine Sylvis
4. **Review work completed by working group on Solutions:**
   - Main committee divided into 3 working groups (leads in Red)

Economic		Training		People	
Chris	Boyles	Elizabeth	Nutt	Mark	Speltz
Sean	Dunleavy	Dan	Okenu, Ph.D.	Dan	Tew
Jeffrey	Edelen	Susan	Quam	Shelly	Wallingford
Jeff	Jackson	Todd	Rossow	Lisa	Whitlock
Naomi	Macias	Heather	Sanders	Yolanda	Woods
Monique	Crawford	Colleen	Smith	Linda	Zaziski
Vanessa	Bussiere	Martin	Flusberg	Melissa	Smith
Herman	Crawford, Ed.D.	Hsing-Yi	Hsieh	Laura	Temke
Theodore	Dohnal	Troy	Huffman	Laura	Wildey
Ashley	Eisenbeiser	Evelin	Pollock	David	Wilson
		Mario	Seminara	JEREMY	ZENLEA
		Christine	Sylvis		
		Mandy	Sedlak		

   - Economic and People working groups each met and submitted consolidated solutions.
   - Kudos to Economic and People group for work done!
   - **ACTION:** Training group needs to meet.
   - **ACTION for all members:** Review people and economic solutions consolidated list for discussion at next meeting

5. **Review Committee Work Plan**

Definition of Food Safety Management System; Most Current Version

- Goal: Feedback/Incorporation and Agreement/Vote on definition moving forward
- Discussion on where this definition came from
  - Definition for the National Retail Study
  - FSMS can be in any form; more documented more sustainable. But documentation is not required.

- Most were happy with procedures, still working through the training portions
- **Procedure's component**… Positive reaction from group
- **Training Component:**
    - Do we need to mention risk factor interventions in this section?
    - Might be narrowing things by too much
    - Focus on critical limits.
    - There are some hazards not included that would be related that would be controls (ie Covid). Can FDA comment
    - Add in beginning over food safety risk factors.
    - Are we getting in the weeds? Conceptualize the groups work to work on barriers/solutions.
    - Pre requisition programs, GMP, other areas are important as well.
    - Continue to keep interpretations broad. Allow for maximum flexibility. Group Agreed
- **Monitoring Component**
    - Adequately and consistently – is it too definitive?
    - Change verbiage "Conveys adequate amount of knowledge to …
    - Original Charge – asking us to make recommendations to creating documented HACCP Based Food Safety Management System. Are we meeting intent of our charge?
        - Clarification on issue itself; right above numerical listing.
        - **ACTION**: Add full listing of charges on spread sheet
        - Beginning paragraph is the crem dela crème – slow process that would begin to facilitate a forward movement towards a food safety management system. Baby steps not all or nothing… Be wary of approach.
        - 30,000 not narrowing change down any further. May later be parched out into smaller sections.
        - Group in agreement; that tier approach as first step; going in right direction.
        - Starting a food safety management system is better than having nothing at all.
    - Add Jessica language
    - Group agreed with verbiage changes as presented.
- **Examples Section**
    - Examples provide ideas on how to incorporate. To have procedure, a diagram could contain steps.
    - Really not writing a procedure here. Well-developed procedure would be to have the diagram above the 3-compartment sink
    - Point of Clarification: Where diagram is, procedures should include recontamination; is why that was added in might need some word smithing. Having a nice diagram can be your written procedure (do not need written SSOP)
    - Is the example helpful? Or does it need to be more streamlined.
    - Example - Way to detailed. (not have as specific SOP)
    - Take off prewash to air dry
    - Trepidation – those written procedures too much; making simplest solution ie poster could serve as procedures. Does not need to be difficult.
    - Simplistic – Beneficial pointing back to the food code. Food code will answer all of the questions. Use that as a resource/reference.
    - In the procedure – procedures can be as simple as posted visual reminders?
    - Evolution of definition – did have within definition; getting too long – hence example was created to demonstrate how all those steps could be incorporated. Goal to control length and complexity of the definition.

- Example – too prescriptive (small retailer and regulatory) getting pretty prescriptive. Way too much work – I am not doing this. Having an example this detailed setting the bar too high/expectation of regulatory. Is biggest concern. Might be doing the opposite of what we are trying to achieve.
- Conceptually agree on FSMS
- Example may be better suited for barrier or solution section.
- Q&A section better way to use example piece.
- Examples sometimes thought as a benchmark (one size does not fit all)
- Biggest challenge to try and break this down in bite size pieces. IE Employee Health as one section. How to package this back to the conference.

- **NEXT STEPS**: Christine will send out final version w/o examples, group review; Will Vote on definition next meeting. Continued incorporation and discussion of examples

6. **Overview of Committee Working Plan:**
    a. Next milestone, July 2022: Conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code. In the assessment, the committee should consider providing feedback on:
    a) the hurdles/challenges involved in such a requirement; and
    b) recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries.
    The committee should also consider a gap analysis of § 2-103.11 as a starting point.
7. **Action Items:**
    a. **ACTION: Training Subgroup** needs to meet to complete Solutions Lists, (ASAP)
    b. **ACTION For all Members** – Continue to review consolidated People and Economic Solutions Lists for discussion next meeting
    c. **ACTION For all Members** – Review definition of FSMS – Vote Next Meeting

8. **Next Meeting Date: July 19, 2022, 3:00 EST**

Meeting Adjourned 11:03pm

Meeting Number: 8
DATE: July 26, 2022
TIME: 3:00 EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisor: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Mandy Sedlak/Linda Zaziski

Agenda

1. Welcome, Call to Order	Christine Sylvis	
2. Rollcall	Christine Sylvis	
3. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis	
4. Charge #3	Christine Sylvis	
5. Review of Committee Work Plan	Christine Sylvis	
6. Action Items	Christine Sylvis	
7. Next meeting date: July 19, 2022	Christine/Mandy	

2021-2023 CFP
Food Safety Management System (FSMS) Committee

MEETING MINUTES:

1. Meeting Called to Order:

- 8th FSMS Committee meeting called to order at 3:10pm

2. Roll Call:

- Roll Call Conducted by Christine Sylvis, documented by Christine Sylvis
- Quorum not established – all votes put on hold (only 6 voting members present); Voting via email discussed; to be coordinated by Sylvis/Sedlak

3. Conference for Food Protection, Inc. Antitrust Statement

- Reminder by Christine Sylvis

4. Commence work on Charge #3:

Conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code. In the assessment, the committee should consider providing feedback on:

a) the hurdles/challenges involved in such a requirement; and
b) recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries. The committee should also consider a gap analysis of § 2-103.11 as a starting point.

Plan to complete Charge #3:

- Mandy Sedlak and Christine Sylvis met with Courtney Halbrook, Council II Chair, and Wendy Bell, Council II Vice Chair and John Marcello regarding the progress of the committee and the charges. They were very impressed with the amount of work already completed by the committee! They agreed with assessing Charge #3 at an overview level. They acknowledge that this committee will likely be reformed (or a similar one formed) and encourage for us to think about those next steps and suggest charges.
    - Suggested that Charge 3 as an overall broad umbrella. Suggested Pro/Cons be developed/looked with an overall perspective Overview
    - List of barriers, pros, cons with really nothing coming out of it. To help expediate. Looking at pro/cons at an overview level
    - Coming up with a project of sorts that would show FSMS as it is being implemented
    - Liked example for manual ware washing on how easy it is to initiate a FSMS with more details in documentation/SOPs
    - The committee could do the committee a great favor of coming up with more then just a list.
    - FDA developed an employee health policies w/tool kit tying it in w/Norovirus. Perhaps that type of recommendations that an association or entity develop a project with learnings be rolled into a national strategy.
    - Take a microcosm on what we learn with would have a drastic impact on public health.
    - Tool out of this group from industry on how they need to work/manage a toolkit or step by step process on how to roll out/develop in business-based concept. Industry can provide helpful insight into development – voluntary approaches.

- Consider/suggest charges for a newly formed committee resulting from 2023 CFP
- Assess lessons learned on pros/cons and barriers/solutions before making suggestions on how to proceed. How can we incorporate our experiencing into context?
- Annex 4 of the food code. Incorporate Pros/Cons having FSMS as a requirement in the food code. Once barriers are solved items/topics FSMS incorporated into the Food Code.
- Provision – FSMS; responsibilities on the PIC have various controls and KSA of employees. High Level approach. If group took a look at that provision discussed strength and weakness of how it exists in the Food Code. Are jurisdictions using this provision if so, how, if not why-not? How is industry seeing use of this component? This be the starting point as it is already in the food code. (2-103.11)
- Not about putting more content in the code. How does the PIC – support or positively impact retail.
- How is regulatory authority applying this provision when inspecting the food code. For example: temperature violation is observed, mark cooking violations. If PIC portion on FSMS is marked, is there a double violating. How is this assessed?
- Suggestion: Helpful if Food Code had defined term for FSMS. Definition will provide a criterion on how to evaluate PIC. Annex 4 written more in industry vernacular then regularity speak.
- FSMS mentioned 54 times, all in Annex 4.
- What is experience with PIC provision? Challenges/How applied. Make sure all members have read PIC provision.
- Hesitancy to double dip citations. Identify a problem not driving to the underlying problem. Consultative way but not as a citation/regularity enforcement mode. Never found a way to address w/o alienating industry. The way it is written there are things intertangled not just concise or aligning well with Annex 4. Not a connective method to jive with other documents.
- Jurisdiction – the only time double debited. If failed, then PIC would be marked. Not for temperature violation only if they failed the inspection.
- Underutilized marking due to double dipping.
- One agency developed a flow chart on when to use PIC violation. Did use a lot more; had framework for not double dipping and not beating up on industry. Not written in code or pushed to regularity/industry. Can this template be shared?
- Data from AFDO on how often PIC demonstrates knowledge is marked. One of top 5 violations cited. Counts really climbed. Considerations and causes of this. Demonstration and Duties (Mandy has data via a presentation)
- There is some guidance for using 2-103.11 in marking instructions of Annex 7, but it is worded broadly. (Con) The section, does discuss PIC citations as being a judgement call.
- Send pros/cons in broad fashion. Something to meet changes then individual project for Charge 5. Include some experiences of what we learned
- Food code already requires a FSMS by practice does not explicitly state. Does ask that management make sure employees are following a program.

5. **Status of Committee Charges**
   - **a.** Definition of Food Safety Management System – vote next meeting
   - **b.** Work on “Training solutions” continues
6. **Action Items:**

a. Training Subgroup needs to meet to complete Solutions Lists, (ASAP)
b. **ACTION – All Members Send to Mandy:**
   - A listing of the hurdles/challenges (pros/cons) of Including FSMS into the food code specifically hurdles and challenges of the requirement and recommendations on how to best incorporate into the food code.
   - Also include Recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries. Use § 2-103.11 as a starting point. Include: Suggestions on how this provision can be used. What and how it is currently being used or not being used. Provide any info sheets/guidance documents/flow charts that may exist.
c. **ACTION For all Members** – Continue to review consolidated People and Economic Solutions Lists.
d. **ACTION For all Members – Review definition of FSMS**
e. This is the last week to submit applications for Council membership at the 2023 Biennial Meeting: deadline 11:30 p.m. EST on Wednesday August 3, 2022. A final message will be sent out next week to let people know the application deadline has been moved to Friday, August 5.

7. **Next Meeting Date: August 16, 2022, 3:00 EST**

Meeting Adjourned: 3:59pm

Meeting Number: 9
DATE: September 20, 2022
TIME: 3:00 EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisor: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Mandy Sedlak/Linda Zaziski

Agenda

7. Welcome, Call to Order	Christine Sylvis
8. Rollcall	Christine Sylvis and Mandy Sedlak
9. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis
10. Committee Roster Update	Christine Sylvis and Mandy Sedlak
11. Vote on FSMS Definition	Christine Sylvis and Mandy Sedlak
12. Completed Charges Format	All
13. Status of Committee Charges	Christine Sylvis and Mandy Sedlak
14. Future of FSMS Committee	Christine Sylvis and Mandy Sedlak
15. Action Items	Christine Sylvis and Mandy Sedlak
16. Next meeting date: October 18, 2022	Christine Sylvis and Mandy Sedlak

MEETING MINUTES:

1. **Meeting Called to Order: 3:02pm**
   - 9th FSMS Committee meeting called to order at 3:00 EST
2. **Roll Call:**
   - Roll Call Conducted: Quorum Established
3. **Conference for Food Protection, Inc. Antitrust Statement**

- Reminder by Christine Sylvis

4. **Roster Update**
   - Remove voting members Mark Speltz (Regulator – Sate) and Naomi Macias (Regulator – Local) who respectfully asked to be removed from the committee due to a new job responsibilities.
     i. Elizabeth Nutt - **MOTION** made to remove Speltz/Macias at their request: Seconded: Dan Okenu. Vote: No opposition: **MOTION APPROVED**
   - Remove voting members Sean Dunleavy (Regulator – State) and Shelly Wallingford (Industry- Food Service) due to missing at least 3 consecutive meetings and not responding to an email inquiring about future participation.
     i. Elizabeth Nutt made friendly amendment - **MOTION** to move Dunleavy/Wallingford to alternate/non-voting; Seconded Dan Okenu. Vote: No opposition: **MOTION APPROVED**
     ii. Discussion regarding how both were contacted; to verify non-interest, if not needed for full vote. Suggested to move forward then make contact; then work on reinstating/bringing back to group. Perhaps move to non-voting roll by committee then reach out. Move members around to have voting structure.
   - Transfer Troy Huffman and Evelin Pollock from alternate members to voting members to replace those Speltz/Macias.
     i. **MOTION** by Dan Okenu to move Troy Huffman (regulatory) from non-voting representative to voting representative. Seconded by Elizabeth Nutt. Vote: No opposition: **MOTION APPROVED**
     ii. **MOTION** by Elizabeth Nutt to move Evelyn Pollak from an alternate to a voting member (regulatory) Pending Pollak acceptance. Seconded by Jeff Edelen. Vote: No opposition: **MOTION APPROVED**
     iii. Possible industry representatives to voting position: Hsing Yi, Laura Tempke, Laura Wilding
     iv. **MOTION** by Jeff Edelen to move Hsing Yi from alternate to voting member Troy Huffman seconded Voting: No opposition: **MOTION APPROVED**

5. **Vote on FSMS Definition:**

FSMS refers to a specific set of actions (e.g., procedures, training, and monitoring) to help achieve active managerial control.

Procedures (P): A defined set of actions adopted by food service management for accomplishing a task in a way that minimizes food safety risks. Procedures may be oral or written and include who, what, where, when, and how a task should be performed. The goal is to move toward complete, consistent, and primarily written procedures and may include topics such as when to wash your hands, how to set up a 3-compartment sink, how food temperatures are achieved and maintained/monitoring food temperatures.

Training (T): The process of management's informing employees of the food safety procedures within the food service establishment and teaching employees how to carry them out. Information may be presented in formats such as a set of instructions/illustrations, recipe cards with process instructions, wall charts, wallet cards, or live demonstration. The goal is to provide and document training for all food safety tasks in a format and frequency adequate to ensure employees have the knowledge to carry out the procedures consistently and effectively.

Monitoring (M): Routine observations and measurements conducted to determine if food

safety procedures are being followed. Monitoring systems should include who, what, where, when, and how monitoring is to be performed and may be conducted visually or documented in writing. The goal is to move toward a well-documented system that can be verified and may include use of automated systems, digital thermometers, logs, charts, checklists, and other job aids and tools

- Elizabeth Nutt made **MOTION** to accept the definitions as presented. Motion Seconded by Hsing Yi. Motion amended to add verbiage under "training": Information may be presented "in formats such" as a set of instructions/illustrations…" for Voting: No opposition: **MOTION APPROVED**
    - Excellent start to begin our discussion on FSMS. May have some wordsmithing but great start.
    - Consider adding on-line/virtual verbiage. Consider not putting in these words to keep broad. Consider adding word "such as"

6. **Completed Charges Format:**
    - Changed format of barriers and solutions
    - Currently in list format included all buckets and sub buckets (took everything we had and put it in one listing)
    - Suggestions on other method to format? Consider a table or chart with each bullet being a table. Same format in table opposed to bullet. Group agrees that bullets are good for formatting.
    - Recommendation to use numbers instead of bullets to be able to identify topics as individual discussion points.
7. **Status of Committee Charges:**
    - Review pros and cons submitted.
        i. Special Meeting: September 29, 2022, at 8:00 Pacific/11:00 Eastern
    - Vote next meeting: Charge 1 (Barriers), Charge 2 (Solutions) and Charge 3 (Pros/Cons)
    - Discuss Charge 4 (recommendations on next steps) next meeting.
    - Develop prospective Committee Issues to present to Council II Chair and Vice Chair by November 2022.
    - Revised Final Committee Reports and Issues submitted to Issue Chairs for preliminary review and comment by November 2022.
    - Issue Submission December 2022.
8. **Future of FSMS Committee**
    - Summary of Retail Food Safety Regulatory Association Collaborative project and possible resource/assistance by David Lawrence.
        i. David Lawrence and Brenda Bacon; Introduction and high-level overview of Collaborative.
        ii. Collaborative working with NACCHO for project funding; CFP Board currently in discussion to accept funded program.
        iii. Brenda and David asked to attend future FSMS meetings so that they can be in know of committee activity/recommendations so that through the Collaborative's partnership with NACCHO - documents/information developed by the committee can be made publish-ready. Allows them to get a pulse for what is going on and how their partnerships can get ahead of the curve to make the process more streamlined while tying in possible resources.

iv. Objectives of this committee and the Collaborative dovetail very well together.
v. FDA request to truly involve the Collaborative.

- Consider recreating FSMS Committee – Committee Charges will need to be developed. Barrier's list can be used as a starting point
- Consider idea presented by Eric Moore and Ben Chapman, Digital Food Safety Systems (DFSS) Committee Co-Chairs, about submitting an Issue to establish a Standing Committee to encompass the work of the FSMS and DFSS Committees.
    i. Any movement forward on this initiative will be taken up by the FSMS in collaboration with the DFSS Co-Chairs and in consultation with Council II Chairs.

9. **Action Items:**
    - **ACTION For all Members –** Conduct a final review on consolidated pros/cons list. Send any recommended changes to Many and Christine. Plan to vote on final list at next meeting.
    - **ACTION For all Members** – Conduct a final review of consolidated People, Economic, and training Solutions and Barriers Lists. Send any recommended changes to Many and Christine. Plan to vote on final list at next meeting.
    - **ACTION For all Members** – Think about Issues regarding FSMS that may be submitted for the 2023 CFP. Possibly Recreate committee
    - NEHA AEC abstract submission contact Laura Widley
10. **Next Meeting Date:** October 18, 2022, 3:00 EST

Meeting Adjourned: 4:00pm

Meeting Number: 10
DATE: October 18, 2022
TIME: 3:00 EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisor: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Linda Zaziski

Agenda

17. Welcome, Call to Order	Christine Sylvis
18. Rollcall	Christine Sylvis and Mandy Sedlak
19. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis
20. Changes Document	Christine Sylvis and Mandy Sedlak
21. Charge 4	Christine Sylvis and Mandy Sedlak
22. Status of Committee Charges	Christine Sylvis and Mandy Sedlak
23. Future of FSMS Committee	Christine Sylvis and Mandy Sedlak
24. Action Items	Christine Sylvis and Mandy Sedlak
25. Next meeting date: October 18, 2022	Christine Sylvis and Mandy Sedlak

MEETING MINUTES:

1. **Meeting Called to Order: 3:01pm**
    - 10th FSMS Committee meeting called to order at 3:01pm EST
2. **Roll Call:**

- Roll Call Conducted; Quorum Established

3. **Conference for Food Protection, Inc. Antitrust Statement**
   - Reminder by Christine Sylvis
4. **Completed Charges Document:**
   - Changed format of Barriers and Solutions to use numbers instead of bullets to be able to identify topics as individual discussion points.
   - No comments received on Barriers and Solutions.
   - Vote: Charge 1 (Barriers), Charge 2 (Solutions)
     i. Items still in red:
        1. (2) Comment/discussion questioned group to put under equipment or cost barriers. Put under cost barrier subset vs a standalone. Suggestion made to Bucket out. Group good with leaving as a standalone
        2. Process Solution Bucket for sub processes – number 3 was removed
        3. Idea for additional cost: unacknowledged cost if a foodborne illness incident occurs. People do not recognize a cost if something does not occur … more of a solution piece (4a iii, or add as a subset under bullet 4 under b). Group agreed/added in.
   - Christine will ensure that all formatting is consistent
   - **Vote**: Lisa made motion to approve solutions and barriers (Charges 1 and 2) accept the documents; Troy Seconded. Discussion: non. Vote; no objections or abstentions. **Charges 1 and 2; Motion Passed**

5. **Charge 4:**
   - Charge 4: Developing recommendations on next steps to promote universal development and implementation of documented FSMSs consistent with Annex 4.
     i. Retail Food Safety Regulatory Association Collaborative/NACCHO project resources. Also: AFDO/NEHA (Active Managerial Control), Plan Review Committee
        1. Cost/benefit analysis of implemented FSMSs
        2. Toolbox resources (draft SOPs, job aids, case studies, etc.)
           Note: David Lawrence mentioned the year one goals of collaborative. Document to be shared with group on current status and support for present and forward movement. Added to teams site and Food Shield.

     ii. CDC EHS-Net project on Employee Health Policy
     iii. Retail Food Safety Specialists – Train the Trainer type program
   - Develop prospective Committee Issues to present to Council II Chair and Vice Chair by November 2022.
     i. **Consider recreating FSMS Committee –** Committee Charges will need to be developed. Barrier's list can be used as a starting point
     ii. Consider idea presented by Eric Moore and Ben Chapman, Digital Food Safety Systems (DFSS) Committee Co-Chairs, about **submitting an Issue to establish a Standing Committee to encompass the work of the FSMS and DFSS Committees.**

1. Do not need to recreate committee every year. Charges would be included in the bylaws.
2. Standing committee
    - Can be explored as an option if we can pin-point criteria. The other committees usually have some oversight of standards with ANSI/reviewed yearly. Lots of overlap.
    - More research may be necessary regarding standing committees or when a committee moves into a standing option.
    - Big thing outside of FSMS – regulated to conference administration vs standard maintained as long as CFP has that standard. may be new territory to create a new standing committee that would not have a sunset every two years.
    - Executive committee will need to have a discussion on. Standing committee reports to executive committee. Board tracking constitutionals charges, plus charges from board meeting or from conference. Constant maintenance and other charges, benefit rational two council committees doing similar to bring both committees together. Argument in background. Constitutional bylaws outlined. Procedures document to the board. Rational is there.
    - Putting into the issue along with the background. Retail foods is also a standing committee. Constantly maintaining program as well. Huge amount of work.
    - Large committee with multiple subcommittees to support to spread out work.
    - Prepare a case and get some feedback from others with experience to see if we are on the right track with fall back in council. Committee were to propose, would this be an issue or would it go through the executive board. Not pan out then there would be some charges to move forward. Issues submitted for acknowledgement in November. This would be seen by board to garner support. Would be an issue by one of two committees Christine/Mandy and Ben/ co-submitting. Get all players with co-chair of to committees. Publication committee was the last standing committee that was formed. (in Richmond).

6. **Status of Committee Charges:**
    - Special Meeting: September 29, 2022, at 8:00 Pacific/11:00 Eastern reviewed Pros
    - Complete review of Cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code October 21, 2022 at 8:00 Pacific/11:00 Eastern.
    - Vote next meeting: Charge 3 (Pros/Cons)
    - Revised Final Committee Reports and Issues submitted to Issue Chairs for preliminary review and comment by November 2022.
    - Issue Submission December 2022.

7. **Future of FSMS Committee**
    - Summary of Retail Food Safety Regulatory Association Collaborative project and possible resource/assistance by David Lawrence.
        i. David Lawrence and Brenda Bacon; Introduction and high-level overview of Collaborative.
        ii. Collaborative working with NACCHO for project funding; CFP Board currently in discussion to accept funded program.
        iii. Brenda and David asked to attend future FSMS meetings so that they can be in know of committee activity/recommendations so that through the Collaborative's partnership with NACCHO - documents/information developed by the committee can be made publish-ready. Allows them to get a pulse for what is going on and how their partnerships can get ahead of the curve to make the process more streamlined while tying in possible resources.
        iv. Objectives of this committee and the Collaborative dovetail very well together.
        v. FDA request to truly involve the Collaborative.
    - Consider recreating FSMS Committee – Committee Charges will need to be developed. Barrier's list can be used as a starting point
    - Consider idea presented by Eric Moore and Ben Chapman, Digital Food Safety Systems (DFSS) Committee Co-Chairs, about submitting an Issue to establish a Standing Committee to encompass the work of the FSMS and DFSS Committees.
        i. Any movement forward on this initiative will be taken up by the FSMS in collaboration with the DFSS Co-Chairs and in consultation with Council II Chairs.
8. **Action Items:**
    - **ACTION For all Members** – Think about Issues regarding FSMS that may be submitted for the 2023 CFP. Possibly Recreate committee or standing committee
    - **ACTION For all Members – Special meeting on Oct 31 review cons and complete**
    - **ACTION: Smaller/Identified members/guests** to discuss standing committee option prior to the 31st. (Becky, Todd, Mandy, Christine, David, Devine)
    - **ACTION For all interested Members: Meeting prior to the 15th to create the issue submission for vote on the 15th.**
    - **ACTION for Voting Members/Others:** Meeting scheduled for November 15th – Vote on Charge 3 Pros/Cons and Charge 4 Next Steps.
9. **Next Critical Voting Meeting Date:** November 15, 2022, 3:00 EST

Meeting Adjourned: 3:55pm EST

Meeting Number: 11
DATE: November 15, 2022
TIME: 3:00 EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisor: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Linda Zaziski

Agenda

26. Welcome, Call to Order	Christine Sylvis
27. Rollcall	Christine Sylvis and Mandy Sedlak
28. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis
29. Changes Document – Pros and Cons vote	Christine Sylvis and Mandy Sedlak
30. Charge 4 – Future of the Committee	Christine Sylvis and Mandy Sedlak
31. Charge 4 - Issues for next Committee	Christine Sylvis and Mandy Sedlak
32. Issue – Final Report	Christine Sylvis and Mandy Sedlak
33. Issue – FSMS Definition	Christine Sylvis and Mandy Sedlak
34. Status of Committee Charges	Christine Sylvis and Mandy Sedlak
35. Action Items	Christine Sylvis and Mandy Sedlak
36. Adjourn	

MEETING MINUTES:

1. **Meeting Called to Order: 3:02 pm**
    - 10th FSMS Committee meeting called to order at 3:02pm EST
2. **Roll Call:**
    - Roll Call Conducted; **Quorum Established**
3. **Conference for Food Protection, Inc. Antitrust Statement**
    - Reminder by Christine Sylvis
4. **Completed Charges Document:**
    - Thank you to those who attended the Special Meeting on September 29, 2022. Pros and Cons were completed!
    - Edited Barriers and Solutions to use FSMS/FSMSs correctly and consistently
        i. Unbolded items and single/plural consistency
        ii. Con #2; wordsmithing to address all the bullets/flow
    - Added Pros and Cons to the document.
    - No comments have previously received regarding Pros and Cons.
        i. Discussion by Group
            1. No Discussion
        ii. Other Comments:
            1. Clarification regarding revisiting some charging for this group to look at charges not directly dealt with due to time constraints Yes, future of committee and/or standing committee can address open ended items/unaddressed items
    - **VOTE:** Elizabeth Nutt; **Motion to Accept Pros/Con report as written to be included in final report submission.** Second Yolanda Woods. No Discussion; Vote: No Dissentions, No abstentions. **MOTION PASSED**
5. **Charge 4 Future of the Committee:**
    - Charge 4: Developing recommendations on next steps to promote universal development and implementation of documented FSMSs consistent with Annex 4
    - 2 Options:
        i. Consider **recreating FSMS Committee** – Committee Charges will need to be developed. Barrier's list can be used as a starting point
        ii. Consider idea presented by Eric Moore and Ben Chapman, Digital Food Safety Systems (DFSS) Committee Co-Chairs, about submitting an Issue to establish a **Standing Committee to encompass the work of the FSMS and DFSS**

Committees. Meetings have been held with Council II Chair (Courtney Williams) and Vice Chair (Wendy Bell) and with CFP Constitution and Bylaws Committee Chair (Daveen Sarrocco-Smith), Issue 2020-II-030 submitter (John Marcello), and DFSS Committee Co-Chairs (Eric Moore and Ben Chapman). A Standing Committee is a practical option.

iii. Discussion:

1. Standing Committee well received by members
2. Are we already incorporating the merging of all of those groups?
3. Standing committee would incorporate FSMS and Digital Committee The new committee would have charges in both.
4. It is very difficult for committees to deal with charges when merging groups. Concern what is being suggested is bandwidth of committee to deliver and move bar forward.
5. Sustainably of Food Safety Management Systems, if it did get put into the food code.
    - Envision 4 years down the road.
    - Aspects of FSMS in pieces into the food code.
    - The thought was that incremental editions will be made into the food code over a longer period of time.
    - On-going changes as time goes along.
    - Not as big as programs standard committee but would have charges to committee.
    - Sustainability was discussed based on interest for committees. Would 2-4 committee formed be enough interest to join committees
6. Question: Would considerations be made for standing committee w/o combining with the Digital Food Safety System Committee work
    a. What is the vision for synergize of both committees combining?
        i. Component of FSMS, having digital portion incorporated into it
        ii. Christine shared charges of collaborative on how digital would fit into FSMS
7. Suggestion was to have standing committee for FSMS as standalone standing committee w/o having them work as one
8. The 4 deliverables of the collaborative are tied to new era for food safety. Listed separately for scope under broad idea of FSMA. Standing committee would need sub committees and workgroups. Complexed need lots of work but need lots of symmetry.
9. 2 thoughts standing committee for FSMA. Digital as standalone or combining with separate charges/combining them perhaps at a later time.
10. If they go separate; not likely to get 2 standing committees; be sure to give that some consideration. 2 is very unlikely.
11. Not sure that that would matter. We can request, if not standing, then request to be a continued committee. To be prepared for that; Standing Committee let digital address their own perspective. To be proactive, our

committee should be proactive if we are not looking to be a standing committee then look at a recommendation for reforming/extending

12. If both ask to be a standing committee; then executive committee could recommend to combine.
13. **Will of Committee:** Request standing committee (w/o digital committee) if that does not look favorable then default fall back to council committee. Council members for council 2 would need to recommend be recreated as a council committee
14. Council 2 FSMS Members; (Courtney WIlliams, Chair) Christine and Ashley Eisenbeiser

iv. Recommended solution language/other thoughts:

1. Add Active Managerial Control of Risk Factors
2. Charges in the Public Health significance need to be in Solution. What is the committee going to work on. Charges and recommended are in the solutions point.
3. Advise from Daveen, one issue to create committee to change bylaws then a separate issue to recreate w/charges of committee.
4. Consider recreation of committee then based on public health significance to standing committee. Council Chairs determine what order issues are addressed in. They determine order the CFP ordering system. Once council beings they can change order w/recommendation and vote.
5. Some of the charges for this new committee next biennium will be solution on other charge/issue on charges would be incorporated into next biennium and explaining on why this needs to be a standing committee. Council chair confers with council members on order. Has been standard, not impossibility to this order.
    a. Good idea; insure committee gets created. If becomes standing committee that is another issue, but at least the committee will continue.
6. Recreate committee w/ charges. Separate issue submitted to create as standing committee. (Might be more straight forward to do it this way)
7. Charges on public health significance – carry over some of the items on initial FDA and CDC studies FSMA have strongest statistical correlation to reduction of FBIs
8. Health People; Norovirus reduction. Developing health policies program. Better focus on one specific area. Number one case of FBI at retail level with focus of employee health

- **VOTE** Lisa Whitlock made motion to recreate the committee as council committee w/chargers with separate issue to change from council committee to a standing committee w/duty as stated by constitution and bylaws. Jeff Jackson seconded. No objections, no abstentions **MOTION PASSED**

6. Charge 4: Charges for FSMS Committee during 2023-2025 biennium

- Considerations for Charges:
    i. Risk Factor for PIC provision

ii. Cost benefit analysis (NACCHO/collaborative)
iii. Develop a toolbox, develop verbiage to outline prerequisites (SOPs) that are not covered. Review results of EHS-Net/CDC collaboration and incorporate into toolbox
    1. Focus on Employee Health, Healthy people
    2. Use the school USDA/HACCP SOPs as a possible guide/tool; consider reviewing #4 "Guidance for School Food Authorities, "Developing a Food Safety Program based on the process approach to HACCP Principles" Consider having CDC provide an overview of project and what tools may come out of this down the road.
    3. CONSIDER: Pilot a FSMS for Employee Health program to see how it might work. Find industry volunteer to develop FSMS; site visits to support and verify effectiveness. Industry/Regulatory Partner. Note this is something that CDC is already using this approach/project. Initialed via EHS-Net
    4. Get understanding of EHS-Net project as how it relates to FSMS committee work. Consider collaboration
    5. The overarching thread of these suggestion is that we need to increase awareness, communication and idea sharing with initiatives area underway. A committee may not be well suited to do a pilot study themselves but give the results they could give guidance.
iv. Reviewing a charge for Barriers, Pros/Cons provide solutions/remedies
v. Items not covered in our current charges
vi. Complete gap analysis of PIC Provision
vii. Committee Charge to fil in the gaps between all areas working on aspects of employee health and all aspects of collaboration/projects currently being done.
viii. NOTE: Christine typed up charges and read as written
ix. Items to be word smithed; Charges Can Vote to have 4 items incorporated into the charges submitted for the reformation/standing committee

7. **Review Issue to submit committee final report**
8. **Review Issue to include where FSMS definition fits into Food Code**
    - Where does definition of FSMS belong in the Food Code discussion
    - Annex 4, under active managerial control
    - Place after AMC, put in FSMS definition
    - Soft roll-out in code: Put somewhere under the radar; time to include into definition Chapter One for the Food Code. PIC duties, que Employees begin using FSMS to begin voluntary implementation of systems to reduce FBI.
9. **Status of Committee Charges:**
    - Final Committee Report to be submitted to Council II Chair and Vice Chair by November 18, 2022.
        i. Thank you, Linda Zaziski, for reviewing!!
    - Revised Final Committee Issues submitted to Council II Chair and Vice Chair and Issue Chairs for preliminary review and comment by November 2022.
    - Issue Submission December 2022.
        i. Summary of Issues to be submitted

1. 1. Accept FSMS Committee Final Report
2. 2. Recreate FSMS Committee
3. 3. Create FSMS as a Standing Committee
4. 4. Charges for FSMS Committee during 2023-2025 biennium.

10. Action Items:

- **ACTION For Christine and Mandy** – Finalize final report and issues and submit to Council II Chair and Vice Chair within deadlines
- **ACTION For all Members –** Thank you for your outstanding work and dedication to this committee and your dedication to food safety every day and adjourn.
- **ACTION– For All Voting Members: Need to determine where definition falls into Food Code. (Vote needed)**
  - **i. Next meeting November 18, 2022 at 10:00 EST**

11. Meeting Adjourned 5:03pm

Meeting Number: 12
DATE: November 18, 2022
TIME: 10:00am EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisor: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Linda Zaziski

Agenda

37. Welcome, Call to Order	Christine Sylvis
38. Rollcall	Christine Sylvis and Mandy Sedlak
39. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis
40. Location of FSMS in the Food Code	Christine Sylvis and Mandy Sedlak
41. Charge 4 - Issues for next Committee	Christine Sylvis and Mandy Sedlak
42. Issue – Final Report	Christine Sylvis and Mandy Sedlak
43. Action Items	Christine Sylvis and Mandy Sedlak
44. Adjourn	

MEETING MINUTES:

1. **Meeting Called to Order: 10:03am**
   - 10th FSMS Committee meeting called to order at 3:02pm EST
   - Quorum Established
2. **Roll Call:**
   - Roll Call Conducted; Quorum **Established**
3. **Conference for Food Protection, Inc. Antitrust Statement**
   - Reminder by Christine Sylvis
4. **Location of FSMS Definition in Food Code**
   - Term Active Managerial Control around for 20 plus years. Not made its way into definition of food code. Think time to put on radar going hand in hand with FSMS. Employees begin using AMC by using FSMS. Deal with compliance. Allows for a soft roll-out. No specification gives wiggle room but gets the ball rolling. Time to be in codified portion in the food code.

- If definition in food code, if in annex can it be in the definition. Terms defined n codified section. If you want it in Chapter 1. Language needs to be in codified section so it can appear in purpose and definition. Excellent definition and concept. Do not need to be prescriptive in definition. FDA please incorporate as appropriate.
- Council will need vision to move forward
- If in multiple sections Chapter 1, 2 and annex; Council chairs recommended do multiple issues. Don't include too many in a single issue. Multiples allow options. Annex a no-brainer. If we want to get it in the food code – optional at this stage. Making it an "and: (hard call) Making it an "or" – more receptive
- FSMS are actual things… tend to lead to AMC; makes it difficult/tricky
- Proposed mechanism/intent; less on where it is placed. Angle of intended outcome. Want it to be codified. opposed to danker with language.
- Active managerial control in definition. PIC use FSMS as an example fo what they can do to achieve AMC
- PIC responsible for developing the FSMS. PIC would be the executer of the system. In the italicized section is more of explanation; call out permit holder implement some type of FSMS. Interesting angle –
- Agree on FSMS definition. Grappling with where does it go? Struggle; what does this look like. Duties of AMC is FSMS, how do we rationalize the PIC provision. Struggle may be related to the work that is still needed.
- 2-101.11 best place to include. Section P, written plans where specified required (health policy/vomit clean-up) FSMS is not always written… goal for written. Permit holder would develop.
- FSMS members in committee support concept and code concept/definition inclusion. May get pushback from industry.
    i. Teaching concept in food safety classes to include small industry
    ii. Many SOPs for larger organizations already refer to PIC/systems
- 2-101.11 Duties, Assignment, AMC in 2-111.2
- If several avenues, list several for consideration; in code somewhere not sure where in code. Not sure where it would fit just that you want it in there. Options to consider.
- there are concurrent Issues to be submitted by the Program Standards Committee to add plan review with a FSMS perspective to Standard 3 and to re-create the CFP Plan Review Committee to update the Food Establishment Plan Review Guidance Document to be inclusive of FSMS
- It would be a big challenge during plan review to have a full menu developed to drive a complete FSMS but I could see some components being available then.
- could go under responsibilities of the permit holder in Chapter 8
    i. Some agencies do not adopt Chapter 8. But then again everyone can pick and choose any code provision.
    ii. Need to find out why regulatory agencies are not using Chapter 8 – need deeper dive
    iii. Many not using Annex's

- Appears that we are moving too quickly. AMC must go hand in hand with FSMS. FSMS used widely. Is there a way we can move AMC into definitions then our task will be to develop a more clear perspective on what a FSMS. AMC in codified section.
- FSMS is a tool to achieve AMC
- Want to have in the code, but more to be done on development and interpretation of getting FSMS in code.
- Options: 2-103.11 incorporate FSMS AMC into duties but not be prescriptive or 2-101.11, chapter 8 incorporating AMC this go around.
- Under 2-103.11: **The Person In Charge shall maintain Active Managerial Control by ensuring:....** Will also allow for definition of AMC in codified.
- FSMS tool – massage them to work together. FSMS to become mandatory . Tool of choice to obtain AMC. Consider a FSMS to achieve AMC
- Could you add FSMS into 2-103.11 (P) Written procedures and plans, where specified by this Code and as developed by the FOOD ESTABLISHMENT or those created as part of a FOOD SAFETY MANAGEMENT SYSTEM, are maintained and implemented as required.
- VOTE Motion – would require specificity, perhaps later in the future.
- Let FDA find location.
- Submit issue provides AMC and FSMS in the code by ensuring really conveys the concept. Not worry about where it goes, probably the best use of groups time.
- Incorporate AMC into 2-201.11 and 2 other asks - define AMC and include FSMS defined in the code.
- Motion/friendly amendment to recommend verbiage presented on Charge 4 Incorporating **"voluntary use"**
- AMC is already in code that 'shall ensure' by including the AMC; already in code – hence reason why deep dive is needed and addressed as group.
    i. A through P is this in a nutshell.
    ii. FSMS is not well defined, required. AMC is getting a title and a definition
    iii. New names to old interventions.
- How to get the definition into the code.
    i. Into Annex 4, right after AMC
- Have defined FSMS; not have to decide exactly where it goes. Perhaps in public health significance section. Definition be incorporated into chapter 1 and that FSMS and definition incorporated into to AMC
- **VOTE: Motion to include FSMS, AMC into code w/voluntary use terminology** made by Jeff and seconded by Lisa. Discussion, no objections, no abstains **MOTION PASSED.**
- Vote was on inclusion to the food code; actual verbiage does not require vote.

5. **Charge 4; Issues for next committee**
    - Draft issues shared on screen - verbiage as currently written.
    - Based on conversations today, these items will be wordsmithed and then shared with all members.
6. **Final Committee Report – Submission Due November 18**
7. **Action Items:**
    - **ACTION For Christine and Mandy** – Finalize final report and issues and submit to Council II Chair and Vice Chair within deadlines (Deadline Nov 18)
    - **ACTION – For Christine/Mandy and All Voting Members: Christine will wordsmith and send final issue verbiage to committee members. Please review ASAP.**

- **ACTION For all Members –** Thank you for your outstanding work and dedication to this committee.
- **ACTION For all Members – Need new Co-Chair Committee for next biennium all members encouraged to consider this opportunity.**

8. **Meeting Adjourned: 11:06am**

Committee Name: Demonstration of Knowledge

Y=In Attendence **N=Not in Attendence**

Last	First	Committee Position	Meeting 1 11/16/21	Meeting 2 12/14/21	Meeting 3 01/18/22	Meeting 4 02/14/22	Meeting 5 04/19/21	Meeting 6 5/17/2022	Meeting 7 06/24/22	Meeting 8 07/26/22	Meeting 9 9/20/2022	Meeting 10 10/18/2022	Meeting 11 11/15/2022	Meeting 12 11/18/2022	
Sedlak	Mandy	Co-Chair	X	X	X	X		X	X	X	X	X	X	X	0
Sylvis	Christine	Co-Chair	X	X	X		X	X	X	X	X	X	X	X	0
Boyles	Chris	Voting	1	1	1	1	1	1	1	0	1	1	1	1	9
~~Dunleavy~~	~~Sean~~	~~Alternate~~	0	0	1	0		0	0	0	~~NA~~	~~NA~~	~~NA~~	~~NA~~	~~1~~
Edelen	Jeffrey	Voting	1	1	0	0		0	0	0	1	1	1	1	4
Jackson	Jeff	Voting	1	0	1	1		1	1	0	0	0	1	1	5
~~Macias~~	~~Naomi~~	~~Voting~~	~~0~~	~~0~~	~~0~~	~~0~~		~~0~~	~~0~~	~~0~~	~~0~~	~~0~~	~~0~~	~~NA~~	0
Crawford	Monique	Voting	1	1	1	1	1	1	1	0	0	0	1	0	7
Nutt	Elizabeth	Voting	0	1	1	1		1	1	1	1	1	1	1	8
Okenu, Ph.D.	Dan	Voting	1	1	1	1		0	0	1	1	1	1	0	7
Quam	Susan	Voting	0	0	1	1		1	1	1	0	1	1	0	6
Rossow	Todd	Voting	1	1	1	1		0	1	1	1	1	0	1	8
Sanders	Heather	Voting	1	1	1	1	1	1	1	0	1	1	1	1	9
Smith	Colleen	Voting	1	1	1	1		1	1	0	0	0	1	1	6
~~Speltz~~	~~Mark~~	~~Voting~~	~~1~~	~~1~~	~~0~~	~~0~~	~~1~~	~~0~~	~~0~~	~~0~~	~~0~~	~~1~~	~~0~~	~~NA~~	4
Tew	Dan	Voting	1	1	1	1		1	0	1	1	1	0	1	8
~~Wallingford~~	~~Shelly~~	~~Alternate~~	~~0~~	~~1~~	~~0~~	~~1~~		~~0~~	~~0~~	~~0~~	~~NA~~	~~NA~~	~~NA~~	~~NA~~	2
Whitlock	Lisa	Voting	1	1	0	1	1	1	1	1	0	1	1	1	8
Woods	Yolanda	Voting	0	1	1	1	1	0	0	0	1	1	1	1	6
Zaziski	Linda	Voting	1	1	1	1	1	1	1	1	1	1	1	1	11
Huffman	Troy	Voting	NA	NA	NA	NA	NA	NA	NA	NA	1	1	0	0	
Pollock	Evelin	Voting	NA	NA	NA	NA	NA	NA	NA	NA	0	0	1	1	
Hsieh	Hsing-Yi	Voting	NA	NA	NA	NA	NA	NA	NA	NA	1	0	0	1	
			12	14	15	15	7	10	10	7	11	13	13	13	
Otto	CRD Jessica	FDA Consultant	0	1	1	1		1	1	1	1	1	0	1	8
Marcello	John	FDA Alterante	1	1	1	1	1	1	1	1	0	0	1	1	8
Wittry	Beth	CDC Consultant	0	1	Fill in	Jana Johnson	1	1	0	0	1	0	0	0	4
Otto	Mark	CDC Consultant Alternate	1	1	1	1	1	1	1	1	1	1	1	0	10
Bussiere	Vanessa	Alternate	1	1	1	0		0	1	0	0	0	0	0	4
Crawford, Ed.D.	Herman	Alternate	0	1	1	0	1	0	0	1	1	0	0	0	5
Dohnal	Theodore	Alternate	0	1	1	0		0	1	1	1	1	0	0	6
Eisenbeiser	Ashley	Alternate	1	1	1	1	1	1	0	1	1	1	1	0	9
Flusberg	Martin	Alternate	1	1	1	1		0	1	1	1		0	0	7
~~Hsieh~~	~~Hsing-Yi~~	~~Alternate~~	1	1	0	1	1	1	1	1	1		0	0	8
~~Huffman~~	~~Troy~~	~~Alternate~~	1	1	1	0	1	0	1	0	1		0	0	6
~~Pollock~~	~~Evelin~~	~~Alternate~~	1	1	1	1	1	1	1	1	0		0	0	8
Seminara	Mario	Alternate	0	1	0	0		0	1	0	0		0	0	2
Smith	Melissa	Alternate	1	1	0	0		0	0	0	0		0	0	2
Temke	Laura	Alternate	1	1	0	1		0	0	0	1		1	0	4
Wildey	Laura	Alternate	1	1	1	1	1	1	1	1	0		0	0	8
Wilson	David	Alternate	0	0	1	0		0	0	0	0		0	0	1
ZENLEA	JEREMY	Alternate	0	1	1	0		0	0	0	0		0	0	2
Dunleavy	Sean	Alternate											0	0	
Wallingford	Shelly	Alternate											0	0	
			11	17	14	10			11	10	10		4		83
Johnson	**Jona**	**CDC Consultant fill-in while Beth Wittry on leave**					1								1

															0
NOTES:															0
Vanessa Bussiere emailed 8/3/22, she missed a few meetings due to family issues and send pros and cons															0
Mark Speltz emailed 5/25/22 that due to a new job assignment that will take up a significant amount of time he will no longer be able to participate in the committee.															0
															0
															0
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***** Serving in the consumer group slot under a temporary waiver appoved by

Large documents posted online (e.g., Food Code) are to be referenced only by the web address along with a notation of the specific page and/or section numbers; large publicly available documents are NOT to be attached in their entirety.

The downloaded document is too large, and we were unable to save.

We were unable to insert a web address.

Attachment link:

https://www.fda.gov/media/117509/download

References for FSMS #4 – Create FSMS Committee as Standing Committee:

- FDA Report on the Occurrence of Foodborne Illness Risk Factors in Fast Food and Full-service Restaurants, 2013-2014 (2018). https://www.fda.gov/media/117509/download
- Cormier, R.J., Mallet, M., Chiasson, S., Magnusson, H., and Valdimarsson, G. (2007). Effectiveness and Performance of HACCP-based Programs. Food Control, 18(6), 665-671.
- Luning, P.A., Bango, L., Kussaga, J., Rovira, J., and Marcelis, W.J. (2008). ComprehensiveAnalysis and Differentiated Assessment of Food Safety Control Systems: A Diagnostic Instrument. Trends in Food Science & Technology, 19(10), 522-534.
- Luning, P.A., Marcelis, W.J., Rovira, J., Van der Spiegal, M., Uyttendaela, M., and Jacxsens, L. (2009). Systematic Assessment of Core Assurance Activities in a Companyspecific Food Safety Management System. Trends in Food Science & Technology, 20(6), 300-312.
- Ropkins, K., and Beck, A.J. (2000). Evaluation of Worldwide Approaches to the Use of HACCP to Control Food Safety. Trends in Food Science & Technology, 11(1), 10-12.

Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME *Digital Food Safety Management Systems*

DATE OF FINAL REPORT: *11/10/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: ERIC MOORE AND BEN CHAPMAN

COMMITTEE CHARGE(S):

1. Identifying best practices, existing guidance documents, and research that relate to the use of digital food safety management systems including digital temperature monitoring equipment.
2. Developing a guidance document for food establishments and regulatory authorities that establishes General Best Practice Guidelines for Digital Food Safety Management Systems (DFSMS) including digital temperature monitoring equipment.
3. Determining appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to FDA requesting that the Food Code, Annex 4 (Management of Food Safety Practices - Achieving Active Managerial Control of Foodborne Illness Risk Factors), Annex 2 (References, Part 3-Supporting Documents) be amended by adding references to the new guidance document as well as any existing guidance documents that the committee recommends, and the posting of information on the CFP website.
4. Reporting the committee's findings and recommendations to the next Biennial Meeting of the Conference for Food Protection.

COMMITTEE WORK PLAN AND TIMELINE:

Workplan:

- *Monthly full committee meetings (Started in Nov. 22)*
- *Collect existing literature, guidance, and research documents related to Digital Food Safety Management System (DFSMS)*
- *Create basic best practice guidance document from document research findings for use as a working outline*
- *Create two working subcommittees to edit working outline*
- *Sub-Committee meetings started 06/01/2022*
- *Meetings scheduled to occur by-weekly*
- *Committee review and approval of best practice guidance document*
- *Create sharing plan*
- *Report findings and recommendations*

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

1. ***Overview of committee activities:***

- *Committee determined that monthly full committee calls (when feasible) were appropriate.*
- *Created file and document sharing process for committee members access and use for research documents and working group documents.*
- *Committee identified several existing documents (research, industry articles, regulatory guidance) during the research discovery.*
    - *Received and reviewed over 30 documents and publication*
- *Committee determined the need to develop alignment around terminology of what a Digital Food Safety Management Systems (DFSMS) and Digital Temperature Monitoring Equipment (DTME) is and is not. This was accomplished by creating definitions that the committee came to consensus on.*
- *Committee agreed that a good starting point for a Best Practice Guidance document would be to use an existing regulatory guidance document as a starting point (FDA-Guide to Inspections of Computerized Systems in the Food Processing Industry) for the committees work on developing a best practice document to simplify format and approach with an existing regulatory best practice document.*
- *Committee determined the need to establish two working subcommittees to revise/edit the existing guidance document with the goal of developing an appropriate retail focused best practice guidance document.*
    - *Two subcommittees were created; one to focus on DFSMS, and the other to focus on DTME*
    - *Subcommittees determined that bi-weekly meetings (when possible) would be needed to complete necessary edits/revisions.*

Subcommittees also agreed to providing progress reports on monthly full committee calls.

- *Subcommittee outputs were combined into a single document: General Best Practice Guidance for Food Establishments and Regulatory Authorities for Digital Food Safety Management Systems.*

- *Chairs of this committee have been in communication with the CFP liaisons for the Retail Food Regulatory Association Collaborative on future steps (such as FDA grant funded industry research) and deliverables of this* committee's *work. These efforts focus on a grant objective to encourage the application of digital tools and incentives that prompt desired behaviors (e.g., handwashing) in collaboration with retail food and foodservice industry trade organizations.*

- *On 12/12/2022 a 2-day voting member electronic vote to Approve the final version of the DFSMS Best Practice document was initiated for all 19 voting members.*
  - *Voting closed on 12/14/2022.*
  - *Voting member quorum was obtained (18 yes, 1 no),*

COMMITTEE AND SUBCOMMITTEES MET ON THE FOLLOWING DATES: *NOVEMBER 16, 2021 – FEBRUARY 8, 2022 - MARCH 18, 2022 - APRIL 29, 2022 - MAY 23, 2022 - JUNE 17, 2022 - JULY 1, 2022 - JULY 15, 2022 - AUGUST 12, 2022 - SEPTEMBER 7, 2022 - SEPTEMBER 9, 2022 - SEPTEMBER 23, 2022 - OCTOBER 7, 2022 - NOVEMBER 2, 2022 - NOVEMBER 4, 2022 - NOVEMBER 7, 2022* - DECEMBER 8, 2022

2. ***Charges COMPLETED and the rationale for each specific recommendation:***
   a. All charges completed
3. ***Charges INCOMPLETE and to be continued to next biennium:***
   a. None

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***
☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**
1.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. ***Committee Issue #1: Report – Digital Food Safety Systems Committee***

   List of content documents submitted with this Issue: ***Committee Member Roster:***

   ☐ ***See attached revised roster PDF*** ☒ ***No changes to previously approved roster***
   "Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

   (1) ***Digital Food Safety System Committee Final Report***
   (2) ***Digital Food Safety Management Committee Member Roster***
   (3) ***Draft General Best Practice Guidelines for DFSMS***

   a. **List of supporting attachments:** ☐ ***Not applicable***

   (1) ***Attachment 1_Original CFP ISSUE)2020_II_021***
   (2) ***Attachment 2_DFSSC Meeting Minutes***
   (3) ***Attachment 3_DFSSC Definitions Accepted***
   (4) ***Attachment 4_Computerized Systems in Food Processing FDA***
   (5) ***Attachment 5_SubCommittee DRAFT DFSMS Best Practices Doc***

2. ***Committee Issue #2: Approve/Post General Best Practice Guidelines for Digital Food Safety Management Systems***
3. ***Committee Issue #3: Amend Food Code Annex to Include Reference to General Best Practice Guidelines for Digital Food Safety Management Systems***

Committee Name: Digital Food Safety

Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Moore	Eric	Co-Chair	Industry	Testo Solutions	West Chester	PA	215.806.4717	emoore@testo.com
Chapman	Ben	Co-Chair	Academia	N.C. State	Raleigh	NC	919.809.3205	bjchapma@ncsu.edu
Brandt	Matthew	Member	Regulatory - State	Colorado Department of Public Health and Environment	Denver	CO	720.550.0322	matthew.brandt@state.co.us
Samples	Jarryd	Member	Regulatory - State	Idaho Department of Health and Welfare	Boise	ID	208.866.0934	jarryd.samples@dhw.idaho.gov
Splawn	Travis	Member	Regulatory - State	Oklahoma State Department of Health	Oklahoma City	OK	405.535.5813	traviss@health.ok.gov
Vauls	Patricia	Member	Regulatory - State	Maryland Department of Health	Baltimore	MD	443.609.3072	patricia.vauls@maryland.gov
Matulis	Katie	Member	Regulatory - State	WI DATCP	MILWAUKEE	WI	414.551.2510	katie.matulis@wisconsin.gov
Nord	Jennifer	Member	Regulatory- Local	University of Michigan OSEH	Ann Arbor	MI	734.709.7582	harrisjl@umich.edu
Pascucilla	Michael	Member	Regulatory- Local	East Shore District Health Department	Guilford	CT	203.619.1286	mpascucilla@esdhd.org
Coffman	Vanessa	Member	Consumer	Stop Foodborne Illness	Chicago	IL	971.409.4968	vcoffman@STOPfoodborneillness.org
Abney	David	Member	Industry	Pizza Hut	Plano	TX	405.210.1278	david.abney@yum.com
Abouchar	Julie	Member	Industry	Whole Foods Market	Peachtree	GA	678.255.1202	julie.abouchar@wholefoods.com
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Roberson	Michael	Member	Industry	Publix	Lakeland	FL	863.688.1188	michael.roberson@publix.com
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Yang	Lilly	Member	Industry	Acheson Group	Blacksburg	VA	808.646.1554	Lily.Yang@AchesonGroup.com
Owen	Gina	Member	Industry	Ecolab	Greendboro	NC	336.688.5461	gina.owen@ecolab.com
Ruiz Espejo	Jonathan	Member	Industry	Retail Business Services	Salisbury	NC	704.640.7015	m
Last Name	**First Name**	**Position on Committee**	**Constituency**	**Employer**	**City**	**State**	**Phone**	**Email**
Sudler	Robert	FDA Consultant	Regulatory - Federal	FDA			240.402.1943	Robert.Subler@fda.hhs.gov
Wittry	Beth	USDA Consultant	Regulatory - Federal	USDA			770.488.7333	Xks5@cdc.gov
Kramer	Adam	CDC Consultant	Regulatory - Federal	CDC			404.498.1228	ank5@cdc.gov
Last Name	**First Name**	**Position on Committee**	**Constituency**	**Employer**	**City**	**State**	**Phone**	**Email**
Bhatt	Chirag	Alternate	Industry - Support	HealthSpace USA	Houston	TX	281.684.6883	chirag.bhatt@hscloudsuite.com
Ciarimboli	Ellen	Alternate	Industry - Retail Food	Hy-Vee Inc	West Des Moines	IA	515.453.2789	eciarimboli@hy-vee.com
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Lindholm	Jeffery	Alternate	Industry - Support	iCertainty	Chevy Chase	MD	240.908.4111	jeff.lindholm@icertainty.com
Martin	Eric	Alternate	Industry - Food Service	Texas Roadhouse	Louisville	KY	502.515.7382	ericm@texasroadhouse.com
Melichar	Wayne	Alternate	Industry - Vending and Distribution	Feeding America	Elmhurst	IL	312.399.5281	WMELICHAR@FEEDINGAMERICA.ORG
Nardone	Angela	Alternate	Industry - Support	Share-ify	Longwood	FL	805.907.2233	nardone@share-ify.com
Pascoe	Roxanne	Alternate	Industry - Retail Food	Metropolitan Market	Seattle	WA	206.549.5613	rpascoe@metropolitan-market.com
Scott	Kevin	Alternate	Industry - Support	Ayro Inc	Stephens City	VA	540.974.2092	kevin.scott@ayro.com
Seaman	Charles	Alternate	Industry - Retail Food	Hy-Vee, Inc.	Racine	WI	262.488.3131	pokie102@gmail.com
Sperber	Michael	Alternate	Industry - Support	UL	Simi Valley	CA	818.388.9890	michael.sperber@ul.com
Wiser	Darrell	Alternate	Industry - Retail Food	Ecolab	Lehi	UT	479.426.5738	darrell.wiser@ecolab.com
Wynnw	Rebecca	Alternate	Industry - Food Service	Darden	Denver	CO	303.895.4042	rwynne@darden.com
Woodbury	Thomas	Alternate	Industry - Support	ComplianceMate	Holladay	UT	801.330.9511	thomas.g.woodbury@gmail.com

Note: *Minimum council committee size is 11 (as noted above): 1-Chair; 1-Vice Chair; 1-State; 1-Local; 2-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise;*

Maximum council committee size is 23 voting members: 1-Chair; 1-Vice Chair; 4-State; 4-Local; 8-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise; 36 -Non-voting alternates.

Membership on standing committees is defined by the Executive Board. On all CFP committees, the committee chair, co-chair(s), and vice chair(s) all count towards constituency balance.

General Best Practice Guidance for Food Establishments and Regulatory Authorities for Digital Food Safety Management Systems

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A. Introduction and Scope

The use of Digital Food Safety Management Systems (DFSMS) within the retail food industry, regulated by the Food and Drug Administration (FDA), continues to gain widespread interest, acceptance, and use. The use of DFSMS is expected to continue to grow in the retail food industry as technology improves and components become more readily available. As technology advances the retail food industry continues to replace paper-based records associated with traditional food safety management systems with digital documentation. Recent FDA Risk Factor study results have shown that utilizing a robust management system leads to a reduction in food safety risk factors.

An oft-used component of a DFSMS, Digital Temperature Monitoring Equipment (DTME) can improve awareness, response, and documentation of temperature conditions. This technology allows more accurate, reliable, and efficient food and equipment temperature control impacting safety and quality improvements. As DFSMS and DTME become more common in the retail food industry, the visibility, awareness, and availability of information that these systems and technology can provide should support improvements in controlling food safety risk factors in food retail.

This guidance will outline food safety management approaches specific to the implementation and use of technology in food retail. Best practices provided in this document serve as a foundational guide for the collection of accurate, consistent, and reliable data that can be used to make risk-reduction decisions. This document has been written with the assumption that a food retail establishment has a food safety management system and that they have identified and addressed HACCP Principles 1, 2 and 3 as referenced in Annex 4 of the most recent version of the U.S. FDA Model Food Code.

B. Definitions

Digital Food Safety Management System (DFSMS)

An interactive, digital, or electronic archive intended to collect, store, and analyze data that supports a food safety management system as defined in Annex 4 of the most recent version of the U.S. FDA Model Food Code. DFSMS specifically supports ongoing quality control and assurance, monitoring and recordkeeping of specific food safety goal-oriented plans, like Risk Control Plans (RCPs), that outline procedures for controlling foodborne illness risk factors. A DFSMS is intended to enable a proactive approach to support the consistent safe production, transport, preparation, storage, and service of safe wholesome food as defined in the most recent version of the FDA model Food Code. A DFSMS employs active user-based workflows that support decision making, that can be reviewed and acted upon, and may be housed locally (on-premises) or be accessed remotely using off-site servers or cloud storage.

DFSMS may include but are not limited to functionality that allows a user to:

- capture, record, and store multiple types of data
- provide real-time feedback to users
- generate record keeping reports (i.e., Trends over time)

Other components, tools, and records within a DFSMS may include:

- specific policies, procedures, recipe cards, and critical limit monitoring actions and corrective actions including training tools
- risk control plans
- product storage/movement information and inventory supporting recalls and market withdrawals
- equipment maintenance documentation
- active alerting
- networked and/or IOT devices

Digital Temperature Monitoring Equipment (DTME)

Automated purpose-built temperature measuring device(s) that often includes sensors capable of generating and capturing temperature data for analytical use. This equipment may include the functionality of automatically measuring, monitoring, storing, transmitting, documenting, and sharing the temperature of food, air, or water. Monitoring equipment that captures and stores temperature data over a period of time that may connect to a system that may be capable of delivering alerts and exception reports.

Software

Software is the term used to describe the total set of programs, procedures, rules, and any associated documentation pertaining to the operation of a technology-based system that

includes, but is not limited to application, operating system, and utility applications used by the computerized system.

C. Prerequisites

Best practice for a DFSMS is to employ purpose-built hardware and software when designing and implementing an approach. The appropriateness of hardware and software should meet the goals of any RCP. Maintenance of the system and the proper replacement of system hardware is critical for it to function as designed. Design specifications of the hardware and software should be determined and periodically reviewed to ensure the system and its functional components do what is intended to support food safety.

This document recognizes that DFSMS are built and utilized to support the most recent version of U.S. FDA Model Food Code, Annex 4, HACCP Principles specifically:

Principle #4: Establish Monitoring Procedures
Principle #5: Establish Corrective Actions - implementation of the corrective action specifically
Principle #6: Verification/Sharing for equivalency for regulatory checks
Principle #7: Record keeping procedures and documentation

Personnel operating, maintaining, and programming DFSMS should have adequate training to complete their assigned duties. Determine the extent of operator, system managers, and software system technical personnel training in the functions, requirements and operation of the computerized system.

Examples of training may include but are not limited to:

- system operation
- malfunctions
- regulatory requirements
- system changes
- security procedures
- manual operation of the system
- documentation of system errors

D. DFSS Inputs

Digital Food Safety System Equipment (DFSSE)

DFSSE typically include various purpose-built and designed stationary and handheld measurement instruments, tools, and sensors capable of the collection, storage, and

transmission of data into software. The food contact surface of DFSSE must meet the design and placement characteristics in Chapter 4 of the most recent version of the U.S. FDA Model Food Code and must be designed to meet or exceed NSF Standard 2 - Food Equipment or equivalent. Examples may include but are not limited to mobile device(s), sensors, thermometers, RFID/QR Code scanner/receiver, etc.

Stationary Monitoring Devices

Purpose build devices which are permanently or semi-permanently affixed, mounted, installed, attached to equipment or surface using food grade mounting/installing materials, maintained free of accumulated soil, and cleaned per manufacturer instructions. When devices do not include an external measurement display, access to the measurement data should be easily accessible and viewable. These devices when appropriate should meet the design and placement characteristics in Chapter 4 of the most recent version of the U.S. FDA Model Food Code and must be designed to meet or exceed NSF Standard 2 - Food Equipment or equivalent.

> *Note: DFSS Stationary temperature monitoring devices must meet the requirements outlined in the most recent version of the U.S. FDA Model Food Code 4-204.112 Temperature Measuring Devices*.

Device examples may include but are not limited to equipment or wall mounted data loggers, humidity sensors, door open/close sensors, camera's, etc.

Data access examples may include but are not limited to: Software report on mobile, desktop, tv monitor/screen, etc.

DFSSE Accuracy

Handheld and stationary temperature measurement instruments must meet the most recent version of the U.S. FDA Model Food Code 4-203.11 & 4-203.12. In the event that a handheld or stationary temperature device does not have a display; the operator should be able to easily demonstrate/record the reading/actual monitored temperature (value) for review and record. Follow OEM recommendations & guidelines and follow their procedures.

DFSSE Functionality

Regular and ongoing equipment and system operation functionality are recommended to be conducted (refer to manufacturer for frequency) to verify that DFSMS, DFSSE and DTME in use are operating as intended, if/when issue(s) are identified appropriate action is taken to correct issue(s).

Examples of device functionality issues are but are not limited to:

- Power loss
- Improper device installation
- Device damage/defective

- Software communication/connectivity
- Device communication/connectivity

It is recommended that records of software and equipment functionality verification be maintained and readily available.

Examples of functionality verification may include but are limited to:

- Handheld measurement device accuracy & functionality
- Stationary measurement device accuracy & functionality
- Software and device connectivity/communication

E. Data and System Infrastructure

DFSMS data are the measurement values and user inputs captured by DFSSE, DTME and DFSMS users that are then stored in DFSMS software. Data storage may be stored locally (on-site) or virtually (cloud storage) but access to this data must be readily available for use and display on-site. This makes it possible to retrace which value occurred at which time.

Examples of, but not limited to, measurement values that may be recorded and stored as data in a DFSMS:

- Time points and Account IDs which are assigned to certain quality checks
- Description of the area
- Description of the equipment
- Description of the products/product categories
- Description of the measurement locations of the equipment
- Description of suppliers
- Check lists/Quality handbook
- Tasks (Daily, Shift, On-Demand)
- Reports (Daily, Shift, On-Demand)
- Product specific quality and safety measurement data points (Temperature, pH, TPM, PPM, humidity, time)
- Alerts (alerts are notifications to users)
- Alarms (is the result of an unacceptable software or hardware reading)
- Alert recipients
- Corrective actions associated with checklists and measurement points
- Manual data entry (for immutability and data integrity)

When DFSSE, DTME or a DFSMS user completes a measurement this value is stored in DFSMS software. Each measurement value represents a unique permanent data point represented in the DFSMS software, additional or new data (including that which is associated with an existing or old data point) are then stored in a sequential manner allowing for the original data point to remain. This can be described as a time-based progression of record keeping. The DFSMS software should also be capable of recording all previously recorded data should be readily accessible and documented when changed and available for reporting.

Digital Temperature Monitoring Equipment (DTME) Data

There are three broad ways of capturing temperature and humidity data; they are commonly identified as hand-held, stationary, or Integrated temperature measuring devices. An important consideration for DTME is that devices have the ability to cache/store data locally when connectivity is interrupted, if/when data connectivity is interrupted a DTME device should have the ability to push/send cached/stored data to the DFSMS system when connectivity is restored.

Verification / Immutability

A retail food business may have measures in place to ensure that data captured by the computerized system cannot be altered without a digital signature record or other means of tracking history of inputs. If provisions are made to allow correction of data entries, the entry may identify the person making the changes, the reason for the change and reference to the originally captured data.

Data and System Integrity and Access

Data Integrity and Access are both important aspects of a DFSMS that should be considered to ensure that quality of the information collected by the system is accurate and reliable. To support the integrity of a DFSMS it is recommended that reasonable controls are in place to ensure that stored and/or in-process data is not able to be altered in an unauthorized manner, and that any changes to the DFSMS and/or the stored/in-process data is captured.

Data access is also a way to support effective data integrity. Access to a DFSMS should be controlled and limited only to those persons to whom permission is granted. All data and information should be protected through reasonable use of encryption protocols.

Examples of encryption may include, but are not limited to:

- Utilizing passwords,
- User management and,
- User rights.

Examples of information and/or data for encryption include but are not limited to:

- Passwords
- Proprietary business information
- Data transferred between the input devices and local/cloud-based reporting and storage programs/locations.
- Login occurrences
- Access to information within the DFSMS should also be tailored according to a user's role and responsibilities, writing, or reading rights.

Manual Data Entry

Determine if and how manual interventions are documented; a separate log may be kept of such interventions. The computerized system may be such that it detects, reacts to, and automatically records manual interventions. It is important that system operators are trained in manual backup systems as a best practice this should be documented and conducted prior to DFSMS usage. To ensure business continuity, it is recommended that users have their own SOP for review (redundancy) to ensure practices are being enacted.

Manual Back-Up

A manual back-up system is frequently utilized as a function of business continuity in the event of a computerized system (e.g., hardware or software) failure. Functions controlled by computerized systems may sometimes also be controlled by parallel manual backup systems. As a best practice, functions that are manually controlled and/or manually backed up should be identified and noted re: the firm’s protocols or the system’s protocol. Critical process controls are particularly important. Determine the interaction of manual and computerized controls and the degree to which manual intervention can override or defeat the computerized function. The firm's operating instructions should describe what manual overrides are allowed, who may execute them, how and under what circumstances.

F. DFSMS Outputs

System Outputs and Notification(s)

Typical DFSMS and DTMS include the capability to include user level notification(s) tailored around programmable components of an organization's Standard Operating Procedures (SOP), see What Data is Stored section above for measurement examples that may be involved.

Examples of user level system notification(s) may include but are not limited to the following:

- Reports
- Trends
- Automated emails
- SMS or text message
- Phone calls
- Visual indicators (lights)
- Audible indicators (sounds)

A best practice is to associate one or more corrective actions with an alert. To assure corrective actions are completed in a timely fashion, alerts can be escalated when corrective actions are not completed within a set timeframe.

G. Committee Members

Academia/Industry Members				Regulatory Members	
Ben	Chapman	Eric	Moore	Justin	Asberry
Vanessa	Coffman	David	Abney	Robert	Sudler
Julie	Abouchar	Amanda	Douglas	Beth	Wittry
Jaime	Estes	Julian	Graham	Adam	Kramer
Matthew	Jenkins	Michael	Roberson	Matthew	Brandt
Joey	Yoo	Lilly	Yang	Jarryd	Samples
Gina	Owen	Jonathan	Ruiz Espejo	Travis	Splawn
Chirag	Bhatt	Ellen	Ciarimboli	Patricia	Vauls
Brianna	Davis	Jean	Edsall	Katie	Matulis
Martin	Flusberg	Jeffery	Lindholm	Naomi	Macias
Eric	Martin	Wayne	Melichar	Jennifer	Nord
Angela	Nardone	Roxanne	Pascoe	Michael	Pascucilla
Kevin	Scott	Charles	Seaman		
Michael	Sperber	Darrell	Wiser		
Rebecca	Wynnw	Thomas	Woodbury		

Conference for Food Protection
2020 Issue Form

Issue: 2020 II-021

Council Recommendation:	Accepted as Submitted		Accepted as Amended	**x**	No Action		
Delegate Action:	Accepted		Rejected				

All information above the line is for conference use only.

Title:

Creation of a Digital Food Safety System Committee

Recommended Solution: The Conference recommends...:

the creation of a Digital Food Safety System Committee to complete the following charges and report its findings at the next CFP Meeting.

The Committee will be charged with:

1. Identifying best practices, existing guidance documents, and research that relate to the use of digital food safety management systems including digital temperature monitoring equipment.
2. Developing a guidance document for food establishments and regulatory authorities that establishes General Best Practice Guidelines for Digital Food Safety Management Systems including digital temperature monitoring equipment.
3. Determining appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to FDA requesting that the Food Code, Annex 4 (Management of Food Safety Practices - Achieving Active Managerial Control of Foodborne Illness Risk Factors), Annex 2 (References, Part 3-Supporting Documents) be amended by adding references to the new guidance document as well as any existing guidance documents that the committee recommends, and the posting of information on the CFP website.
4. Reporting the committee's findings and recommendations to the next Biennial Meeting of the Conference for Food Protection.

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

Meeting Number: 1
DATE: 11/16/21
TIME:11am – 12:30pm (Est)

Co-Chairs: Eric Moore & Ben Chapman
FDA Advisors: Robert Sudler & Justin Asberry
USDA Advisor: Beth Wittry
CDC Advisor: Adam Kramer
Scribe: Eric Moore

Agenda

1. Welcome, Call to Order
2. Rollcall,
3. Conference for Food Protection, Inc. Antitrust Statement
4. Identify a Committee Scribe:
5. Review CFP Timeline for Committee Work:
6. Review of Committee Charges:
7. Overview of Committee Plan of work:
8. Action Items:
9. Determine next meeting date:

MEETING MINUTES:

1. **Meeting Called to Order:**
    - First D0K Committee meeting called to order at 11:10am,
        - Motion to begin meeting: Eric Moore
        - Motion accepted 1st Matt Brandt, 2nd Tom Woodbury
    - Committee chairs thanked all members for interest and agreement in being part of this working committee
    - Active participation in committee work was stressed given the condensed work timelines
    - Councill II Chair (Joetta Defrancesco) will be speaking to CFP leadership to get a clear understanding around the level of access for committee members to use Teams as a preferred file sharing platform. More details to be provided during the next meeting.
2. **Roll Call:**
    - Roll Call Conducted by Eric Moore
    - Roll call will be completed using Teams participant list to check for voting member quorum
    - Current voting member quorum requirement is 11 voting members
    - Attendance record captured on committee attendance log
3. **Conference for Food Protection, Inc. Antitrust Statement**
    - Full CFP Antitrust read by Ben Chapman
    - Complete antitrust statement review will be suspended for future meeting
    - Brief review of CFP-Antitrust will be completed for all future full & sub-committee meetings
4. **Identify a Committee Scribe:**
    - Lily Yang agreed to be committee scribe
    - Julian Graham agreed to be stand-by scribe to ensure continuity
5. **Review CFP Committee Work Timeline:**
    - Meeting was not recorded due to committee chairs not having Teams recording access
    - Current plan is to have full committee calls completed monthly, beginning in December

        - A straw poll about full committee monthly calls was with unanimous support.
    - Review of CFP Master Calendar identified the following key dates:
        - October 2021 – 1st Periodic report sent to Council Chair (PDF copy provided to committee)
        - March 2022 – 2nd Periodic report due to Council Chair
        - July 2022 – 3rd Periodic report due to Council Chair
        - November 2022 – Final report due to Council Chair
6. **Review of Committee Charges:**
    - Committee charges review completed
    - Committee was reminded that the charges are not able to be changed
    - Chairs provided a note of caution related to “Scope Creep” away from the charges
7. **Overview of Committee Working Plan:**
    - Full committee call all frequency to be monthly
    - 7 full committee meeting meets are going to be planned over the next 12 months
    - These meetings will act as a review/report out of sub-committee actives
        - Sub-committee meetings will occur in between these meetings
    - Meeting 0: Introductions
    - Meeting 1: Define committee focus, identify sub-committee needs, members, etc.
    - Meeting 2 & 3: Focus on work completed around charges 1 & 2
    - Meeting 4: Determine structure of documents identified in Charge 3
    - Meeting 5 & 6: Review of documents
    - Meeting 7: Review of Final Report
        - Slide deck was used to provide work plan details
        - Deck was provided to all committee members for reference
8. **Action Items**:
    - Charis to provide a voting member meeting poll to be sent out to determine most appropriate reoccurring monthly meeting dates & time
    - Committee members we requested to notify chairs of any committee conflicts that a member may have that will limit a member's active engagement.
    - Committee members were requested to:
        - Further review the committee charges
        - Think about how to define:
            - Digital Food Safety System
            - Digital Temperature Monitoring System
9. Questions – The following questions were asked by committee members:
    - Q1: How will meeting frequency be determined?
        - A1: Through voting member feedback
    - Q2: Will the use of organizational “Use-Case” documents be appropriate for use by committee?
        - A2: All documents are welcome for review and use by the committee
    - Q3: To reduce the potential for committee member work duplication around document research, will it be possible to have industry members and regulatory members focus on documents and information specific to constituency?
        - This is a great idea and will be part of further committee conversations
    - Q4: Is there a project management tool (ex-Smart Sheets) that could be used by the committee to support better transparency of work progress
        - A4: Great idea, committee chairs will look into if this is possible

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-

10. Next Meeting Date:

- TBD after voting member poll is completed

Meeting Number: 2
DATE: February 8, 2022 **TEAMS and phone in options in calendar invite**
TIME: 10am ET
Co-Chairs: Eric Moore and Ben Chapman
FDA Advisors: Robert Sudler & Justin Asberry
USDA Advisor: Beth Wittry
CDC Advisor: Adam Kramer
Scribe: Julian Graham (on behalf of Lily Yang)

Agenda

1.	Welcome, Call to Order
2.	Rollcall/ Conference for Food Protection, Inc. Antitrust Statement
3.	Discuss Definitions
4.	Discuss documents collected by committee members (is anything missing? Next steps)
5.	Review FDA computerized document as a model for our committee guidance?
6.	Refine/add to/further outline what else would be captured
7.	Wrap-up

Link to definitions document:
https://docs.google.com/document/d/1uUsCjqeYG65sSG3oTYy738I7QG9JJhpSq70KY_kR3Wk/edit
Link to Google Drive for resources
https://drive.google.com/drive/u/0/folders/1jcAkf4fypF1pxEsiOUwYcW3FgV0sdIZg
Next Meeting Date: March 18, 2022 1pm ET

I. Welcome, Call to Order

Eric called meeting to order
Michael Robison call
Tom Woodburry second

II. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement

Eric did roll call
Eric reviewed antitrust statement & shared link in the chat

III. Discuss Definitions

Eric shared screen
Ben lead discuss
1st charge

Digital food safety management system: A digital or electronic collection of policies, procedures, data, monitoring actions, cloud-based functionality including real-time alerting, automated reporting, and supporting documentation to support the consistent safe production, transport, preparation, storage, and service of safe wholesome food and food products intended for human consumption. .,

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Digital temperature monitoring equipment: Electronic sensors/devices capable of automatically measuring, monitoring, storing, transmitting, documenting and sharing the temperature (and potentially other characteristics) of food, air, or water. Monitoring equipment allows for the capture and storage of temperature data over a period of time and connects to a system capable of delivering alerts and exception reports.

Highlighted cloud-based functionality including real-time alerting not all system need to be cloud based some organization do not house data in the cloud.

Open Committee Discussion on Definitions:

Michael Roberson - I recommend striking "cloud based." Not all digital systems will be cloud based, especially when companies work to address data security concerns. Larger companies have their own servers and will not place all data into the cloud due to these data concerns.
Woodbury, Thomas - As a "Teams" novice... if you need to zoom in on the text displayed, hold down control/command and use your mouse wheel to scroll to zoom in/out
Rebecca Wynne - Added visibility
Angela (Guest) - Added capture/recording
Michael Roberson - I agree with Ben, as the Food Safety Management System is inclusive of all parts - policies, procedures, records, and monitoring actions. YES to recalls.
Adam Kramer - What should be the minimum requirements be.
Michael Roberson -Policies on a company intranet is one component. It may be helpful to have separate core components. Policies alone would not necessarily constitute having a digital food safety management system. Likewise, having an electronic recall system, without any policies and procedures, would not constitute having a digital food safety management system. Think "Active Managerial Control" components that are actively engaged on a regular basis.

Justin Asberry: Wanted to drop in the definition from the Food code for a FSMS:

Elements of an effective food safety management system may include the following:
• Certified food protection managers who have shown a proficiency in required information by passing a test that is part of an accredited program
• Standard operating procedures (SOPs) for performing critical operational steps in a food preparation process, such as cooling
• Recipe cards that contain the specific steps for preparing a food item and the food safety critical limits, such as final cooking temperatures, that need to be monitored and verified
• Purchase specifications
• Equipment and facility design and maintenance
• Monitoring procedures
• Record keeping
• Employee health policy for restricting or excluding ill employees
• Manager and employee training
• On-going quality control and assurance
• Specific goal-oriented plans, like Risk Control Plans (RCPs), that outline procedures for controlling foodborne illness risk factors.

Conesus on removing Animal Foods

Angela - Is “auditable” a sufficient replacement for “legally defensible”

Edsall, Jean V - There are existing legal precedents regarding recordkeeping systems. This may already expand to digital recordkeeping systems.

Travis Splawn - Agree with others. Not sure if "Legally defensible" is the best language, or used elsewhere.

Asberry, Justin - Let me ponder on that legally defensible question.

Travis Splawn - Perhap use something like "has an audit tracking feature"?

Asberry, Justin (Guest) - I will consult with FDA-CFSAN as well to give a Food Code Interpretation on the legal defensible conversation.

Moved on to 2nd Definition:

Digital temperature monitoring equipment: Electronic sensors/devices capable of automatically measuring, monitoring, storing, transmitting, documenting and sharing the temperature (and potentially other characteristics) of food, air, or water. Monitoring equipment allows for the capture and storage of temperature data over a period of time and connects to a system capable of delivering alerts and exception reports.

Engaging conversation on both definitions. Ben & Eric will share final definition to all members for Reminder to review documents between meetings.
Motion to adjourn

Thomas Woodbury - Strike other characteristics

Comments collected by committee members (is anything missing? Next steps)

IV. Review FDA computerized document as a model for our committee guidance?

V. Refine/add to/further outline what else would be captured

VI. Wrap-up

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

Meeting Number: 3
DATE: March 18, 2022 **TEAMS and phone in options in calendar invite**
TIME: 1pm ET
Co-Chairs: Eric Moore and Ben Chapman
FDA Advisors: Robert Sudler & Justin Asberry
USDA Advisor: Beth Wittry
CDC Advisor: Adam Kramer
Scribe: Lily Yang

Agenda

8.	Welcome, Call to Order
9.	Rollcall/ Conference for Food Protection, Inc. Antitrust Statement
10.	Past meeting minutes
11.	Voting member Definitions Poll Results Review
12.	Discuss FDA computerized document as a model for our committee guidance?
13.	Wrap-up

Link to definitions document:
https://docs.google.com/document/d/1uUsCjqeYG65sSG3oTYy738I7QG9JJhpSq70KY_kR3Wk/edit
Link to Google Drive for resources
https://drive.google.com/drive/u/0/folders/1jcAkf4fypF1pxEsiOUwYcW3FgV0sdIZg
Next Meeting Date: April 29, 2022 1pm ET

VII. Welcome, Roll Call

- Eric conducted roll call!

VIII. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement

- Ascertained that all individuals are comfortable of Antitrust. If anyone is uncomfortable with it, please do let Eric Moore know.

IX. Welcome, Call to Order

- Amanda Douglass approved meeting to be in order
- Julian Graham seconds
- Chirag – we may not need to do this next time as other CFP committees are *not* doing this.
- Eric – this meeting is being recorded; if anyone has questions around this, can discuss OFFLINE
    - Ben is currently unable to join today and sends his regards

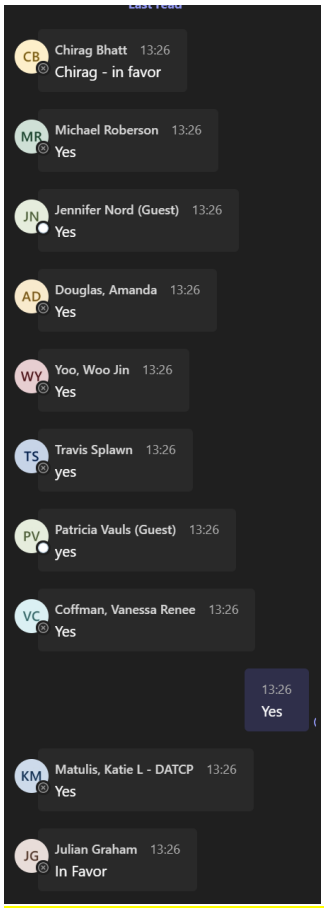
X. Last Meeting Recap

- Good discussion around the definitions that were shared with everyone for feedback. There was a lot of good discussion and Julian captured the comments accordingly.
- In the last meeting, committee discussed both definitions that were identified that were part of Charge 1
- First Definition for Digital Food Safety Management System
- Second Definition for Digital Temperature Monitoring Equipment
- With some post-editing per discussion with Eric/Ben, definitions were put into a place that everyone could be comfortable with. Yesterday, voting members completed a poll (agreement/disagreement) with the definitions that were made.
    - Consensus of vote:

    - Yes: Voting members of the committee agree with the definitions.
- (see “Discuss Definitions”)

XI. Discuss Definitions

- Eric – extends appreciation for Michael Roberson (email to Ben and Eric) stating that in a few areas, the definition used the word “must” as opposed to using another type of word. The intent, originally, was not to make rigid definitions
    - Perhaps the reason why one member voted “NO” may be due to the word “must”
    - Question for Voting Members: Do voting members feel that it would appropriate for an additional revision to the two definitions to edit the words that are very constrictive (i.e. ‘must’) and replacing with lighter words (i.e. ‘shall’) OR are voting members in agreement (now) with minor editorial revisions?
    - Michael Roberson –
        - “words matter” especially once issues and recommendations get to the Council.
        - For Council – often comes down to the wording
        - Is good with the content but did want to bring to the Committee’s attention of “the use of extremes; when we can provide flexibility, it helps”.
    - Eric – agrees with Michael – there shouldn’t be an issue with removing “most” and replacing with “shall”
- Michael Roberson, brings motion to floor: “To allow Chair and Vice-Chair Editorial Positions to address some of the words like “must” to make amendments to provide flexibility” for the two definitions.
    - Jennifer Nord seconds that motion
    - Jean (in comments)
    - Chirag: I agree with what Michael says. In order to avoid the lengthy discussion and Council discussion, it is probably in our best interest to change that word. And as we al know, Michael has been in CFP for a long time”
    - Robert Sudler: “To add to what Chirag and Michael have said. As I look at the definition themselves, the word ‘shall’ does really make a difference. We don’t want to regulate through definition”.
- Eric: “Let’s call the vote for the motion that has been provided” – votes are done via “text” in text window (see figure below).



- **Conclusion of Vote: There is voting member quorum to allow Chair and Vice-Chair editorial lee-way to replace terms like "must" with terms like "shall"**

XII. Review FDA computerized document as a model for our committee guidance?

- Is any of what is currently there usable? Any section? Content? Let's have a discussion around "that" [usability] and begin to identify – as in Charge 2 of Committee Charges – create guidance document around best practices specific to:
  - Use of Systems,
  - What these systems are (or aren't), and
  - How Regulatory Bodies can Assess Validity (including: if current system in place is viable or not)
- We all agree that a digital FSMS is *not* a PDF on a mobile device; it's more than that. Hence why we created the aforementioned two definitions.
- FDA's "Computers Systems in the Food Processing Industry" (link)
  - One of the questions – was anybody aware of the existence of this document?
    - Is it appropriate for the Committee to recommend, back to FDA, to make revisions to the existing document in relation to what our goals are OR

        - Is it better for the Committee to use it as a starting point for what we've been charged w/ creating and submitting *the created* at Biennium.
    - Michael Roberson – I don't recommend editing existing regulatory documents. Better to stick to what Council charge is. Use doc as a starting point.
    - Robert Sudler – agrees with Michael. He recently reviewed the article and noted it was updated last in 2014. Although it was created by ORA but also CFSAN. Justin (ORA) and him (CFSAN) will do their due diligence to identify if there is an update flying around.
        - This should be used as a starting point – needs to be tailored to what *we* want to focus on. There's a lot, he believes, of work that needs to be done.
    - Eric – Just to be clear, if Committee identifies portions/components of this document, are we (we are) allowed to choose portions of the verbiage, right? Since this is public domain documentation; want to ensure there is no potential issues with.
        - Robert Sudler – "It's a public facing document that's out there for people to use. Certainly nothing wrong with what you've described. No, no problem"

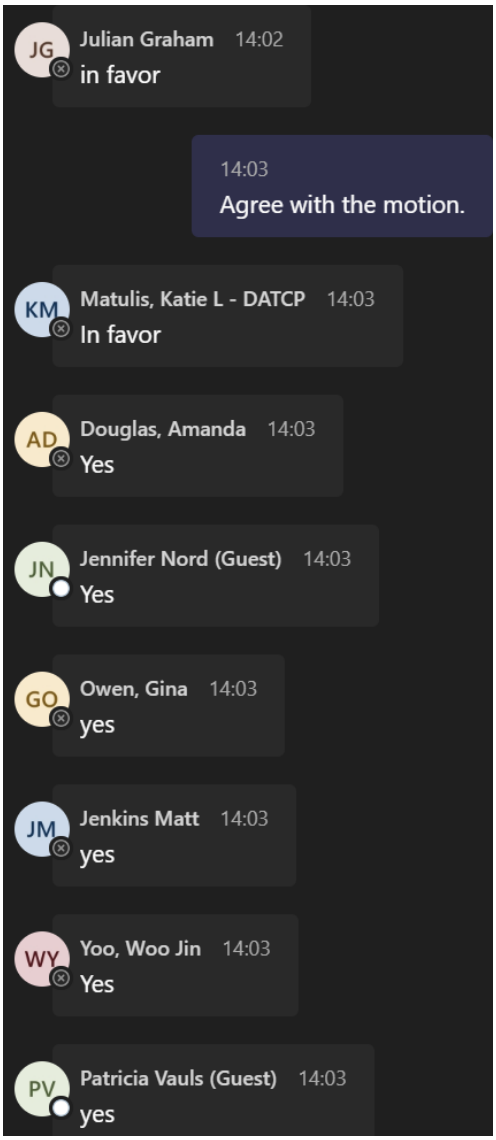
XIII. Discussion Time re: above

- Eric – for those that were able to go through this (he read it 4X):
    - What did you like?
    - What did you *not* like?
    - Is the format of this, appropriate? Format being – how the TOC is laid out ← is this format what we, as a committee, think will be appropriate for us to develop for the two documents to be created as part of the Charge? OR do we need to blow the format up and think of something new and different?
- LY: Wanted to better understand, are you referring to Chapter?
    - Eric: Right, this is the question – do we want it to mirror like that? "This has a very federal feel to it. Is that format appropriate for what we want to produce? OR does anybody have any suggestions for a different format that would be user-friendly for industry and/or regulatory individuals"
    - Robert Sudler - "is your attempt to modify or create a similar document that's geared towards the retail sector? Is that the eventual goal –that is able to cite Food Code provisions?"
        - Eric: In essence, yes. To replace wording. But we all know that isn't a possibility Leading to the next question – what portions of this document do Committee members are appropriate for Use or Adaptation for what *we* want to create?
            - Ask the latter question first.
            - Response for above re: formatting (LY) – it needs to be revised b/c it's not really useable
- Eric – Table formatting, let's focus on CONTENT
- Current Document - https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/computerized-systems-food-processing-industry
    - Provided segregation of topics based on HARDWARE, SOFTWARE, PROCESS, PERSONNEL
        - Do we want to copy these topics over? Or do we want to reorganize parts of it?
        - Does there need to be sections of "Technology Overview" and such sections?
    - Julian – does not believe that this is the best approach to reading the document.
        - Explore from the Different Buckets. Thinking about a "DFSMS", there's some autonomous measurements that happen (e.g. IoT systems, people-driven

systems wherein handheld BT probes may be used, to digital version of checklists) – Using those three buckets

- Eric: What do people feel like? Hypothetically (below list) are the core sections of the document that we will create which mirror **Chapter 2** of document.
    - Overview
    - Hardware/peripherals
    - Software
    - Data storage and access/sharing
    - Maintenance and calibration
    - User/training/knowledge
- Chapter 2 seemed to have the most useful information to both BC & EM to move the project forward
    - Are there any buckets missing, from above? Or are any of them subsets of one/other?
- Jean Edsall
    - Has paged through document and while it has good definitions and descriptions of hardware and software and with rapid changing of technology (and the out-dated ness of this – what we write must be more generic and not as specific).
    - On proposed topic – there needs to be a MANAGER's piece of it for discussion management systems.
        - What's the manager's role and responsibilities
        - Who is responsible for it?
    - Eric: So looking at "User/training/knowledge" ← let's consider revising *this* title to have discussion
        - Adding "manager role and responsibilities" underneath
    - Jean: What are acceptable substitutions? How do you prove to regulatory? And how does regulatory utilize this document to assess that things are done right
        - What is industry moving towards?
        - What is regulatory going to use to assess the systems.
    - Eric – do you think that the above are subsets or a new section?
        - Jean – we need more feedback
- Eric:
    - While this document is outdated, a lot of the information within the current FDA document is not applicable to what is being created.
    - Example: should we include "inspection concepts" as part of that list?
    - Robert Sudler: Something to consider – if you're making a guidance document, one thing to focus on should be…if someone was reading the Food Code, what is missing and what doesn't currently fall in the Food Code.
        - When it comes to the Food Code, what is currently falling short & it should be addressed in the guidance document.
        - Ultimately this document should be able to assist with what may be missing and address potential gaps.
- Jin Woo Yoo –
    - It wouldn't hurt to add regulatory compliance section. Under the regulatory compliance section, we can add the details of the regulation that we can provide to regulator. It can act as a good chain-of-custody & be able to provide guidance for what to provide to regulators.

    - Jennifer Nord: To add to that, we not only need to think about regulators, but also how industry will be using/doing with this guidance.
- *Current updated List* @ 13:54 ET
    - Overview
    - Hardware/peripherals
    - Software
    - Data storage and access/sharing
    - Maintenance and calibration
    - User/training/knowledge
        - Manager role and responsibilities (person in charge – FC)
    - Regulatory Compliance
        - From Katie Matlulis - we could make a regulatory compliance checklist with the main points from the guidance document (more of a cheat sheet)
        -
- Justin Asberry (w/ FDA)
    - "How would the two definitions from last call fit into this document? In the beginning? In the definition?"
    - Eric: Yes. Ben and I chat that while we were creating the list above, we do all need to ensure that these definitions also cover the overlapping document itself
        - Yes, a definition aspect needs to be included for sure
- Katie Matulis DATCP (in chat):
    - A suggestion, we could make a regulatory compliance checklist with the main points from the guidance document (more of a cheat sheet)
    - Eric: great idea!
- Looking at the other sections of *List* – any opinions, perspective, recommendations for what would fall within each of the *Sections* – portions of this existing FDA document could begin to incorporated if Committee would like to do that!
    - Eric: We need to conceptually and mentally aware that we will be creating two different documents. The definition exercise was the generator for the document(s) that we would need to create. Each of the lists – one for DFSMS & another for Best Practice for digital temperature monitoring equipment – would be addressed.
        - Moving into a final place (from editing & finalizing perspective), can probably blend the two; however, for right now's ease of workstream, if Committee agrees that it may make the most sense to split into two subgroups to focus on each of the areas separately with the intent that it'll become a whole overarching document.
    - Amanda Douglas – Agrees, there should be two
    - Eric: While there may be some redundancy, needs to be considered separately.
        - We need to be aware of the usability & real-world application that companies are in.
        - Not everyone is going to need to use both at the same time.
        - Sounds like two working committees will be what makes sense!
        - Should we make motions to start the two subcommittees?
- Amanda brings a motion that we start the process to split into two subcommittees to work within the second Charge
    - Julian Graham – seconds.
    - Voting members vote through chat window



    -
    - Matt Brandt = Yes
    - Travis Splawn = Yes
  - **Voting members have approved the creation of two subcommittees to begin to work on addressing Charge #2**
- Establishing Members of Those Committees:
  - Option 1 – Provide polls to
    - 1) voting members – needs continuity between both subcommittees & voting member quorum – once established
    - 2) At-Large Members – poll will also be out there to identify which workstream to be involved with
  - Does anyone have other suggestions?
    - “Silence means acceptance” - Eric
    - Julian & Amanda & Lily think above option are great!

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XIV. Refine/add to/further outline what else would be captured

- Committee meeting got through what Eric & Ben wanted to discuss
- OR do we want to discuss FDA documents that the Committee agrees for what the two subcommittees will be allowed to moving in it.
- We will need to start working on this expeditiously! – "Thanks, COVID"
- Julian – can we discuss the Timeline for the Subcommittees? What's our expectation for time, etc.?
    - Eric: Hope to get the poll out early next week (Week of March 21) for Voting Members – complete this ASAP – executed by end of next week (Week of March 21).
        - Secondary poll can be finalized by end of March 2022.
    - On next call, can identify:
        - Subcommittee completion times
        - Subcommittee reporting to the larger Committee
    - Subcommittees:
        - Will need to work independently of each other
        - However, must provide monthly progress updates.
- Which voting members would like to be Chairs of Subcommittees?
- Courtney (on phone) –
    - When you send out the poll, also let people vote who wants to self-nominate
    - Also believes it's a good idea for people to read the FDA document to figure out pieces.
    - With poll, remind people on what the Charge is and what needs to happen (since this is both for industry & regulatory – needs to be general so it's not just "old technology")
        - Will be useful to have experts lean on the sections
        - For those not as focused in this, let them ask the questions
    - Email from Joetta – deadline reminder progress report by 25th of March
        - Please be comfortable with where things are before sending in.
        - Eric – will have this part completed before next Wednesday (3/23)
- Katie Matulis (in chat) –
    - It may be useful to open up the FDA document for comments on the shared teams page/google documents/
        - Julian will convert the PDF doc to a Google Doc to allow for comments!
- Eric:
    - If you don't get the FDA podcast alerts that are coming out, there is going to be a new podcast that the FDA is pushing out that has absolute relevance to what we listen to.
    - Podcast Link (release on March 21): https://www.fda.gov/food/cfsan-constituent-updates/fdas-third-techtalk-podcast-will-be-artificial-intelligence

XV. Wrap-up

- Able to get 12 minutes back! 😊
- We will talk in a few weeks – keep an eye out for the polls!
- **Next meeting – April 29, 2022 from 1PM – 2:30PM ET**

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Meeting Number: 4
DATE: April 29, 2022 **TEAMS and phone in options in calendar invite**
TIME: 1pm ET
Co-Chairs: Eric Moore and Ben Chapman
FDA Advisors: Robert Sudler & Justin Asberry
USDA Advisor: Beth Wittry
CDC Advisor: Adam Kramer
Scribe: Lily Yang

Agenda

14. Welcome, Call to Order
15. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement
16. Past meeting minutes review
17. Sign-Up Reminders: a. Sub-Groups b. Future meeting dates/times
18. CFP Executive Meeting Overview
19. CFP Support of Future (2025) Committee Activities
20. Wrap-up

Link to definitions document:
https://docs.google.com/document/d/1uUsCjqeYG65sSG3oTYy738I7QG9JJhpSq70KY_kR3Wk/edit
Link to Google Drive for resources
https://drive.google.com/drive/u/0/folders/1jcAkf4fypF1pxEsiOUwYcW3FgV0sdIZg
Next Meeting Date: TBD

XVI. Welcome, Roll Call

- Justin Asberry does not always receive the things they are hoping to receive (from either Ben or Eric) – Ben uses the Calendar invite for meetings (that might be the meeting and not having that).
- Completed w/ Quoroum

XVII. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement

XVIII. Welcome, Call to Order

- Don't need to be following protocols for Robert's Rules
- Antitrust statement by Eric

XIX. Last Meeting Recap

- If anyone has specific questions as it relates to the last meeting, raise them NOW or email Ben and/or Eric

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- Access last meeting notes here: https://drive.google.com/drive/u/0/folders/1F7XyuNLXR5s8AepF7BjgQvQkaYblPGuz Committee documents - Google Drive

XX. Sign-up Reminders

XXI. Sub-Committee

- **Please complete by next Tuesday**
- Question: Can you see on the back end which committee we picked?
    - YES. Your email is logged
- Link: https://docs.google.com/forms/d/e/1FAIpQLSdgA5Qssxbwd0a9lCKRxs6Rx8JCfQWSvZCvz08lalAxm2utYw/viewform?usp=sf_link

XXII. Future Meetings

- **Please complete ASAP.**
- Want to get a few more, in the books
- Meeting 4 (May) - http://whenisgood.net/89m3de8
- Meeting 5 (June) - http://whenisgood.net/hrff9hx

XXIII. CFP Executive Meeting Overview

XXIV. Wendy Bell (Council 2)–

- The former Council II chair is no longer in the regulatory role.
- Courtney Halbrook (vice-chair) has stepped into Council 2 chair position
- Wendy Bell has been brought on as the new Vice-Chair for Council 2

XXV. Overview of Executive Board Meeting

- Our committee came up in a number of discussions – focusing around publications, sharing, what to do with "best practices" guides going forward
- There is a plan to release the next iteration of the Food Code in 2022
    - As we think about our recs for the 2023 bi-annual, there is a goal by FDA (supplements, not full updates) – so if there are things we'd like to recommend Food Code related, there is a potential that is on a quick turn-around
- There is a Publications Commtitee for CFP looking at the best way to distribute information to stakeholders from what comes out of conference
- Potential that CFP website will be updated

XXVI. CFP Support of Future (2025) Committee Activities

- CFP is currently in the process of applying to different funding sources to supprot a vaariety of activities
- Group who was responsible for this had reached out to inquire if there were any potential needs for funds
- We can decide/discuss what the system/interface should be for (a) temperature recording; (b) digital management systems

  - We won't be able to get to: Implementation & Barriers around these systems
    - As there is exploration for grants – do we want to get public health grants or interns that could do some exploration/research into what is available for mid- and small businesses
    - Explore barriers to implementation?
- Put together some proposals that when/if this committee is reofrmed, we can put those into the charges
  - There is a high likelihood that this committee will be reformed
- CFP has been working with NEHA and others to bolster the ability to do inside-the-organization-help-for-resaerch-committees
- Julian: How would the money be used? What are some of the ideas, when we are out there, to do X? What is X?
  - Ben: When supporting a change in implementation – what are some problems people may have achieving best practices? Is it time, resources, lack of understanding and knowledge? Funds can provide starting point to fill gaps. As we're writing the best practices documents, we are making a bunch of assumptions.
  - This might allow us to park some of the assumptions and learn, somehow – through interviews or focus groups or visits or surveys – what the reality is across the industry (as opposed to speculation).
  - Likewise, could be working across the regulatory world about implementation.
  - Or utilization of resources (either Intern, or Consultant, or Contract) who can answer the questions about the implementation of the best practices
  - Often there are gaps that are filled by people outside of this process that committees use to move forward; but, maybe there are ways for CFP to support next steps for this committee
  - Eric – right out of the gate for this undertaking, it's working with FDA to CFP – we are the "guinnea pigs"
- Once we get an adequate number of voting members divided between the two subgroups, Ben and Eric will start the process by providing each committee with a general template that will be loosely framed and based to incorporate some components of the FDA document that was previously discussed to place comments within (via G-Drive)
  - **Please provide comments on the Google Document – re: Guide to Inspections of Computerized Systems**
  - **https://docs.google.com/document/d/1OlanY6xpA1WzLEo0eNsNR5hmQByuiaIN/edit**

XXVII. Wrap-up

- **Next meeting – TBD**

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

Meeting Number: 5
DATE: May 23, 2022 **TEAMS and phone in options in calendar invite**
TIME: 2pm ET
Co-Chairs: Eric Moore and Ben Chapman
FDA Advisors: Robert Sudler & Justin Asberry
USDA Advisor: Beth Wittry
CDC Advisor: Adam Kramer
Scribe: Julian Graham

Agenda

1.	Welcome, Call to Order
2.	Rollcall/ Conference for Food Protection, Inc. Antitrust Statement
3.	Past meeting minutes review
4.	Review of revised definitions
5.	Introduce sub-committee leads
6.	Sub-Group: a. Introduce leads b. Review charges c. Discuss meeting frequency
7.	Wrap-up

Link to definitions document:
https://docs.google.com/document/d/1uUsCjqeYG65sSG3oTYy738I7QG9JJhpSq70KY_kR3Wk/edit
Link to Google Drive for resources
https://drive.google.com/drive/u/0/folders/1jcAkf4fypF1pxEsiOUwYcW3FgV0sdIZg
Next Meeting Date: TBD

XXVIII. Welcome, Roll Call

- Some Members At Large & Voting are traveling
- Completed w/ Quoroum

XXIX. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement

XXX. Welcome, Call to Order

- Don't need to be following protocols for Robert's Rules
- Antitrust statement by Ben

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

XXXI. Last Meeting Recap

- If anyone has specific questions as it relates to the last meeting, raise them NOW or email Ben and/or Eric
- Access last meeting notes here: https://drive.google.com/drive/u/0/folders/1F7XyuNLXR5s8AepF7BjgQvQkaYblPGuz Committee documents - Google Drive

XXXII. Review of revised definitions

No Comments on latest revision
https://docs.google.com/document/d/1uUsCjqeYG65sSG3oTYy738I7QG9JJhpSq70KY_kR3Wk/edit

Digital food safety management system (DFSMS): An interactive, digital or electronic archive intended to collect, store, and analyze data that supports a food safety management system. A DFSMS is intended to enable a proactive approach to support the consistent safe production, transport, preparation, storage, and service of safe wholesome food as defined in the FDA model food code. A DFSMS employs active user-based work-flows that support decision making, report generation (including trends over time) that can be reviewed and acted upon, and may be housed locally (on-premise) or be accessed remotely.

DFSMS should include but not limited to may havemust have functionality that allows a user to:

- capture, record, and store multiple types of data
- provide real-time feedback to users
- generate record keeping reports, for exampleand trends over times

Other components, tools, and records within a DFSMS may include:

- specific policies, procedures, recipe cards, and critical limit monitoring actions and corrective actions including training tools
- risk control plans
- product storage/movement information and inventory supporting recalls and market withdrawals
- equipment maintenance documentation
- active alerting
- networked and/or IOT devices

Digital temperature monitoring equipment: Automated temperature measuring device(s) that shouldmust include electronic sensors capable of generating and capturing temperature data for analytical use. This equipment may include the functionality of automatically measuring, monitoring, storing, transmitting, documenting, and sharing the temperature of food, air, or water. Monitoring equipment that captures and stores temperature data over a period of time may connect to a system that may be capable of delivering alerts and exception reports.

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

XXXIII. Introduce sub-committee leads

XXXIV. Systems

lily.yang@achesongroup.com (co-lead)
jonathan.ruizespejo@retailbusinessservices.com (co-lead)
brianna@savorymanagement.com
patricia.vauls@maryland.gov
harrisjl@umich.edu
Matt.jenkins@us.mcd.com
Katie.matulis@wisconsin.gov
michael.roberson@publix.com
RWynne@darden.com

XXXV.

XXXVI. Charge

Developing a guidance document for food establishments and regulatory authorities that establishes General Best Practice Guidelines for systems based on our consensus definitions.

XXXVII. Equipment

Julian.Graham@sodexo.com (co-lead)
jaime.estes@albertsons.com (co-lead)
wmelichar@feedingamerica.org
Amanda.douglas@wawa.com
traviss@health.ok.gov
matthew.brandt@state.co.us
ECiarimboli@hy-vee.com

XXXVIII. Charge

Developing a guidance document for food establishments and regulatory authorities that establishes General Best Practice Guidelines for digital temperature monitoring equipment on our consensus definitions.

XXXIX. Format

Using existing FDA Document as scaffolding and bullet points/outline of best/good practices.

XL. General Discussion

- Ben and Eric will lead expectation meeting with Co Leads
- Co Leads will identify scheduling with the group
- Ben and Eric will share meeting invites with the entire committee, everyone is welcome to drop in.
- Edsall, Jean V

  how would you like non-voting members to join the sub-committees?

You may join either group as a non-voting member. Please email Ben if you have strong preference on subcommittee.

XLI. Wrap-up

- **Next meeting – TBD**

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

Meeting Number: 6
DATE: September 7, 2022 **TEAMS and phone in options in calendar invite**
TIME: 2PM ET
Co-Chairs: Eric Moore and Ben Chapman
FDA Advisors: Robert Sudler & Justin Asberry
USDA Advisor: Beth Wittry
CDC Advisor: Adam Kramer
Scribe: Lily Yang

Agenda

UPDATED Agenda:

8. Welcome, Call to Order
9. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement
10. Past meeting minutes review
11. CFP Reporting Deadline Review
12. Sub-Committee Progress Report Out: a. Digital Food Safety Management System i. Q&A b. Digital Temperature Monitoring Systems i. Q& A
13. General Q&A
14. CFP & NACCHO Research Grant Overview
15. Wrap-up

Link to definitions document:
https://docs.google.com/document/d/1uUsCjqeYG65sSG3oTYy738I7QG9JJhpSq70KY_kR3Wk/edit
Link to Google Drive for resources
https://drive.google.com/drive/u/0/folders/1jcAkf4fypF1pxEsiOUwYcW3FgV0sdIZg
Next Meeting Date: TBD

XLII. Welcome, Roll Call

- Do not have Voting Member Quorum
- Will continue to have the meeting
- Eric will run through Voting Member Names quickly that isn't marked off.
- Agenda
- Need to change certain individuals for names and positions (USDA v CDC)

XLIII. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement

- Operating under CFP Anti-Trust operations – no talk about pricing & customers and all that goodness.

XLIV. Past Meeting Minutes Review

- Reviewed. Need to change a date

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

XLV. CFP Reporting Deadline Review

- Periodic review for Fall Meeting must happen by end of tomorrow (9/8/2022) because that document is due to CFP Executive Director by October 13, 2022 in preparation for OCT 5 & 6th Grand Rapids MI Board Meeting
- Coming up on due-dates very very quickly!
- Issues open December 19, 2022 (for 30 days)
- April 23 – 28 – Biannual Meeting

XLVI. Subcommittee Progress Report Out

- Digital Temperature Monitoring
    - They have mostly completed
    - They will have a cleaner version of the document by next week for everyone to review
    - Do you feel that subcommittee member engagement is adequately supporting the process as things are progressing?
        - Yes.
    - Do you think things are achievable within 4 – 5 weeks.
        - Yes. Taking a "simple" approach. Should get a version of that quickly
- Digital Food Safety Management
    - Taking each section and wordsmithing and eliminating verbiage and writing comments. As a group we have regular communication between the two sub-committee chairs and within group for providing comments
    - More than halfway through the document and at a good pace to complete in 5 weeks.
    - Handheld and stationary device*

XLVII. General Q&A

- Question from David & Brenda Bacon – to clarify – DFSM is editing the FDA Guidance Document that the edits are being made to?
    - Yes. Both Committees are using the original document from FDA 2001
- David Lawrence: for follow up to Eric – this subcommittee work will be two separate documents?
    - Yes. At this time, we don't have a voting member quorum, but we could have asked the committee (today) to vote whether or not there would be value in two independent documents (one on software component and other on hardware technology component) OR if it would be better to bring them back together into one final product. But since we can't vote today; we are mentioning this as something for Committee to think on and consider.
- Doing a Straw-Poll or Any Comments on the above?
    - Thomas Woodbury – generally deployment should be together for both aspects, he would vote to do a combined document
- 09/09/22 AMMENDED NOTES:

- During the call I mentioned that a vote may need to be conducted to determine if the documents our 2 subcommittees are working on should be combined into a single document or left as two standalone documents. I apologize but was not correct and a vote will not be required to combine the two documents into a single document. According to our second committee charge (see below or attached) our committee is charged with creating a single document, not multiple. Sorry for any confusion this may have created.
  - *DFSMS Charge 2) Developing a guidance document for food establishments and regulatory authorities that establishes General Best Practice Guidelines for Digital Food Safety Management Systems including digital temperature monitoring equipment.*

XLVIII. CFP & NACCHO RESEARCH GRANT REVIEW

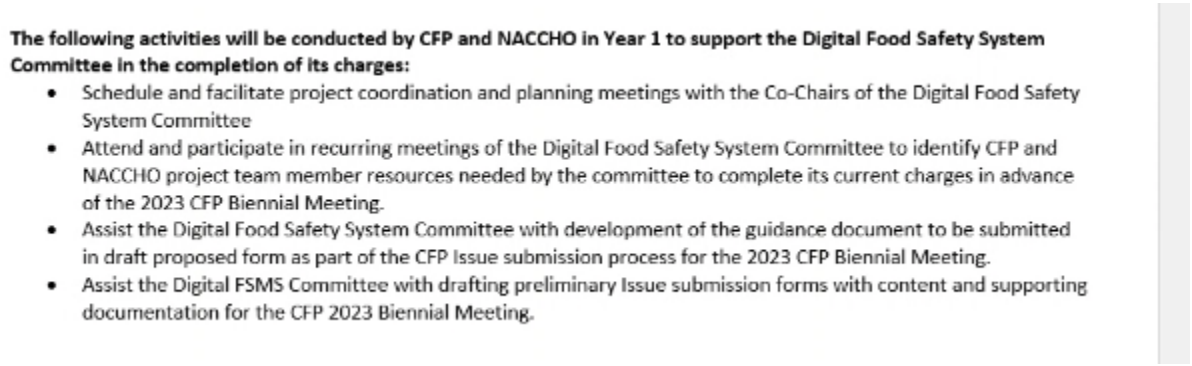
New Update: Retail Food Regulatory Association Collaborative (www.retailfoodsafetycollaborative.org) -- discussion the CFP & NACCHO research grant that has been awarded related to research incorporating what is being done in this Committee work (2 parts)

- Brenda and David want to thank everyone (including Ben & Eric) for being on this call.

- Regarding this Collaborative – long term objectives and priorities for the collaborative (multiple partners). There are ways to create grant funding.

  - If you don't know about the Collaborative already, there are many resources from Cycle 1, etc. FDA/CDC/etc that is maintained by NEHA) in the website.
  - Love the opportunity to market the Collaborative and what it's doing
  - The FDA funding has provided much needed support to complete Objectives
- There are two grant cycles for funding.
- Year 1 of Grant Cycle 2 = started August 1st – Year 1 is guaranteed funding for research funding strategy.
  - Works supporting Specific Aim #5 – 4 Objectives
    - Brenda & David working on this work
    - Angie Wheeler & Dr. McSwaine work together in a research team
- Provide assistance for grant funding and ability to leverage resources beyond CFP (like from NACCHO) to support charges of committees – including this one!
- As we are forming issues, if we want to continue this committee, what additional continuation would we have? What would we add to these charges?

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets



The following activities will be conducted by CFP and NACCHO in Year 1 to support the Digital Food Safety System Committee in the completion of its charges:

- Schedule and facilitate project coordination and planning meetings with the Co-Chairs of the Digital Food Safety System Committee
- Attend and participate in recurring meetings of the Digital Food Safety System Committee to identify CFP and NACCHO project team member resources needed by the committee to complete its current charges in advance of the 2023 CFP Biennial Meeting.
- Assist the Digital Food Safety System Committee with development of the guidance document to be submitted in draft proposed form as part of the CFP Issue submission process for the 2023 CFP Biennial Meeting.
- Assist the Digital FSMS Committee with drafting preliminary Issue submission forms with content and supporting documentation for the CFP 2023 Biennial Meeting.

-
    - The first bullet is already being worked on
    - The second bullet is happening today.
- There are changes that might happen to this guidance document but timeframe that occurs after the Biannual meeting to get ready for publication/posting, that's what we've asked NACCHO help us with to help achieve final publication standpoint.
- Brenda:
    - David and her are not part of the committee; they are here to help support the committee as it runs parallel to our committee. Don't want to be disruptive to our committee work – want to be supportive and assist as much as we'd like in being prepared for the biannual in 2023.
- Eric – Due to this condensed timeline, your support will be invaluable. Supportive of all the cooks in the kitchen.

Get on track for where things are going with the workstreams. Get on the subcommittee documents and provide documents.

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

Meeting Number: 7
DATE: October 07, 2022 **TEAMS and phone in options in calendar invite**
TIME: 4 PM ET
Co-Chairs: Eric Moore and Ben Chapman
FDA Advisors: Robert Sudler & Justin Asberry
USDA Advisor: Beth Wittry
CDC Advisor: Adam Kramer
Scribe: Lily Yang

Agenda

Agenda:

16. Welcome, Call to Order
17. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement
18. Past meeting minutes review
19. CFP Reporting Deadline Review
20. Sub-Committee Progress Report Out: a. Digital Food Safety Management System i. Q&A b. Digital Temperature Monitoring Systems i. Q& A
21. General Q&A
22. Wrap-up

XLIX. Welcome, Roll Call

- Do not have Voting Member Quorum
- Status update

L. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement

- http://www.foodprotect.org/administration/policies/antitrust-policy/

LI. Past Meeting Minutes Review

- Reviewed. Need to change a date

LII. CFP Reporting Deadline Review

- Moving things forward on the Best Practices Update
- Committee Update for Timeline (Now and when Report is Due on November 18)
- Engagement from the Entire Committee

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

LIII. Subcommittee Progress Report Out

- Current Version of Combined Best Practices Document Link: https://docs.google.com/document/d/1ICYp069DJSqQOJKezzlbjfp2gmBj7zDLLpiu8Qc00wM/edit
- Opening up **TWO WEEK REVIEW TIME (October 21st) FOR ADDITIONAL COMMENTS/SUGGESTIONS/EDITS** to Best Practices Document Draft (above)
    - Document is ~8 pages of content – digital food safety systems & digital monitoring equipment
    - Identifying best practices per charge
    - Ben and Eric feel that this is practical; however, utilize next two weeks for feedback and discussion on holes/gaps in document that need to be included (or cut)
- After October 21st, David Lawrence and Brenda will work as part of the Retail Food Safety Collaborative to support with writing
- **By October 31st, want it to be ready for voting by the entire committee.**
- **Proposition for vote on November 2nd (as next planned meeting)**

- Review by David Lawrence – to review content as the whole committee has done and to provide editorial revisions – no intent to change content/information included

- Ben: Is two weeks enough time to review and provide additional feedback?
    - Jenn Nord – two weeks is perfect. Anymore time, it'll slip away from people
- David Lawrence – End of Business (Oct 21) is end of the review/comment period. Afterwards, is that when things will be cleaned up and ready for vote?
- Lily:
    - Shout-out to DFSM Sub-committee, you know who you are
    - If you, as a reader, are confused by any of the "techy" terms, please let us know. Part of the document is supposed to allow for tech people to ultimately understand the food safety of things. If things aren't understandable (especially as it comes to the food safety management system aspect), please comment and we'll address
- Julian:
    - Shout-out to Temperature Sub-Committee, you know you are
    - The section on "Guidance to Inspector" – decided that this part shouldn't be in this document and/or that it is necessary to complete this document.
        - Bringing up to the group at large to have this discussion.
- Ben: next agenda item was to tackle the "Do we need guidance for inspector"? – is this what we should talk about now or discuss in G-Document?
    - This document is an adaptation of existing FDA document on Digital Systems (aimed at processors – and in that document, there was a section on what inspector should know).
    - Need consensus on this

  - David Lawrence (CFRP): I am aware that the Program Standards Committee is looking at adding a food safety management system perspective to the plan review process conducted by regulators
    - Has been brought to the Program Standards Committee and sees that there is in-tandem as collaborative focus
- Any specific thoughts for the regulators? >> No response
- Does anyone feel strongly that it should (or shouldn't) be included in best practices document?
  - Julian: Subcommittee looked at hardware components of the digital food safety management system, and decided that it would be very hard to evaluate a data logger that didn't have a screen (and the efficacy of it working) other than "looking" at it. The hardware components that make up the food system are so different
    - Also included OEM as a means of capturing that data? Because some municipalities would find it different or difficult.
      If we do it, would be hard.
  - David: I'm thinking for the regulatory assessment of digital systems that might be used for specialized food processes like ROP
- Ben/Eric – Feel we are in a good spot to meet our charge and meet the charge on-time.

LIV. General Q&A

- Question from David Lawrence (CFP) on chat:

[16:09] David Lawrence, CFP (Guest)

- Ben & Eric, I would like to have the CFP Collaborative grant team take a look at this for feedback and comment if that is okay with the committee.
- Courtney Halbrook – did you propose of where the document will be posted?
  - Will be part of the November 2nd meeting
- David Lawrence: Are we trying to ensure that tech people can understand food safety?
  - Lily: Yes, because ultimately those will be the people to "put those things into place" and still have the food safety people (validation, verification, etc.) understand as a mainstay.
  - Ben: Yes, we are trying to bridge the gap of the people who are managing the DFSMS & those that'll be doing the IT behind that. That pathway between those two – so it's not just about, "this is what's important from food safety" but also incorporating the knowledge for the people who will be incorporating the systems from behind-the-scenes.
  - David – Definitely want to know that there is someone in the background who is managing the system/IT. Don't have to go looking for it.
- Courtney Halbrook - how do you want to collect that feedback in the document?
  - Ben: Yes. Everything that goes into the document, at this time, will be "comments and suggestions" – however you feel comfortable.
- Eric – if any individual will suggest a deletion or removal of sentences/sections; instead of just suggesting "Delete", please provide some comments/perspectives as to "why you don't feel this is appropriate and/or could be placed somewhere else"

- Chirag – The document is very comprehensive. Do you want everyone to do grammatical suggestions?
- Very close to being done! Just a little bit more work and we'll seal the deal – there have been no big Kerfuffle!!!

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

Meeting Number: 8
DATE: November 2, 2022 **TEAMS and phone in options in calendar invite**
TIME: 2 PM ET
Co-Chairs: Eric Moore and Ben Chapman
FDA Advisors: Robert Sudler
USDA Advisor: N/A
CDC Advisor: Adam Kramer
Scribe: Eric Moore

Agenda

Agenda:

23. Welcome, Call to Order
24. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement
25. Past meeting minutes review
26. Review & Discuss Outstanding Document Questions
27. Issues Overview: a. Issues to submit i. Final report, supporting docs and member recognition ii. Approval and posting of draft guidance on CFP website iii. TBD – committee reformation as a sub-committee of the larger FSMS standing committee b. Proposed Issue(s) i. Combine DFSMS Committee with FSMS Committee ii. Create new FSMS Standing Committee
28. Next Steps: a. Volunteers for writing Issues b. E-vote on final document c. Create Final Report
29. Key Dates: a. 11/18/22 – Draft Final reports due to Council Chair b. 12/2/22 – Revised Final Reports due to Council Chairs c. 12/19/22 – 01/22/23 Issue Submission

LV. Welcome, Roll Call

- Do not have Voting Member Quorum

LVI. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement

- http://www.foodprotect.org/administration/policies/antitrust-policy/

LVII. Past Meeting Minutes Review

- Reviewed, no changes

Review & Discuss Outstanding Document Questions

- Process started to review the editorial revisions completed by Committee Chairs (Eric & Ben), each paragraph was provided to members to view on screen for comment.

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

- Introduction & Scope comment(S):
    - Robert Sudler - Hyper link to FDA Retail Risk Factor Study Homepage provided in chat
    - David Lawrence – Does the most recent risk factor study highlight Digital FSMS?
        - Robert Sudler – It does not mention Digital no edits required
    - Adam Kramer – Would the Annex 4 number change with a new version of the food code?
        - Robert Sudler – Annex number would not change with a new food code version of the food code
- Definitions Comment(s):
    - David Lawrence – It's likely that FDA will release 2022 FDA Food Code by years end and suggested removing 2017 Food Code reference in DFSMS definition and replacing with "most recent version of the FDA Model Food Code"
- Best Practices Comments(s)
    - Eric raised question around the need for the mention of ieee & siia in the DTME paragraph.
        - Suggested change provided by Brenda Bacon. to remove the term back-end to eliminate confusion
- Handheld Devices Intended for Direct Food Contact Comment(s):
    - Eric updated the food code reference to include "most recent version of the FDA Model Food Code"
    - Robert Sudler – If this section is intended to focus only on food thermometers the specific section of the code should be reference
        - Ben & Eric – Intent of the section is to focus on more than just food thermometers, pH meters and humidity for example.
        - Robert – It is ok as stated if intended to be inclusive of other devices
- Integrated Temperature Measuring Devices Comments(s):
    - There was much discussion on the intent of this paragraph and the inclusion of OEM devices, the need for redundant thermometers in the food code
        - Robert Sudler & Adam Kramer – No specific requirements in the food code for 2nd thermometers
        - Katie Matulis - A secondary thermometer is not required with an OEM thermometer, but an OEM thermometer/digital readout is still required with a DFSMS (sensors, etc.).
    - Ben and Eric plan to make revisions based on the discussion and bring back to whole committee for further discussion.
    - **This is where discussion stop due to time**
        - **Follow Meeting to be scheduled to occur as soon as possible to review additional changes and the remaining sections of the document.**

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

LVIII. Issues Overview:

1. Issues to submit
    I. Final report, supporting docs and member recognition
    II. Approval and posting of draft guidance on CFP website
    III. TBD – committee reformation as a sub-committee of the larger FSMS standing committee
2. Proposed Issue(s)
    I. Combine DFSMS Committee with FSMS Committee
    II. Create new FSMS Standing Committee

LIX. Next Steps:

I. Volunteers for writing Issues
II. E-vote on final document
III. Create Final Report General Q&A

Key Dates:

a. 11/18/22 – Draft Final reports due to Council Chair
b. 12/2/22 – Revised Final Reports due to Council Chairs
c. 12/19/22 – 01/22/23 Issue Submission

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

Meeting Number: 9
DATE: November 07, 2022 **TEAMS and phone in options in calendar invite**
TIME: 3 PM ET
Co-Chairs: Eric Moore and Ben Chapman
FDA Advisors: Robert Sudler & Justin Asberry
USDA Advisor: Beth Wittry
CDC Advisor: Adam Kramer
Scribe: Lily Yang

Agenda

This meeting is being scheduled to pick-up where Call 7 (11/2/22) left off:

- Revised document will be sent out before end of day tomorrow for full committee review and comment on Monday
- We realize that this date/time may be a challenge but please do your best to attend if your schedule permits

Agenda:

1. Welcome, Call to Order
2. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement
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4. Review & Discuss Outstanding Document Questions
5. Issues Overview: a. Issues to submit i. Final report, supporting docs and member recognition ii. Approval and posting of draft guidance on CFP website iii. TBD – committee reformation as a sub-committee of the larger FSMS standing committee b. Proposed Issue(s) i. Combine DFSMS Committee with FSMS Committee ii. Create new FSMS Standing Committee
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2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

LX. Welcome, Roll Call

- Do not have Quorum – only 8 voting members (Quorum is for 11 voting members)
- Will be conducting voting member polls to move the document into its finished stage for "time being"

LXI. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement

- Operating under CFP Anti-Trust Rules
- http://www.foodprotect.org/administration/policies/antitrust-policy/

LXII. Past Meeting Minutes Review

- Finished to General Usage Section

LXIII. Review of Document

- Changing "system faults (bugs)" to "system malfunctions"
- Include Food Code #s – there may be changes in the future; unlikely that these will be changed. But doc should be reviewed every 4 years (Robert Sudler) – then these numbers will need to be updated; and any cross-references that mention the Code, if they change, also will be noted. Not something tht needs to be updated or worried about now; but definitely long-term, needs to be kept on the radar to review (don't wait 10 years). Need to include that these documents will be updated and reviewed periodically
- Data Storage – that system has some type of programming that is not acceptable despite what it is that it doesn't overwrite what was originally recorded (need to make sure)
- Finished review of document
- Review last week's edits from inputs:
    - Edited "Inputs – Digitl Food Safety Management System Equipment"

LXIV. Issues Overview

- Straw Poll of voting members? Will they accept as it is right now? – 8 of 8 YES (in agreement)
    - Non-voting members – are you also comfortable with the document? YES – 6 of 7 non-voting are in agreement
    - Total: 15 members

LXV. Issues to Submit

LXVI. Proposed Issues

- Request that *this* specific committee be reformed to further explore and work on identifying research information (work with Collaborative) to do a funded research study for the next biannual.
- In parallel, Ben & Eric – along with food safety Council 2 chair/vice-chair & David Lawrence & David McSwane have discussed the possibility of Food Safety Management Committee transitioning to a standing committee to identify specific charges to discuss formation of Standing Committee to begin during the next biennium.
    - Standing FSM Committee
    - Sub-committee standing - for digital food safety

    - To ensure alignment in wording and approaches moving forward
- Does anyone see any issues with this committee falling under a Food Safety Management Systems Committee (not yet proposed) – currently no one on the team feels negatively about this

LXVII. Next Steps:

- Co-Chairs to make minor document changes determined during today's meeting
    - Revisions completed 11/8/22
- Draft Final reports due to Council Chair
    - To be sent to Council Chair tomorrow 11/9/22
- Voting Member e-vote on Final Report
    - TBD based on Council Chair feedback
- Final Reports due to Council Chairs (12/2/22)
- Biennial Issue Submission (12/19/22 – 01/22/23)

Digital Food Safety System Committee Definitions

Digital Food Safety Management System (DFSMS): An interactive, digital, or electronic archive intended to collect, store, and analyze data that supports a food safety management system. A DFSMS is intended to enable a proactive approach to support the consistent safe production, transport, preparation, storage, and service of safe wholesome food as defined in the FDA model food code. A DFSMS employs active user-based work-flows that support decision making that can be reviewed and acted upon, and may be housed locally (on-premise) or be accessed remotely.

DFSMS should include but not limited to functionality that allows a user to:

- capture, record, and store multiple types of data
- provide real-time feedback to users
- generate record keeping reports, for example trends over time

Other components, tools, and records within a DFSMS may include:

- specific policies, procedures, recipe cards, and critical limit monitoring actions and corrective actions including training tools
- risk control plans
- product storage/movement information and inventory supporting recalls and market withdrawals
- equipment maintenance documentation
- active alerting
- networked and/or IOT devices

Digital temperature monitoring equipment: Automated temperature measuring device(s) that should include electronic sensors capable of generating and capturing temperature data for analytical use. This equipment may include the functionality of automatically measuring, monitoring, storing, transmitting, documenting, and sharing the temperature of food, air, or water. Monitoring equipment that captures and stores temperature data over a period of time may connect to a system that may be capable of delivering alerts and exception reports.

Computerized Systems in Food Processing Industry

Pavan Sandeep Kuli

Content sourced as of 17/03/2026

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INTRODUCTION

One of the computerized systems within the food processing industry regulated by the Food and Drug Administration (FDA) continues to increase. The use of computerized control system technology is expected to continue to grow in the food industry as the cost of components decrease, as companies are continually improved to withstand the rigors of the food processing environment, and as computerized systems are used to replace facilities equipment and manufacturing processes in an attempt to produce high quality, high value products. Now process design will strive to achieve safe quality products, while at the same time minimizing production costs. The use of computerized control systems in the production of food products will be vital to fulfilling these goals.

As computer systems become instrumental in providing for the safety of FDA regulated products, the FDA will need to develop expertise to evaluate computerized systems, to examine, comment and validate records on computerized systems, and to conduct on-site storage inspections.

The purpose of this course is to examine the FDA investigation into conducted inspection of regulated food firms that use computers and computer software to control manufacturing processes. Chapter 1 will review the FDA regulations. Chapter 2 will look into reviews by the Office of Regulation Affairs (ORA), Division of Emergency and Investigational Operations (DEIO) and the Center for Food Safety and Applied Nutrition (CFSAN) of computerized systems in food processing establishments. Chapter 3 will examine the criteria for good processing manufacturing quality and conformance, plus communication your written comments or suggestions to DHEO, ORC (or send an e-mail to Internal Bureau address to). DEIO/ORA/FDA/5600 Fishers Lane/HFC-132

CHAPTER 1: REGULATIONS OF COMPUTERIZED SYSTEMS

A. FOOD, DRUG AND COSMETIC ACT

FDA's authority to regulate the use of computers in food plants is derived from the Food Drug and Cosmetic Act (FD&C Act). Section 402 (a) (3) of the Act states: "A food shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have become injurious to health." Section 402 (a) (4) states: "A food shall be deemed to be adulterated if the methods, facilities, or controls used for its manufacture, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such food is not unsafe or lacks sufficient quality and is not properly labeled under section 403 (a) (1) and food shall be deemed to be adulterated if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have become injurious to health." Section 701 (a) authorizes the issuance of regulations for the efficient enforcement of the Act. Section 520 (f) (1) (B) authorizes the issuance of regulations for the control of methods used in, and the facilities and controls used for, the manufacture, processing, and packing of human food.

Before discussing the use of computerized systems under the FD&C Act, it is useful to review the related sections of the Act.

Section 201 (g) (1) defines the term drug to include articles "(B) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, in man or other animals; and (C) intended to affect the structure or any function of the body of man or other animals."

Section 201 (h) defines the term device to include articles "(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

Section 201 (s) defines the term "new drug" as any drug "the drugs, constituents, and conditions of use prescribed, recommended, or suggested in the labeling thereof, as are not held, by such experts, to be established safe, or any other contaminants."

Section 201 (ff) defines the term "**Subpart F Supplement, sun-gel** which is "any food which contributes consumption from any source." It continues to **sub-Pa (3) (A) (i)** to "any food manufacturing ... shall be conducted under such conditions and controls as are necessary to minimize the potential for growth of microorganisms, or for the contamination of food."

Implied and explicit references for the need to have computerized controls for accurate and reliable may be found in other Sections of the FD&C Act. For example, see the function of the computerized system in the food process.

PART 113 SUBPART A: THERMALLY PROCESSED FOOD AS ASSORTED LOW-ACID CANNED FOODS

FDA's General Food Safety and Regulation Division (GFSRD) has determined that the use of computerized systems to control processing operations is necessary to assure the safe production of low-acid canned foods. **Low-acid canned foods (LACF) are foods packaged in hermetically sealed containers, such as CYN Part 113, Thermally Processed Low-Acid Canned Foods in Hermetically Sealed Containers** except for: sealed, aseptic processing systems, and containers that are processed before they are sealed.

Computer equipment makes this task to control computer systems to help control food record keeping functions and to perform real time process deviation corrections, have been used in the food processing industry for many years. Examples of these uses have been:

- a. to aid in FDA by the systems vendor or user to explain the operation of the computer system,
- b. to aid by FDA in the vendor to examine the hardware and software development, validation and documentation procedures, and
- c. to aid by FDA in production to evaluate the computerized record maintenance and change control procedures.

To ensure vendors who submitted their computer systems to FDA for review and were found to be satisfactory, received a letter stating that FDA found the computerized system, as evaluated, to meet the intent of the regulations. Use of this voluntary submission of computerized systems to FDA for evaluation subjected the vendor to FDA's policy and procedures for the review of these systems. Upon receipt of a vendor's system, a requirement that FDA investigators would be provided on site access to the vendor's computer equipment software operating instructions, and a requirement that the vendor would maintain confidentiality of any trade secrets revealed by FDA's computer software and equipment.

Food manufacturers that used CYN Part 113LF computer controlled recording and real time process deviation corrections, have been used in the food industry for many years. The use of computerized systems to control processing operations is necessary to assure the safe production of low-acid canned foods. Low-acid canned foods (LACF) are foods packaged in hermetically sealed containers, such as cans, flexible pouches, and aseptic processing systems, except for: containers that are processed before they are sealed.

The function of the system as it operates can be used to determine if critical factors such as retortchon per minute (rpm), vent time, initial temperature, process, thermal process deviations, and documentation are being controlled by the computerized system. Operation of the FDA's computer equipment software operating instructions, and a requirement that the vendor would maintain confidentiality of any trade secrets revealed by FDA's computer software and equipment. As food product deviations will not have to be reported to FDA, as long as the computer system is functioning properly and properly documented, it will not record the systems functions. This is the automatic food or food process of performance. The only way to develop confidence that the computer system is going to perform correctly is to have a validation program as part of the design, check, or test. The validation program should encompass the entire computer system, including:

The investigator must keep in mind the limitations of specific regulations regarding the use of computers in food processing plants. Most of the current FDA food regulations in the FD&C Act of specific authority to examine computer software and computer hardware records. Section 704 authorizes FDA to conduct factory inspections to determine if a food manufacturer or the activities of a manufacturing process, the manufacturer is operating in establishing that the computerized system functions as it was intended to function. The investigator is not authorized to examine computer software. The investigator is entitled to be provided with the computer software that was intended to be used by the computer system as designed. It is important to remember that computerized systems are used to control the food manufacturing process, quality and consumer controls.

The investigator should evaluate the operations of computerized systems during the inspection to determine if the use of the computer software may lead to adulteration of the finished food product. Many companies used in the food industry may not have the in-house capability to write computer software programs. For example, if there was a misunderstanding on a bill of lading between a purchaser and a seller, the criticality of the inspectional control function may be a matter of reading in a batch of ingredients. Another example of a critical control function would be the temperature maintenance of a lot of process. A review of the computerized formulas provides consistent and reliable performance. HACCP (Hazard Analysis Critical Control Point) computer software programs are used to control critical control points in food processes. Documentation steps established by a computerized system.

This is an important to find out if the operator or management can override any of the computer control functions. If operators/management can override control functions, what are possible details on how this is done, what overrides are possible, and how overrides appear in the processing record should be determined.

The investigator should find out how the system handles deviations from an or expected operations. Does the computer automatically shut down the process, automatically generate parameters, calculate new manufacturing instructions or choose alternate programmed procedures the investigator must determine the parameters for computing or selecting the alternate procedures.

During inspection of food firms using computerized systems to control and monitor critical control points, investigators should review the computer software and hardware documentation to record other factors related to the food process. Examples of these factors are:

- a. The equipment specifications for software and hardware.
- b. The critical factors controlled by the system.
- c. Does the critical factors are controlled?
- d. How does the firm ensure that the microprocessor or computer is indicating the correct information (validation)?
- e. How and how often is the equipment calibrated and/or checked for accuracy?

Investigators should review the computer software documentation to determine responses to the authorization of a food product will take, and whether it fits in the documentation. Development of evidence of food adulteration caused by the operations of a computerized system is also discussed in Chapter 4 of the Compliance Program Guidance Manual.

During the inspection of food processing facilities the responsibility of the food manufacturer to establish that the computerized system functions as it was intended and the critical audit aspects of food manufacturing should be discussed with the facilities management. The FDA investigator should make the firm's management aware that a computerized system is subject to FDA inspection and that the firm must have the procedures required to operate the system. Management of the firm should be made aware that the computerized systems should be validated to place under actual operating conditions by the firm **Close Surface on Computerized System Validation.**

The applicable sections of the listed references should be used, in addition to this guide when inspecting firms using complex computerized systems.

CHAPTER 2: COMPUTER SYSTEM TECHNOLOGY

A. TECHNOLOGY OVERVIEW

In recent years digital electronic controllers have replaced the relays and analog switches that were used to control processing operations. Digital controllers are electronic devices that receive data input from the single loop controller to complex high-end computer systems.

If the function is for controlled consists of numerous sequential (logical) steps, the controlling device can be a fixed-level computer that is often called a logic controller. The logic controller may be set up as a single loop controller.

A single loop controller could be responsible for controlling one function, such as temperature, pressure, or flow. Single loop controllers could be programmable, and could be built-in temperature within set temperature parameters. The loop would consist of the temperature controller, a temperature sensor, a power source for the steam valve that controls the steam flow.

Digital single loop controllers contain Read Only Memory (ROM) which is manufactured into the controller or programmed into the controller by the manufacturer. Random Access Memory (RAM), Erasable Programmable Read Only Memory (EPROM) or Electronically Erasable Programmable Read Only Memory (EEPROM).

PROMs is field programmable by the manufacturer or customer once only by burning out the internal fuses. EPROMs and EEPROMs are erased by exposing the chip to ultraviolet light. EEPROMs are erased by electrical means. EEPROMs are programmed by exposing the chip to ultraviolet light sources that erase the original chip configuration. EEPROM memory is programmed by applying a voltage to the chip. Programmable logic chips (PLC) chip. RAM is normally used to control functions, the values of the parameters of an operator do not need to be changed. Random Access Memory (RAM) using battery backed memory to maintain the values of the parameters during power outages. This requires a power supply for both RAM and its replacement.

Superimposing, Advanced microprocessor or computer systems would normally use a combination of ROM and RAM to program control processing functions.

A more advanced system would use a programmable logic controller (PLC) which could allow the operator or firm to alter the control functions to meet the particular **close Approach** The type of controller would use algorithms in programmed procedures for solving a control problem. Algorithms are a set of logical steps that are performed in order to solve a logical sequence of events for solving a problem **Appendix 3A**

Control of multiple parameters such as temperature, pressure, pumping rate, rotation, etc. would require the application of several logic controllers connected to a PLC or microprocessor or computer.

Companies are different from hardwired controls to three major categories. To provide for adequate control of critical control points in food processing and/or documentation. The design of the computerized controls must address these three major areas:

- a. Proper, conventional hardwired systems, which provide for full-time monitoring of critical functions, the computer performs its task sequentially, and the computer monitors the critical functions on a time-shared basis. Should the system fail, it can malfunction(s) or become long before the computer to carry out these through its task), the critical sensor is not monitored. Normally this is not a problem, because the computer scans the critical sensors at a rate that is sufficient for the control. The problem occurs when the processing computer is directed from its task by another computer, or the computer software program is changed, or a defect occurs in the software. Should this occur, the food processing control computer may stray from its control or monitoring functions.
- b. In a computerized system the control logic may be easily changed if the computer software can be easily changed. Some security measures are needed to limit that the changes.
- c. Some computer experts have stated unequivocally that in computer software can be written error-free. While this may be true for very large software routines with thousands of lines of code, most of the software routines used for control and monitoring functions are relatively short and relatively simple. Because of this, these routines become critical to food safety and should be kept error-free.

B. COMPUTERIZED SYSTEM HARDWARE

Input Devices. Equipment that translates external information into electrical pulses that the computer can understand. Examples are thermocouples, RTDs (thermistor resistance temperature devices), pressure, flow, and conductivity transmitters, pH probes, and switches, such as limit switches, flow rate/y touch screens and operator keyboards.

Examples of hardware are:

- a. Thermocouple/RTD provides temperature input for operation of a retort.
- b. Pressure transmitter provides pressure input for operation of a retort.
- c. Operator keyboard used to input batch, menu number and other processing information.

Output Devices. Equipment that receives electrical pulses from the computer and either causes an action to occur, generally by controlling the manufacturing process functions, or displays data. Examples are chart recorders, valves, motors, printers, CRTs, video (CPU), printers, and alarms. Examples of hardware are:

- a. Solenoid activates the impeller of a mixer.
- b. Valve controls the amount of steam delivered to a thermal process.
- c. Printer records significant events during a sterilization process.
- d. Alarm (buzzer, bell, light, etc.) sounds when operator intervention is or lacking is/ds drops below the desired temperature.

Most output devices will be governed by a low food processing equipment under control, but not necessarily. Due to the CPU. Some output devices such as printers may be located remotely from the computer equipment.

Signal Conversion. Many input and output devices operate by transmitting or receiving electrical signals that are in analog form. These analog signals must be converted to digital form (A/D) before the computer can use them. Similarly, digital signals must be converted into analog signals for use by analog devices (D/A). Examples of hardware are:

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**Computer Hardware

connection between complex computer systems that are geographically distant or they may consist of computer systems which are even several KILOMETRES apart.

If the firm is on a computer network it is important to know:

1. What types, such as batch production records, is sent to other parts of the network;
2. what kinds of input (instructions, software programs) are received;
3. the identity and location of establishments that interact with the firm;
4. the extent and nature of monitoring and controlling activities exercised by remote on-line computer systems;
5. what security measures are used to prevent unauthorized entry into the network and possible unsuccessful/real process alteration, or obliteration of local process controls and records.

Peripheral Devices: All computer associated devices external to the CPU (or the mainframe computer) are referred to as peripherals. Some peripherals are used for input devices. Input peripherals include devices which can be located at the site of operation such as CCD device. These include CRTs, printers, keyboards, disk, modems and tape drives.

C. ENVIRONMENTAL CONTROLS

Location: Potential problems have been identified with location of CPUs signal transmission lines and peripheral devices. Those include:

Humble Environment: Recommended extremes of temperature, humidity, static, dust, and electrical noise should be specified by the computer system manufacturer. Where such conditions may be common in certain computer and the investigator should be alert to locating sensitive hardware in such areas. Environmental safeguards may be necessary to ensure proper operation.

Electromagnetic Interference (EMI): Low voltage electrical lines from input devices to the CPU can be susceptible to electrical noise (EMI). EMI can cause data transmission distorted input data to the computer. Therefore, peripheral devices should be made immune to electromagnetic interference (EMI) such as electrical power lines, motors, radio and TV transmitters, and other devices that may cause EMI in the surrounding area. Peripheral devices and signal transmission lines should be located at least 30 meters (100 feet) away from sources of EMI. Shielding of signal transmission lines, grounding, and filtering of power lines to the computer and installation or housing are acceptable methods to prevent EMI.

Distance Between CPU and Peripheral Devices: Devices proximity to the CPU/computer may be important concerning loss of signal due to electrical resistance of the signal transmission lines. To correct this problem the device may be located near the CPU or signal boosters may be installed. Signal boosters are installed whenever G.A. 1 000 ft/305 m can be used.

Proximity of Input Devices to Food Processing.

Input devices such as employee timeclocks should be located as close as possible to the operation being controlled.

D. MAINTENANCE/CALIBRATION

Computer systems normally require a minimum of complex maintenance. Electronic components rarely fail. Mechanical devices, such as printers, are subject to frequent failure. Frequently software is available which enables them the routine to check computer performance and isolate defective integrated circuits. Maintenance procedures should be included in the firm's standard operating procedures. The availability of spare parts and access to qualified service personnel are important to the operation of the maintenance program.

The firm should use replacement parts which meet specifications of the original equipment system design or the system should be revalidated to document that the replacement parts perform as per the original specifications of the computer system.

Sensors such as part of the computerized system, monitoring or controlling process operations, should be calibrated routinely. Frequency of calibration will depend on the sensor's sensitivity to potential operations that the sensor is designed to detect. Records of calibration should be maintained.

Terms:

Input: Input refers to any entries or input or other certain input or output information that is received by the computer for processing. Input may be in human readable or machine readable forms. This is an old staff in use in the area of producing process. In the example, if a certain piece of input data does not consist of a four character number, software edits can be used to test common errors or omissions in input data. Input may be entered manually or scanned from a coded item in the facility. Security should also be used to limit access to certain users, such as input data. Determine if accountability is maintained for those devices and access is being limited.

An important part of software security is change control. The firm should have in place a system for controlling changes to software programs. Changes may be made to correct errors in a software system, how it was executed, or to accommodate the customer. All changes to software are other portions of the software program, were the changes validated (tested) to ensure that they were correct and that they did not cause other problems? Have the changes been documented? Software has been available that will maintain a detailed maintenance procedure to followed (See Computerized System Validation).

E. PERSONNEL QUALIFICATIONS

Personnel operating, maintaining and programming computerized control systems should have adequate training and experience for performance of their assigned duties. Determine the extent of operator, system managers, and computer system technical personnel training. Training should be documented. Training should be conducted by trained personnel. Training should include on-site training, specialized training, seminars, system changes, security procedures, and software changes. Training should be documented. Personnel working with computerized system processes should be documented by the manufacturer/user.

The investigator should determine the key computerized systems personnel during the inspection. This may include not only the firm's employees but also contractors or consultants. For each of the key employees, determine to the extent possible, that adequate training and experience has been documented. Ascertain that adequate written procedural are available or can be reached during computerized system failures.

G. PROCESS DOCUMENTATION

Most computerized systems are capable of generating accurate and detailed documentation of the food process under computer control. What is important is that the firm has documentation sufficient to assure that the computer is controlling the food process. For example, if production records are generated by computer, determine if they contain all of the information required to be in such records.

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BD. PURPOSEFUL QUALIFICATIONS

Personnel operating, maint

Central Processing Unit

Distribution system

Peripheral devices

Alarms:

Types (visual, audible etc)

Functions

Records

Software:

Documentation:

Manuals

Operating procedures

Personnel:

Type

Training

4.) For computer hardware determine the manufacturer, make and model number.

5.) Obtain or make a simplified drawing of the computerized system control loop including:

Sensors

CPU

Signal converters

Actuators

Peripheral devices

6.) Software:

a. For all critical software determine:

Name

Function

Inputs

Outputs

Set-points

Edits

Input Manipulation of Data

Program Over-rides

b. Who developed software.

c. Software security to prevent unauthorized changes.

d. Firms checks on computerized systems inputs/outputs.

7.) Observe the system as it operates to determine if:

Critical processing limits are met

Records are accurate

Sensor input is accurate

Time keeping is accurate

Personnel are trained in systems operations and functions

8.) Determine if the operator or management can override computerfunctions. Explain.

9.) Explain how the system handles deviations from set or expected results.

10.) Determine the validation steps used to insure that the computerized system is functioning as designed.

a. Was the computerized system validated upon installation?

Under worst case conditions?

Minimum of 3 test runs?

b. Are there procedures for routine maintenance and revalidation?

Does the equipment in-place meet the original specifications?

c. Is validation of the computerized system documented?

d. How often is system:

maintenance performed

revalidated

calibrated

11.) Are system components located in a hostile environment which may effect their operation?

12.) Determine if the computerized system can be operated manually. Explain.

13.) Automated CIP (cleaning in place).

How does firm ensure that cleaning is adequate.

Documentation of CIP steps.

14.) Shutdown Procedures

Does firm use battery backup system?

Is computer program retained in control system?

What is firms procedure in event power is lost to computer control system?

15.) Does the firm have a documented system for making changes to the computerized system which explains:

The reason for the change

The date of the change

The changes made to the system

Who made the changes

16.) Document computer functions which are causing or may cause food products to be adulterated or misbranded.

APPENDIX 2 DIAGRAM OF LOGIC CIRCUIT

APPENDIX 3 DIAGRAM OF ALGORITHM

REPRESENTATIVE DIAGRAM OF A PORTION OF AN ALGORITHM FOR A WATER IMMERSION RETORT WHICH CONTROLS THE PROCESS TIME AND TEMPERATURE

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Combined DFSSC Sub Committee DFSMS Best Practice Guidelines

General Best Practice Guidance for
Food Establishments and Regulatory Authorities
for
Digital Food Safety Management Systems

Prepared by the Digital Food Safety Management System Committee
2021 - 2023 Conference for Food Protection

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A. Introduction and Scope

The use of digital food safety management systems (DFSMS) within the retail food industry, regulated by the Food and Drug Administration (FDA), continues to gain widespread interest, acceptance and use. The use of DFSMS is expected to continue to grow in the retail food industry as technology improves and components become more readily available. As technology advances the retail food industry continues to replace paper-based records associated with traditional food safety management systems with digital documentation. Recent FDA Risk Factor study results have shown that utilizing a robust management system leads to a reduction in food safety risk factors.

An oft-used component of a DFSMS, Digital Temperature Monitoring Equipment (DTME) can improve awareness, response and documentation of temperature conditions. This technology allows more accurate, reliable and efficient food and equipment temperature control impacting safety and quality improvements. As DFSMS and DTME become more common in the retail food industry, the visibility, awareness and availability of information that these systems and technology can provide should support improvements in controlling food safety risk factors in food retail.

This guidance will outline food safety management approaches specific to the implementation and use of technology in food retail. Best practices provided in this document serve as a foundational guide for the collection of accurate, consistent and reliable data that can be used to make risk-reduction decisions. This document has been written with the assumption that a food retail establishment has a food safety management system an that they have identified and addressed HACCP Principles 1, 2 and 3 as referenced in Annex 4 of the U.S. FDA Model Food Code (2017)

B. Definitions

Digital food safety management system (DFSMS)

An interactive, digital or electronic archive intended to collect, store, and analyze data that supports a food safety management system as defined in Annex 4 of the most recent version of the U.S. FDA Model Food Code . DFSMS specifically supports ongoing quality control and assurance, monitoring and recordkeeping of specific food safety goal-oriented plans, like Risk Control Plans (RCPs), that outline procedures for controlling foodborne illness risk factors. A DFSMS is intended to enable a proactive approach to support the consistent safe production, transport, preparation, storage, and service of safe wholesome food as defined in the most recent version of the FDA model Food Code. A DFSMS employs active user-based work-flows that support decision making, that can be reviewed and acted upon, and may be housed locally (on-premise) or be accessed remotely using off-site servers or cloud storage.

DFSMS may include but are not limited to functionality that allows a user to:

- capture, record, and store multiple types of data
- provide real-time feedback to users
- generate record keeping reports (i.e.trends over time)

Other components, tools, and records within a DFSMS may include:

- specific policies, procedures, recipe cards, and critical limit monitoring actions and corrective actions including training tools
- risk control plans
- product storage/movement information and inventory supporting recalls and market withdrawals
- equipment maintenance documentation
- active alerting
- networked and/or IOT devices

Digital Temperature Monitoring Equipment (DTME)

Automated purpose-built temperature measuring device(s) that often includes sensors capable of generating and capturing temperature data for analytical use. This equipment may include the

functionality of automatically measuring, monitoring, storing, transmitting, documenting, and sharing the temperature of food, air, or water. Monitoring equipment that captures and stores temperature data over a period of time may connect to a system that may be capable of delivering alerts and exception reports.

Software

Software is the term used to describe the total set of programs, procedures, rules, and any associated documentation pertaining to the operation of a technology based system that includes, but is not limited to: application, operating system, and utility applications used by the computerized system.

C. Prerequisites

Best practice for a DFSMS is to employ purpose-built hardware and software when designing and implementing an approach. The appropriateness of hardware and software should meet the goals of any RCP. Maintenance of the system and the proper replacement of system hardware is critical for it to function as designed. Design specifications of the hardware and software should be determined and periodically reviewed to ensure the system and its functional components do what is intended to support food safety.

This document recognizes the that DFSMS are built and utilized to support the current version of U.S. FDA Model Food Code, Annex 4, HACCP Principles
Specifically:
Principle #4: Establish Monitoring Procedures
Principle #5: Establish Corrective Actions - implementation of the corrective action specifically
Principle #6: Verification/Sharing for equivalency for regulatory checks
Principle #7: Record keeping procedures and documentation

Personnel operating, maintaining, and programming DFSMS should have adequate training to complete their assigned duties. Determine the extent of operator, system managers, and software system technical personnel training in the functions, requirements and operation of the computerized system.
Training may include but are not limited to:

- system operation
- malfunctions
- regulatory requirements
- system changes
- security procedures
- manual operation of the system
- documentation of system errors

D. DFSMS Inputs

Digital Food Safety Management System Equipment (DFSMSE)

DFSMS Equipment typically include various purpose-built and designed stationary and handheld measurement instruments, tools and sensors capable of the collection, storage, and transmission of data into software. The food contact surface of DFSMS Equipment must meet the design and placement characteristics in Chapter 4 of the most recent version of the U.S. FDA Model Food Code and must be designed to meet or exceed NSF Standard 2 - Food Equipment or equivalent. Examples may include but are not limited to: mobile device(s), sensors, thermometers, RFID/QR Code scanner/receiver, etc.

Stationary Monitoring Devices

Purpose build devices which are permanently or semi-permanently affixed, mounted, installed, attached to equipment or surface using food grade mounting/installing materials, maintained free of accumulated soil, and cleaned per manufacturer instructions. When devices do not include an external measurement display, access to the measurement data should be easily accessible and viewable. These devices when appropriate should meet the design and placement characteristics in Chapter 4 of the most recent version of the U.S. FDA Model Food Code and must be designed to meet or exceed NSF Standard 2 - Food Equipment or equivalent.

Note: DFSMS Stationary temperature monitoring devices must meet the requirements outlined in the most recent version of the U.S. FDA Model Food Code 4-204.112 Temperature Measuring Devices.

Device examples may include but are not limited to: equipment or wall mounted data loggers, humidity sensors, door open/close sensors, camera’s, etc.
Data access examples may include but are not limited to: Software report on mobile, desktop, tv monitor/screen, etc.

DFSMSE Accuracy

Handheld and stationary temperature measurement instruments must meet the most recent version of the U.S. FDA Model Food Code 4-203.11 & 4-203.12. In the event that a handheld or stationary temperature device does not have a display; the operator should be able to easily demonstrate/record the reading/actual monitored temperature (value) for review and record. Follow OEM recommendations & guidelines and follow their procedures.

DFSMSE Functionality

Regular and ongoing equipment and system operation functionality are recommended to be conducted (refer to manufacturer for frequency) to verify that a DFSMS, DFSMSE and DTME in

use is operating as intended, if/when issue(s) are identified appropriate action is taken to correct issue(s). Examples of device functionality issues are but are not limited to:

- Power loss
- Improper device installation
- Device damage/defective
- Software communication/connectivity
- Device communication/connectivity

It is recommended that records of software and equipment functionality verification be maintained and readily available. Examples of functionality verification may include but are limited to:

- Handheld measurement device accuracy & functionality
- Stationary measurement device accuracy & functionality
- Software and device connectivity/communication

E. Data and System Infrastructure

DFSMS data are the measurement values and user inputs captured by DFSMSE and DFSMS users that are then stored in DSFMS software. Data storage may be stored locally (on-site) or virtually (cloud storage) but access to this data must be readily available for use and display on-site. This makes it possible to retrace which value occurred at which time. The following are examples of, but not limited to, measurement values that may be recorded and stored as data in a DFSMS:

- Time points and Account IDs which are assigned to certain quality checks
- Description of the area
- Description of the equipment
- Description of the products/product categories
- Description of the measurement locations of the equipment
- Description of suppliers
- Check lists/Quality handbook
- Tasks (Daily, Shift, On-Demand)
- Reports (Daily, Shift, On-Demand)
- Product specific quality and safety measurement data points (Temperature, pH, TPM, PPM, humidity, time)
- Alerts (alerts are notifications to users)
- Alarms (is the result of an unacceptable software or hardware reading)
- Alert recipients
- Corrective actions associated with checklists and measurement points
- Manual data entry (for immutability and data integrity)

Combined DFSSC Sub Committee DFSMS Best Practice Guidelines

When DFSMSE or a DFSMS user completes a measurement value this value is stored in DFSMS software. Each measurement value represents a unique permanent data point represented in the DFSMS software, additional or new data (including that which is associated with an existing or old data point) are then stored in a sequential manner allowing for the original data point to remain. This can be described as a time-based progression of record keeping. The DFSMS software should also be capable of recording All previously recorded data should be readily accessible, and documented when changed and available for reporting.

Digital Temperature Monitoring Equipment (DTME) Data

There are three broad ways of capturing temperature and humidity data; they are commonly identified as held, stationary, or Integrated temperature measuring devices. An important consideration for DTME is that the devices often have the ability to cache/store data locally when connectivity is interrupted, if/when data connectivity is interrupted a DTME device should have the ability to push/send when connectivity is restored. The infrastructure shall refer to information technology industry cache/storage best practices at the time (such as ieee.org).

Verification / Immutability

A retail food business may have measures in place to ensure that data captured by the computerized system cannot be altered without a digital signature record or other means of tracking history of inputs. If provisions are made to allow correction of data entries, the entry may identify the person making the changes and the reason for the change and what previous data was.

Data and System Integrity and Access

Data Integrity and Access are both important aspects of a DFSM that should be considered to ensure that quality of the information collected by the system is accurate and reliable. To support the integrity of a DFSM it is recommended that controls are in place to ensure that stored and/or in process data is not able to be altered data in an unauthorized manner, and that any changes are captured. Data access is also a way to support effective data integrity. Access to a DFSMS should be controlled and limited only to those persons to whom permission is granted. All data and information should be protected through the use of encryption protocols. Examples of encryption could include, but are not limited to, utilizing passwords,user management and user rights. While examples of things needing encryption include but are not limited to:

- Passwords
- Proprietary business information
- Data transferred between the input devices and local/cloud-based reporting and storage programs/locations.
- Login occurrences
- Access to information within the DFSMS should also be tailored according to a user's role and responsibilities, writing or reading rights.

Manual Data Entry

Determine if and how manual interventions are documented; a separate log may be kept of such interventions. The computerized system may be such that it detects, reacts to, and automatically records manual interventions. It is important that system operators are trained in manual backup systems; as a best-practice this should be documented and conducted prior to DFSMS usage. To ensure business continuity, it is recommended that users have their own SOP for review (redundancy) to ensure practices are being enacted.

Manual Back-Up

A manual back-up system is frequently utilized as a function of business continuity in the event of a computerized system (e.g. hardware or software) failure. Functions controlled by computerized systems may sometimes also be controlled by parallel manual backup systems. As a best practice, functions that are manually controlled and/or manually backed up should be identified and noted re: the firm's protocols or the system's protocol. Critical process controls are particularly important. Determine the interaction of manual and computerized controls and the degree to which manual intervention can override or defeat the computerized function. The firm's operating instructions should describe what manual overrides are allowed, who may execute them, how and under what circumstances.

F. DFSMS Outputs

System Outputs and Notification(s)

Typical DFSMS and DTMS include the capability to include user level notification(s) tailored around programmable components of an organization's Standard Operating Procedures (SOP), see What Data is Stored section above for measurement examples that may be involved. Examples of user level system notification(s) may include but are not limited to the following:

- Reports
- Trends
- Automated emails
- SMS or text message
- Phone calls
- Visual indicators (lights)
- Audible indicators (sounds)

A best practice is to associate one or more corrective actions with an alert. To assure corrective actions are completed in a timely fashion, alerts can be escalated when corrective actions are not completed within a set timeframe.

G. Committee Members

Academia/Industry Members				**Regulatory Members**	
Ben	Chapman	Eric	Moore	Justin	Asberry
Vanessa	Coffman	David	Abney	Robert	Sudler
Julie	Abouchar	Amanda	Douglas	Beth	Wittry
Jamie	Estes	Julian	Graham	Adam	Kramer
Matthew	Jenkins	Michael	Roberson	Matthew	Brandt
Joey	Yoo	Lilly	Yang	Jarryd	Samples
Gina	Owen	Jonathan	Ruiz Espejo	Travis	Splawn
Chirag	Bhatt	Ellen	Ciarimboli	Patricia	Vauls
Brianna	Davis	Jean	Edsall	Katie	Matulis
Martin	Flusberg	Jeffery	Lindholm	Naomi	Macias
Eric	Martin	Wayne	Melichar	Jennifer	Nord
Angela	Nardone	Roxanne	Pascoe	Michael	Pascucilla
Kevin	Scott	Charles	Seaman		
Michael	Sperber	Darrell	Wiser		
Rebecca	Wynnw	Thomas	Woodbury		

DRAFT

Template approved: 7/13/2021

Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME: Council II Allergen Committee

DATE OF FINAL REPORT: *12/5/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Co-Chairs: Dr. Amani Babekir and Michelle Hill CP-FS

COMMITTEE CHARGE(S):

Issue # _2020-II-011__

1. Develop an operational framework for food allergy prevention and control using existing research and other evidence-based materials (for example: CDC guidance in schools and guidance developed by retail food industry) in retail food establishments including:

- **a.** A written template retail food establishments can use to reduce the risk of food allergy reactions and respond to any reactions that do occur. The template can incorporate findings, lessons, materials, etc. from items b-f.
- **b.** Steps to take during a food allergy emergency and identify key components of food allergy emergency plans.
- **c.** Food allergy training for food workers and identify educational content and training needs based on employees' assigned duties.
- **d.** Findings, recommendations, and materials from the 2018 Allergen Committee to ensure retail food establishments have tools to notify customers when menu items contain major food allergens.
- **e.** Food-handling practices, policies, and procedures to prevent food allergens from unintentionally contacting another food.
- **f.** Equal considerations for alternate food sources, such as food pantries and food banks, to ensure equity and access.

2. Recommend changes to the Food Code that support retail food establishments to operationalize framework to prevent and control food allergic reactions.

3. Report back findings and recommendations to the next Biennial Meeting of the Conference for Food Protection.

COMMITTEE WORK PLAN AND TIMELINE: The committee charges are completed; the committee will meet as needed to finalize the documents after the Council II Co-Chair review process.

COMMITTEE ACTIVITIES: *Dates of committee meetings or conference calls:*

A) Allergen Committee: 3/31, 4/14, 4/28, 5/12, 6/9, 6/23, 7/7, 8/4, 8/18, 9/1, 9/15, 9/29, 10/13, 10/27, 11/10, 12/5

B) Sub-group meetings, week of: 3/20, 3/27, 4/3, 4/10, 4/17, 5/8, 5/15, 5/22, 5/29, 7/10, 8/14, 8/21, 8/28, 9/4, 9/8

1. *Overview of committee activities:*

Completed the Framework after addressing the Federal Partners comments.

Finalized the Issue language recommending changes to the Food Code.

Completed the Issues to submit to Council II.

2. *Charges <u>COMPLETED</u> and the rationale for each specific recommendation:*

All charges are completed and the guidance documents, “Major Food Allergen Framework” and “Summary – Major Food Allergen Framework” were produced through the Committee’s hard work.

3. ***Charges INCOMPLETE and to be continued to next biennium:***

   All charges have been completed.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

Issue #1: Allergen Committee (AC) Final Report

List of content documents submitted with this Issue: Committee Member Roster:

☐ ***See attached revised roster PDF*** ☒ ***No changes to previously approved roster***

“Committee Members Template” (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) *Other content documents:*

a. List of supporting attachments: ☐ ***Not applicable***

(a.i.1) “Major Food Allergen Framework” document

(a.i.2) “Summary – Major Food Allergen Framework” document

(a.i.3) Meeting Minutes

(a.i.4) Meeting Attendance Records

1. ***Committee Issue #2***: Publish “Major Food Allergen Framework” and “SUMMARY – Major Food Allergen Framework” to CFPs website.
2. ***Committee Issue #3***: Amend the Food Code.
3. ***Committee Issue #4***: Re-create the Allergen Committee

Committee Name: Allergen Committee

Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Hill	Michelle	Co-Chair	Consumer	Allergen Free Cooking	Woodbury	MN	612-701-4004	michelle@allergenfreecook.com
Babekir	Amani	Co-Chair	Industry - Support	Ecolab	Greensboro	NC	336-931-2139	amani.babekir@ecolab.com
Sylvis	Christine	Member	Regulatory - Local	Southern Nevada Health District	Las Vegas	NV	(702) 759-0507	
Eisner	Crystal	Member	Regulatory - Local	Harris County Public Health	Houston	TX	713-248-0356	crystal.eisner@phs.hctx.net
Garvin	Amanda	Member	Regulatory - State	Michigan Dept of Agriculture and Rural Development	Southhaven	MI	(616)265-9985	garvina1@michigan.gov
Greco	Darby	Member	Regulatory - State	NYS Dept Health	Albany	NY	(518) 209-3992	darby.greco@health.ny.gov
von Bodungen	Steven	Member	Regulatory - State	FL BPRHR	Tallahassee	FL	850-661-5411	steven.vonbodungen@myfloridalicense
Read	David	Member	Academia	IFPTI	North Saint Paul	MN	651-485-8905	davidread2861@gmail.com
Dolhanyk	Anne	Member	Consumer	STOP Foodborne Illness	West Linn	OR	360-601-4264	adolhanyk@gmail.com
Oneal	James	Member	Industry - Food Service	Denny's	Spartanburg	SC	803-480-2079	joneal@dennys.com
Vinson	Scott	Member	Industry - Food Service	National Retail Federation	Washington	DC	(202) 309-2204	vinsons@nrf.com
Baldwin	James	Member	Industry - Retail Food	The Golub Corporation - Price Chopper/Market32	Schenectady	NY	518-379-1516	jimbaldwin@pricechopper.com
Thoma	Libby	Member	Industry - Retail Food	H-E-B	San Antonio	TX	210-425-3390	thoma.libby@heb.com
Wagner	Ben	Member	Industry - Retail Food	Target	Minneapolis	MN	612-280-1452	ben.wagner@target.com
Potts	Amber	Member	Industry - Support	National Environmental Health Association	Denver	CO	2143845981	apotts@neha.org

Non-Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Dutilly	Devin	FDA Consultant	Regulatory - Federal	FDA			301-348-1980	Devin.Dutilly@fda.hhs.gov
Abel	Greg	FDA Alternate	Regulatory - Federal	FDA			612-758-7199	greg.abel@fda.hhs.gov
Green	Jennifer	USDA Consultant	Regulatory - Federal	USDA-FSIS				Jennifer.green@usda.gov
Moritz	Erin	CDC Consultant	Regulatory - Federal	CDC			404-498-2756	nrj8@cdc.gov
Seymour	Jenna	CDC Alternate	Regulatory - Federal	CDC			770-488-5188	zta4@cdc.gov
Brady	Janice	Alternate	Industry - Food Service	Denny's	Spartanburg	SC	803-837-1337	jbrady@dennys.com
Lapore	Nicole	Alternate	Industry - Retail Food	Albertsons	Devon	PA	973-886-7783	nicole.lepore@albertsons.com
Algeo	Susan	Alternate	Industry - Support	WinWam	Mt. Laurel	NJ	610-322-7665	susanalgeo@winwam.com
Meinhardt	Christina	Alternate	Industry - Food Service	Aramark	Philadelphia	PA	267-939-4894	meinhardt-christina@aramark.com
*Larsen	Tom	Alternate (recommended)	Industry - Support	Accounts Coordinator of State Food Safety	Orem	UT		tlarsen@statefoodsafety.com
Noller	Aubrey	Alternate	Industry - Retail Food	Food Lion	Salisbury	NC	8646402760	aubrey.noller@retailbusinessservices.com

*This Alternate member is being added to the roster at the direction of the Conference Chair. Will require Executive Board approval before being moved into a voting position

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Note: *Minimum council committee size is 11 (as noted above): 1-Chair; 1-Vice Chair; 1-State; 1-Local; 2-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise;*
Maximum council committee size is 23 voting members: 1-Chair; 1-Vice Chair; 4-State; 4-Local; 8-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise; 36 -Non-voting alternates.
Membership on standing committees is defined by the Executive Board. On all CFP committees, the committee chair, co-chair(s), and vice chair(s) all count towards constituency balance.

Major Food Allergen Framework

Conference for Food Protection
2023 Biennium
Council II: Allergen Committee
Publication Date: _____

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Contents

Introduction

PURPOSE This document is to serve as a voluntary operational framework for FOOD ALLERGY[1] prevention and control of the MAJOR FOOD ALLERGENS[2] (as defined below) using existing research and other evidence-based materials for FOOD ESTABLISHMENTS[3] and OTHER COMMUNITY FOOD SOURCES[4]. Readers should be aware, however, that people may have other allergies beyond the major food allergens, and food establishments may employ the same practices outlined in this document to assist CONSUMERS[5] with allergies, FOOD INTOLERANCE/SENSITIVITY[6] beyond those listed herein.

Readers should be aware that consumers may have other food allergies, intolerances, or sensitivities (such as celiac disease, Crohn's disease, IBS/IBD, and others) which, although not technically allergies, are triggered by ingestion of particular foods.

SCOPE This document covers food allergy training of FOOD HANDLERS[7]; food handling policies and practices; consumer notification tools for food allergens; a food allergy reaction and emergency response guide; and equal consideration for other community food sources.

BACKGROUND A food allergy happens when a person's immune system overreacts to a food protein. Approximately thirty million people in the U.S. have food allergies, leading to 200,000 emergency department visits per year. FOOD ALLERGIC REACTIONS[8] vary in severity, from mildly itchy skin and lip swelling to severe, life-threatening symptoms (ANAPHYLAXIS[9]) and death. In the United States, 51% of adults and 42% of children with food allergies have experienced a severe reaction.

1 "Food allergy" means the reaction of the body's immune system to certain proteins in food. Reactions can vary in severity from mild symptoms involving hives and lip swelling to severe, life-threatening symptoms, called anaphylaxis, which may involve shock and fatal respiratory problems.

2 "Major Food Allergen" mean the allergens in foods that cause over 90% of allergic reactions: milk, egg, fish (such as bass, flounder, or cod), crustacean shellfish (such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame.

3 "Food establishment" means an operation that (a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; institution; or food bank; and (b) relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

4 "Other community food sources" means food sources that are made available to the public on a need basis, e.g., food bank, food shelf, food pantry.

5 "Consumer" means a person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale

6 An adverse reaction to a substance in food that does not involve the immune system, e.g., the inability to process or breakdown a certain food such as the milk sugar lactose which can lead to discomfort or have ill effects.

7 "Food handler" means a person who handles food utensils or who prepares, processes, or serves food or beverages for people other than members of their immediate household.

8 "Food allergic reaction" means an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food. The immune response can be severe and life-threatening.

9 "Anaphylaxis" means a life-threatening allergic reaction due to over-release of certain chemicals in the body resulting in shock when a person with an allergy is exposed to an allergen. Allergies to food, insect stings, medications, and latex, are most frequently associated with this type of severe response, and may include skin symptoms or swollen lips, difficulty breathing, reduced blood pressure, and gastrointestinal symptoms.

The **Major Food Allergens** that cause over 90% of all allergic reactions in people are these types of food:

- Milk
- Eggs
- Fish (such as bass, flounder, or cod)
- Crustacean shellfish (such as crab, lobster, or shrimp)
- Tree nuts (such as almonds, pecans, or walnuts)
- Wheat
- Peanuts
- Soybeans
- Sesame[10]

This guide includes example procedures, considerations, and resources that a food establishment can use to respond when someone notifies the food establishment about a food allergy or reports an allergic reaction. It also provides a framework for providing consumers accurate information about food ingredients so they can make informed decisions when ordering.

Although comprehensive, this guide might not provide everything that needs to be considered for a food allergy reaction and emergency response plan. It might also contain materials that are not relevant to every food establishment, so please consider internal procedures or standard operating procedures when using this material.

10 Sesame has been added to the list of Major Food Allergens via the FASTER Act of 2021, effective January 1, 2023.

A. Training

PURPOSE This is a framework to educate food handlers about (1) the Major Food Allergens – milk, egg, fish (such as bass, flounder, or cod), crustacean shellfish (such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame; and (2) other allergy and intolerance issues they may encounter.

Duties in food establishment (intensity of training increases with responsibility)

1. PIC - Person in Charge (PIC)[11]

Training should include

a) Definitions for food allergy, food intolerance/sensitivity, and CROSS-CONTACT[12].
b) List of the symptoms of a food allergic reaction, including anaphylaxis.
c) List of the Major Food Allergens in FDA's Food Code.
d) Dangers of food allergens and how to prevent cross-contact.
e) Using proper cleaning methods, such as wash, rinse, and sanitize, to prevent cross-contact.
f) How and when to communicate with consumers and staff about food allergens.
g) Special considerations related to food allergens for workstations and SELF-SERVICE[13] areas.
h) How to handle food allergy requests.
i) How to deal with food allergy emergencies.
j) Proper food preparation for guests with food allergies.
k) How to read a food LABEL[14] and understand the importance of food labels.
l) Personal hygiene practices to prevent cross-contact.
m) How to receive and store foods that contain Major Food Allergens to prevent cross-contact.

2. Front of house; wait staff, hostess/host, to-go personnel

Training should include

a) Definitions for food allergy, food intolerance/sensitivity, and cross-contact.
b) List of the symptoms of a food allergic reaction, including anaphylaxis.
c) List of the Major Food Allergens in FDA's Food Code.
d) How to handle food allergy requests.
e) How to deal with food allergy emergencies.

3. Back of house; Food handler *(as defined in FDA's Food Code)*

Training should include

a) List of the Major Food Allergens in FDA's Food Code.
b) Dangers of food allergens and how to prevent cross-contact.
c) Cleaning and personal hygiene practices to prevent cross-contact.
d) In-depth knowledge of MENU[15] items and preparation as it relates to assigned duties.
e) Proper food preparation for consumers with food allergies.
f) How to read a food label and understand the importance of food labels.

11 "Person in Charge (PIC)" means the person present at a food establishment who is responsible for the operation at the time of inspection.

12 "Cross-contact" means the unintentional transfer of an allergen from a food or food-contact surface containing an allergen to a food or food-contact surface that does not contain the allergen.

13 "Self-service" means areas where a food handler is not present to serve a consumer and the consumer is responsible for serving themselves. Examples: buffets, salad bars, sushi bars, or display cases.

14 "Label" means a display of written, printed, or graphic matter upon the immediate container of any article; and any word, statement, or other information that appears on the outside container or wrapper of the retail package.

15 "Menu" means all written and verbal lists of foods prepared and offered in a food establishment.

4. Understanding Labels

a) Manufacturers of PACKAGED FOOD[16] products that contain a Major Food Allergen are required by law to list that allergen on the product label – including if they are, or are a component of, a flavor, color, incidental additive, or spice (i.e., sesame paste).
b) There are several ways the allergen can be listed, so CONSUMERS[17] must read product labels carefully.
   i. The allergen may be listed in a 'Contains' statement.
   ii. If the product does not have a 'Contains' statement, consumers should review the entire ingredient list.
   iii. A 'may contain' or 'produced in a facility' marking is a voluntary, separate allergen advisory statement when there is a chance that a food allergen could be present. Anything labeled in this manner should be considered to have an allergen present.
c) Common allergens can have other names. For example, caseinates (in all forms), and whey (in all forms) are all milk proteins.
d) Although the same allergen can be present in multiple ingredients, its "food source name" (for example, milk), or common or usual name, must appear in the ingredient list just once to comply with LABELING[18] requirements.

SUPPLY CHAIN CONSIDERATIONS Manufacturers change their ingredients and production methods continually and without warning; it is especially important to read the ingredient label, and ingredient statement, for the presence of major food allergens with each shipment. Contact the manufacturer in advance if you have questions about food allergens that may be in a product.

e) Major food allergen labeling information can be found within:
   - FDA's "21 CFR 101", https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101
   - USDA's "Allergens – Voluntary Labeling Statements," https://www.fsis.usda.gov/guidelines/2013-0010
   - USDA's **"**FSIS Compliance Guidelines: Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling," https://www.fsis.usda.gov/sites/default/files/import/Allergens-Ingredients.pdf

16 "Packaged" means bottled, canned, cartoned, bagged, or wrapped, whether packaged in a food establishment or a food processing plant. "Packaged" does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food handler, upon consumer request.

17 "Consumer" means a person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale.

18 "Labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article.

B. Food-Handling Policies & Practices to Help Consumers with Food Allergies

PURPOSE Example policies and practices are provided here that will reduce the risk of a consumer being exposed to a food allergen.

With food allergens, it is **very important** to avoid having **even small amounts** of an ingredient to which a consumer is allergic come into contact with their food, utensils, tableware, and packaging. The unintentional transfer of an allergen from a food or food-contact surface containing an allergen to a food or food-contact surface that does not contain the allergen is called **cross-contact**. Sometimes it is obvious when an allergy-causing ingredient has gotten into a food through cross-contact because the ingredient can be easily seen, but other times it is not obvious, and great care should be taken to avoid these situations.

Following these guidelines, which apply to **all food handlers** who come into contact with food, beverages, and any food preparation surface, can help consumers with allergies avoid potentially life-threatening allergic reactions.

Train relevant staff in the following procedures

1. Food & Ingredient Storage

a) **Label** and segregate unpackaged foods containing one or more of the Major Food Allergens away from each other, and store separately from other foods and ingredients. *Make sure to read ingredient labels to check for the presence of allergens before labeling and segregating.
b) Spills of any of the Major Food Allergens should be cleaned up immediately, following the usual cleaning procedures used in the food establishment. If any Major Food Allergen accidentally comes into contact with other food ingredients that do not contain that allergen, these ingredients should be excluded from use.

2. Self-Service Items

a) For food items that were made on site, **label** the food items, or place **signs** next to the food items, that clearly identify the presence of one or more of the Major Food Allergens, or keep ingredient lists on site that identify the presence of one or more of the Major Food Allergens.
b) Labels and signage should be in both English and Spanish, and/or other languages appropriate to either the establishment, or the geographic area.

3. Taking a Food Order

a) When a consumer informs staff they have a food allergy, intolerance, or sensitivity, immediately **notify** the Person in Charge (PIC) or designated person (manager, chef, or key employees).
b) Help the consumer **identify** menu items that contain ingredients to which they are allergic and offer suggestions for alternative menu items.
c) If no alternative menu options are available, politely **inform** the consumer.
d) If it is possible to **modify** a menu item so that it does not include ingredients the consumer must avoid, inform the consumer, and ask if the modification would suit their needs.
e) **Verify** with the food handler that the proposed menu item modification is possible, feasible, and can be done safely for the consumer.
f) Make a **note** on the consumer's order that they have a food allergy/intolerance/sensitivity and which ingredients they must avoid so that other food handlers are aware.

4. Preparing a Food Order

a) Thoroughly clean all areas and equipment that will be used for preparing the allergic consumer's meal, even if those areas had already been cleaned for normal use.
b) Wash hands thoroughly before preparing the allergic consumer's meal. In some situations it may be necessary to change apron/chef coat, if previously soiled with potential allergens.
c) Use dedicated equipment or physically separate products to prevent cross-contact.

i. Use color-coded or specially marked supplies, uniforms, equipment, and utensils designated for preparing allergen-free meals.
ii. Avoid using the same cooking medium (e.g., oil or water) and surface (e.g., grill, prep table) when handling ingredients with and without allergens.

d) Use ingredients that do not contain the allergen(s) to which the consumer is allergic. Check ingredient labels for packaged foods.
e) Prepare food in a manner that eliminates cross-contact. All preparation, including garnishes, should be done by only one food handler who is dedicated to ensuring the meal is allergen-free, and who is not preparing other consumers' meals at the same time.

i. **If a mistake is made**, and an ingredient to which the consumer is allergic is accidentally included in the meal, it is **not sufficient** to simply remove the offending ingredient, because cross-contact will have occurred. In case this happens, **re-make** the consumer's meal.
ii. Wash your hands with soap and water before continuing preparation to avoid potential, or additional, cross-contact.

f) Cover the meal with a clean lid to prevent cross-contact and mark the meal as "allergy" so other staff are aware.
g) Notify the PIC, or designated food handler once the allergen-free meal is prepared and ready for service.
h) Wash, rinse, and store special equipment for allergen-free meals to be ready for next use.
i) Wash your hands with soap and water before touching anything else if you have handled a food allergen.

5. Delivering a Food Order

a) Verify with the food handler who prepared the meal that it does not contain the allergen specified by the consumer.
b) Ensure no cross-contact with other meals occurs during transport of the meal to the consumer.
c) Use a separate meal tray to deliver the meal.
d) VERIFY with the consumer that the meal meets their needs.
e) Discard the meal and offer to re-make it for the consumer if the meal contains ingredients to which the consumer is allergic. **Notify** the PIC. **Review** procedures and **retrain** the food handler(s) who prepared and handled the meal on these procedures **before** allowing them to re-make the consumer's meal.

C. Tools to Notify Consumers about Major Food Allergens

PURPOSE The purpose of this guidance is to provide examples of how to give consumers accurate information about food ingredients that are, or that contain, Major Food Allergens so they can make informed decisions when ordering. Giving incorrect or incomplete information can put consumers at risk for allergic reactions.

Consumers with food allergies depend on accurate allergen information when deciding what to eat. It is most effective to tell the consumer both verbally and in writing (e.g., on labels and menus) about the presence of food allergens and the risks of cross-contact.

1. Food Allergens in Menu Items & Self-Served Food[19] Items

a) Review your menu and source ingredients.
b) Use a table (see "Figure 1: Example Food Allergen Matrix" below), listing each menu item and noting the presence of major food allergens including all ingredients such as egg washes, sauces, garnishes, etc. Remember, a food might have more than one allergen.
c) Print "Figure 2. Allergen Matrix – Major Food Allergens Present in Menu Items" (following page) and use it for staff and consumers.
d) Assign a person in charge to regularly, at least once a year, review the food allergen table and update it as needed to verify the ingredients have not changed. Review and update when ingredients, suppliers or processes have changed, and/or a new item has been added to the menu. Consider off-menu items, seasonal and specialty items.
e) Have accessible the full list of ingredients for menu items for consumers with allergies or intolerances beyond the top nine. Consumers may be allergic to ingredients beyond the Major Food Allergens, like gluten. Understanding the full list of ingredients may help you better assist these consumers.

2. Create a Food Allergen Matrix *(based upon your current menu items)*

Figure 1. Example Food Allergen Matrix

Food Items*		Major Food Allergens								
		Egg	Fish	Milk	Peanut	Sesame	Shellfish	Soybean	Tree Nut	Wheat
Breads or Breaded	Bagels	X		X		m		m		
	Gluten Free biscuit	X		X				m	m	
	Sourdough bread									
	Croutons	X		m		m			m	
	Onion rings	X		X						
	Chicken nuggets	X						m		
	Mac and cheese	X		X						
Cheese	American			X						
	Provolone			X						
	Cheddar			X						
	Peanut oil in fryer				X			X		
Lettuce Salad	no Dressing									
	with Dressing	X		X				X		

"X" Contains this allergen.

"m" May contain this allergen or is processed in a facility with this allergen.

19 "Self-served food" means Restaurant-type food that is available at a salad bar, hot food bar, buffet line, cafeteria line, or similar self-service facility, and is served by the consumers themselves. Self-service food also includes self-service beverages, such as drinks dispensed from a soda fountain and coffee available on a self-service basis

Figure 2. Allergen Matrix[20]

Major Food Allergens Present in Menu Items

Food Items *	Major Food Allergens									Other Components			
	Egg	Fish	Milk	Peanut	Sesame	Shellfish	Soybean	TreeNut	Wheat				

"X" Contains this allergen.
"m" May contain this allergen or is processed in a facility with this allergen.
** Include off-menu items, seasonal and specialty items.*

Created on:_____ Reviewed on:_____ Next review:_____

20 A table such as this could be customized for gluten-free and other food intolerances and sensitivities by utilizing the “Other Components” column.

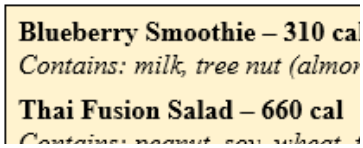
3. Menus & Signage

Design and update existing menus (including those for online ordering, catering, specials, and take-out) to ensure names and descriptions of **all** food items include Major Food Allergens present in each food. For example:

a) Have signage to notify consumers and food handlers an allergen menu exists.
b) Next to each menu item, include text to specify allergens (e.g., *Contains egg, milk*).
c) Use images (or "icons") of food allergens next to menu items where they are present. Include a key so consumers know what the icons represent. Links to websites with pre-made icons are included below.

Figure 3. Examples of notifications

Example 1: In-menu allergen notification.



Example 2: Allergen icons.

4. Talk with Consumers

a) Encourage staff to **ask consumers** about any food allergies they might have.
b) **Provide a list** of menu items and their ingredients for food handlers and consumers as a reference.
c) **Appoint at least one trained food handler per shift** to respond to consumer requests and questions about food allergens.

5. Other Ways to Inform Consumers

a) **Static clings** on display cases provide Major Food Allergen information in consumer view. **Tags or tents** next to food items also work well.
b) **Counter cards, table-talkers, or signs** at the point-of-sale or pick-up to inform consumers.
c) Consider **placing a sign in a prominent location**, when contact with a Major Food Allergen is possible or unavoidable (e.g., French fries prepared in the same fryer as breaded [wheat-containing] items).
d) **Websites** where you can find graphics and other icons for food allergens include:

i. International Association for Food Protection (IAFP) Food Allergen Icons
https://www.foodprotection.org/resources/food-allergen-icons/
ii. StateFoodSafety Allergen Icons
https://drive.google.com/drive/folders/1z_Ie5yxvWq5vFLnWnR7FeIXZDQePhygI?usp=sharing
iii. Erudus Food Allergy Icons
https://erudus.com/standardised-food-allergy-icons/

D. Food Allergy Reaction & Emergency Response Guide

PURPOSE This section is to serve as a resource for food establishments when writing a food allergy reaction and emergency response plan. This guide includes example procedures, considerations, and resources that a food establishment can use to respond when someone reports an allergic reaction. Although this section was written specifically for food allergies, some parts are applicable to reactions caused by other exposures, such as bee stings. Example informational posters are included for you to use within your food establishment.

1. What an allergic reaction may look like

Allergies are complex and allergic reactions can vary from person to person.

Allergic reactions can present in many ways. Food allergic reactions vary in severity, from mildly itchy skin and lip swelling to severe, life-threatening symptoms (anaphylaxis) and death. Some signs and symptoms only affect one part of the body (for example, hives around the mouth). Some signs and symptoms mean that multiple areas of the body are affected (for example, dizziness).

Even within the same person, reactions can differ from food-to-food and day-to-day. For example, a person might experience itching around the mouth after eating an almond, but they could have difficulty breathing and require emergency care after eating a peanut. Even reactions to the same food on different eating occasions can cause different symptoms in the same person.

Different people, including children, experience different symptoms too. For example, not everyone experiences nausea or diarrhea during a reaction. Likewise, it is possible to have a severe life-threatening reaction (anaphylaxis) without any skin symptoms, such as a rash or hives.

2. Allergic reactions in children and adolescents

Children can experience serious food allergic reactions, with an alarming number of fatal anaphylactic reactions occurring during adolescence. Milk, egg, wheat, and soy allergies are more common in childhood than adulthood.

Children can have difficulty communicating what they are experiencing during a reaction. Some children put their hands in their mouths or scratch at their tongues. Their voices may change (for example, becoming hoarse or squeaky), and they might slur their words.

3. If someone reports an allergic reaction

These are **examples** of potential actions to take when a person reports an allergic reaction. Procedures may differ depending on the severity of the reaction. Food establishments should evaluate their need for internal procedures or additional steps. based on corporate policies or other circumstances.

*** When in doubt, call 911 ***

a) Clearly direct one person to dial 911 and report an allergic reaction.
b) Follow the directions of emergency services personnel and the food establishment's food allergy emergency response plan.

4. Epinephrine auto-injectors

a) What is an auto-injector?
EPINEPHRINE AUTO-INJECTORS[21] are medical devices for injecting a measured dose of epinephrine directly into a person experiencing an allergic reaction. The devices are designed to be given through clothing. Multiple brands of auto-injectors are available in the United States, and other countries, and may look slightly different. In the U.S., you cannot buy an epinephrine auto-injector unless you have a prescription from a health care provider. Food establishments will not be able to stock an auto-injector for general use.
Epinephrine auto-injectors have specific directions for use printed directly on the device. **Always follow the instructions printed on the auto-injector**. Always call emergency services when an auto-injector needs to be administered, as a relapse is possible.

b) Here are some example images of what an epinephrine auto-injector might look like; not all auto-injectors will look like these.

Figure 4. Examples of Epinephrine auto-injectors (EAIs)

5. Additional considerations for the food establishment

The following questions and scenarios may be used to develop a detailed food allergy reaction and emergency response plan and/or can be used as a practice drill. Not all questions and scenarios will apply to a food establishment and some food establishments might have additional questions to consider.

a) What ingredient information will be provided to a consumer if they ask? Will this information be written or verbal?

i. If a person experiences a reaction, their first question will be if the allergen was present in any of the food(s) they ate.

b) The exact numbers to dial to reach emergency services should be clearly posted by all telephones.

i. Is there an additional number to dial or extra step to get an outside line?

c) Each person should be aware of any role they play during an emergency. You may consider who will:

i. Be the primary person in charge and ensure each person is performing their duties.

21 A device for injecting oneself with a single, preloaded dose of a drug. The device typically consists of a spring-loaded syringe activated when the device is pushed firmly against the body.

ii. Call emergency services and relay information.
iii. Direct and meet emergency medical services? Are there clear instructions available on how to find the food establishment?
iv. Interact with and physically assist the consumer, if necessary.
v. Keep the area around the person experiencing the reaction clear.

d) Will the food establishment keep any allergy-specific supplies (for example, antihistamines or itch creams) on hand? If yes, when will they be used?

REMINDER Epinephrine is the only medication that can treat a severe allergic reaction and must be prescribed by a health care provider.

e) Will staff have permission to search a person's belongings for an epinephrine auto-injector if they are unable to assist?
f) Can staff administer epinephrine auto-injectors? If yes, which people have permission?
g) Is there an automated external defibrillator ("AED") available? If yes, are staff trained to use it?
h) What are the procedures if the person experiencing a reaction does not want to call an ambulance? If the person leaves before the ambulance arrives, who will pay for any charges incurred?
i) Is there a debriefing and/or reporting requirement after the incident? If yes, include those steps in the allergic reaction response plan.
j) Modify the response plan, as necessary, to better prepare for future incidents.

6. Examples of Posters *(that can be placed within your food establishment to support food allergy preparedness and emergencies)*

E. Equal Consideration for Other Community Food Sources

Other community food sources provide healthy, nutritious food to those in need. For individuals with food allergies, it can be difficult to find safe foods. People with food allergies may need additional support and it is important to consider the food sources' ability to do the following:

- Have at least one well-trained person that is available to speak with those who have allergy concerns. It is important to identify foods that do not contain *at least* the Major Food Allergens so appropriate suggestions can be made.
- Allow consumers the opportunity to review original food packaging so they can read the labels. Know the importance of reading every label, every time, as ingredients can change without warning.
- Make sure staff understand the dangers of cross-contact and how to avoid it. Find out what procedures are in place to avoid cross-contact in the storage and/or preparation of food, if it is being prepared on site, so it can be shared readily.
- If food is cooked and/or served on the premises, be sure workers knows how to recognize the signs and symptoms of anaphylaxis and what the protocols are for a food-allergic emergency.

When offering foods/meals to large groups, encourage preparation of meals that are free of the Major Food Allergens.

- If foods or meals with food allergens are served, provide materials (e.g., signage, labels, tags, tents) in prominent and visible locations to inform consumers.
- While most sections of this document are applicable to both food service venues as well as other community food sources, special attention should be paid to the understanding of how allergens are listed on food labels and the availability of food label information.

Food Sources During an Emergency and Disaster Preparedness

Whether an earthquake, hurricane or wildfire, natural disasters, in addition to man-made ones, can happen at any time, often with little notice. Establish procedures for accessing allergen-friendly foods during an emergency. A crisis is never a time to experiment with a new food or product.

Fig

Food Allergy Reactions

Nine Major Food Allergens

- Milk
- Eggs
- Fish
- Shellfish
- Tree nuts
- Peanuts
- Wheat
- Soybeans
- Sesame

Symptoms of a Severe Allergic Reaction

LUNG
Short of breath, wheezing, repetitive cough

HEART
Pale, blue, faint, weak pulse, dizzy

THROAT
Tight, hoarse, trouble breathing/ swallowing

MOUTH
Significant swelling of the tongue and/or lips

SKIN
Many hives over body, widespread redness

GUT
Repetitive vomiting, severe diarrhea

OTHER
Feeling something bad is about to happen, anxiety, confusion

OR A COMBINATION
of symptoms from different body areas.

FOR **MILD SYMPTOMS** FROM **MORE THAN ONE** SYSTEM AREA, GIVE EPINEPHRINE.

If someone is having a SEVERE ALLERGIC REACTION…

INJECT EPINEPHRINE IMMEDIATELY

Follow the instructions on the device.

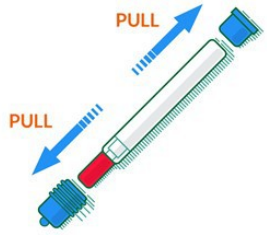
CALL 911

Tell them the individual is having an allergic reaction.

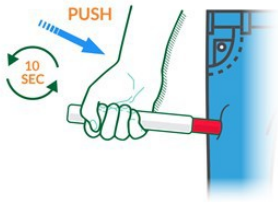
LAY them down.

If breathing is difficult or they are vomiting, let them sit up or lie on their side.

STEP 1. Prepare the epinephrine auto injector for injection by following the instructions on the device.



STEP 2. Administer the injection by firmly push the needle into the leg until a click is heard or felt. Hold the device there.



Written allergic reaction response plan is can be found here: _____

Adapted from Michigan Department of Agriculture and Rural Development, Michigan Restaurant Association, https://www.foodallergy.org/living-food-allergies/food-allergy-essentials/food-allergy-anaphylaxis-emergency-care-plan, and https://www.fda.gov/food/food-labeling-nutrition/food-allergies

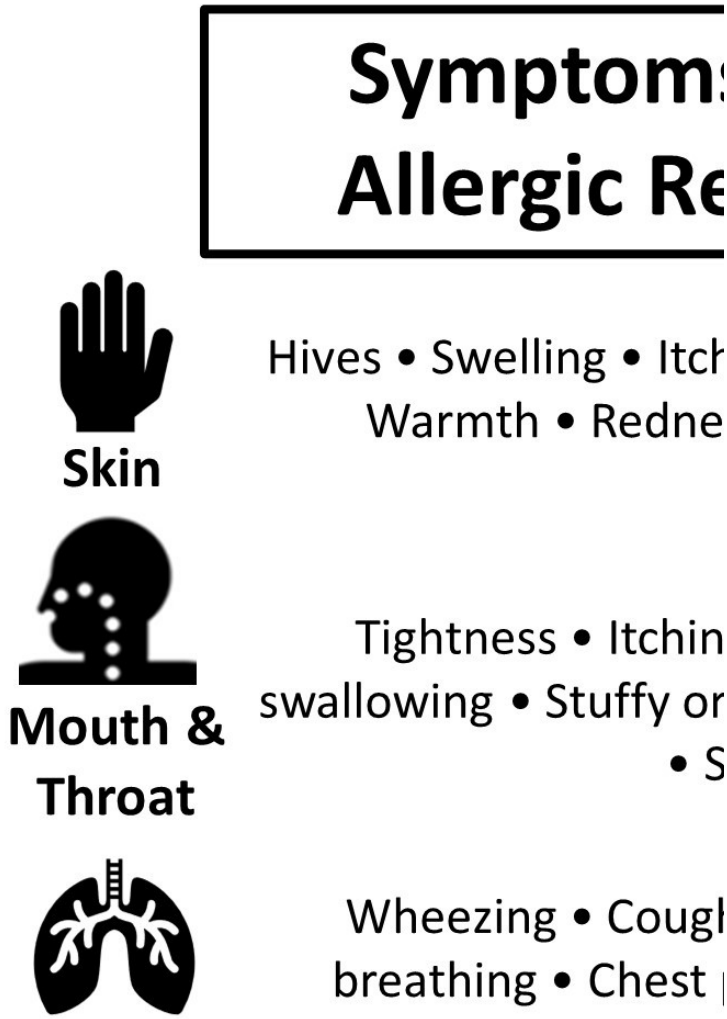


Figure 6. Symptoms of an Allergic Reaction

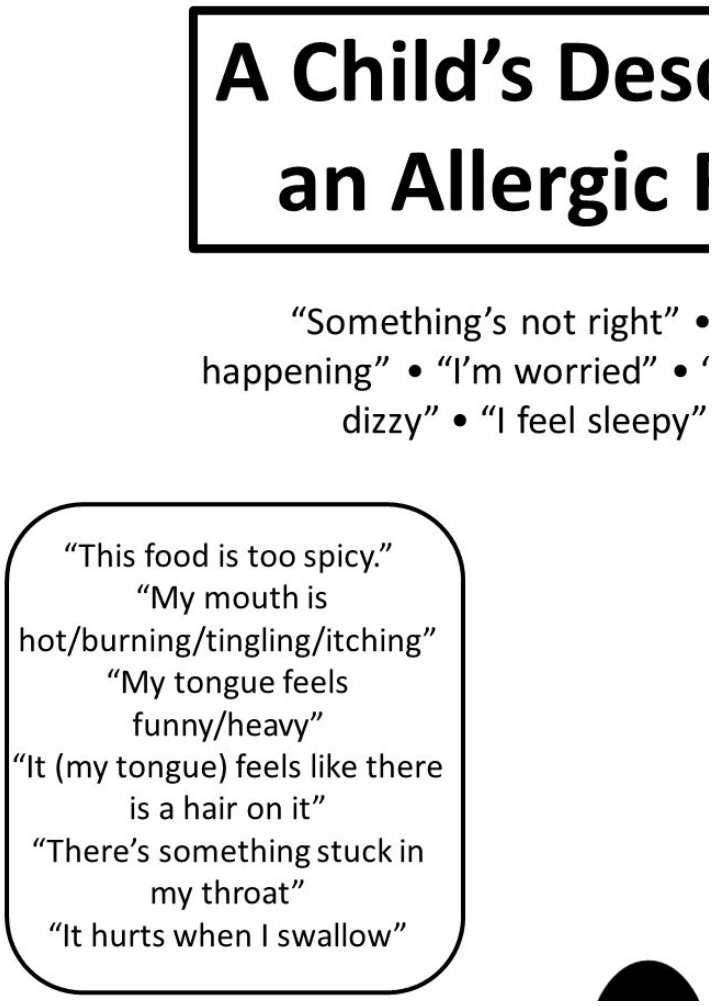


Figure 7. A Child's Description of an Allergic Reaction

Figure 8. Food Allergy Aware - Six that save lives

FOOD ALLERGY AWARE

SIX THAT SAVE LIVES

1

The Symptoms

Signs of a serious food allergy reaction – known as anaphylaxis – are 2 or more of the following after eating a suspect food:

- Hives, itching and/or skin redness
- Swelling of the tongue, lips or throat
- Breathing difficulty, wheezing or coughing
- Stomach cramps or vomiting or diarrhea
- Feeling faint / drop in blood pressure (If only this 1 symptom, it is still anaphylaxis.)

2

In Anaphylaxis: Use the auto-injector right away. Call 911 and report a food allergy emergency.

Epinephrine shots are given via the auto-injector to the outer thigh muscle. This is considered a very safe drug. Antihistamines are acceptable as secondary medication only. They won't halt anaphylaxis. Allergists say: err on the side of using the auto-injector.

3

Time is of the Essence

In studies of those who have died of anaphylaxis, they did not receive an epinephrine injection, or they got it too late, after a reaction had progressed. In anaphylaxis, prompt use of the shot is always essential.

4

Go to the Hospita

A person who had an eme epinephrine shot must be to hospital for observation. transport, IF symptoms ha improved within 10 to 15 n a second auto-injection s be given.

5

Reclining is Best

During the ambulance r the person having the se reaction should be lying d with the legs raised (this im blood flow). NIAID guidel recommend the patient re oxygen and IV fluid.

6

Don't Go It Alone

No person should be exp to be fully responsible fo administration of an epine auto-injector. Assistance anaphylaxis is crucia

From allergicliving.com. Based on guidelines from NIAID and the Canadian Society of Allergy and Clinical Immunology.

Definitions

Anaphylaxis
A life-threatening allergic reaction due to over-release of certain chemicals in the body resulting in shock when a person with an allergy is exposed to an allergen. Allergies to food, insect stings, medications, and latex, are most frequently associated with this type of severe response, and may include skin symptoms or swollen lips, difficulty breathing, reduced blood pressure, and gastrointestinal symptoms.

Consumer
A person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale.

Cross-contact
The unintentional transfer of an allergen from a food or food-contact surface to a food or food-contact surface that does not contain the allergen.

Epinephrine auto-injector
A device for injecting oneself with a single, preloaded dose of a drug. The device typically consists of a spring-loaded syringe activated when the device is pushed firmly against the body.

Food allergic reaction
An adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food. The immune response can be severe and life-threatening.

Food allergy
The reaction of the body's immune system to certain proteins in food. Reactions can vary in severity from mild symptoms involving hives and lip swelling to severe, life-threatening symptoms, called anaphylaxis, which may involve shock and fatal respiratory problems.

Food establishment
An operation that (a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; institution; or food bank; and (b) relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

Food handler
A person who handles food utensils or who prepares, processes, or serves food or beverages for people other than members of his or her immediate household.

Food intolerance/sensitivity
An adverse reaction to a substance in food that does not involve the immune system, e.g., the inability to process or breakdown a certain food such as the milk sugar lactose which can lead to discomfort or have ill effects.

Label
A display of written, printed, or graphic matter upon the immediate container of any article; and any word, statement, or other information that appears on the outside container or wrapper of the retail package.

Labeling
All labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article.

Major Food Allergen
The allergens in foods that cause over 90% of allergic reactions: milk, egg, fish (such as bass, flounder, or cod), Crustacean shellfish (such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, sesame, and soybeans.

Menu
All written and verbal lists of foods prepared and offered to consumers.

Other community food sources
Food sources that are made available to the public on a need basis, e.g., food bank, food shelf, food pantry.

Packaged food
"Packaged" means bottled, canned, cartoned, bagged, or wrapped, whether packaged in a food establishment or a food processing plant. (2) "Packaged" does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food handler, upon consumer request.

Person in Charge (PIC)
The person present at a food establishment who is responsible for the operation at the time of inspection.

Self-served food
Restaurant-type food that is available at a salad bar, hot food bar, buffet line, cafeteria line, or similar self-service facility, and is served by the consumers themselves. Self-service food also includes self-service beverages, such as drinks dispensed from a soda fountain and coffee available on a self-service basis.

Self-service
Areas where a food handler is not present to serve a consumer and the consumer is responsible for serving themselves, such as at a buffet, salad bar, sushi bar, or display case.

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https://www.foodallergy.org/resources/facts-and-statistics
UC Davis: Food allergies in children: Pediatric guidelines, diagnosis and more (ucdavis.edu)
https://health.ucdavis.edu/blog/good-food/food-allergies-in-children-pediatric-guidelines-diagnosis-and-more/2021/07
Serbes 2022: Serbes et al. Clinical features of anaphylaxis in children. Allergy Asthma Proc.
FARE/Child: How a Child Might Describe a Reaction | Food Allergy Research & Education
https://www.foodallergy.org/resources/how-child-might-describe-reaction
SNHD: HACCP-Based SOPs (southernnevadahealthdistrict.org)
https://www.southernnevadahealthdistrict.org/download/FERL-Resources/SOP-ALLERGY-TRAINING-AND-RESPONSE-20190102.pdf
Significant portions of this guidance were informed by materials developed by the Southern Nevada Health District.
https://www.southernnevadahealthdistrict.org/permits-and-regulations/food-establishment-resource-library/food-allergy-awareness-materials/
FARE: Navigating Food Assistance Programs with Food Allergies
https://www.foodallergy.org/resources/food-banks-and-soup-kitchens
FDA: Have Food Allergies? Read the Label
https://www.fda.gov/consumers/consumer-updates/have-food-allergies-read-label

Train relevant staff in the following procedures:

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a) Label and segregate unpackaged foods containing one or more of the Major Food Allergens away from each other, and store separately from other foods and ingredients. *Make sure to read ingredient labels to check for the presence of allergens before labeling and segregating.

b) Spills of any of the Major Food Allergens should be cleaned up immediately, following the usual cleaning procedures used in the food establishment. If any Major Food Allergen accidentally comes into contact with other food ingredients that do not contain that allergen, these ingredients should be excluded from use.

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a) For food items that were made on site, label the food items, or place signs next to the food items, that clearly identify the presence of one or more of the Major Food Allergens, or keep ingredient lists on site that identify the presence of one or more of the Major Food Allergens.

b) Labels and signage should be in both English and Spanish, and/or other languages appropriate to either the establishment, or the geographic area.

3. Taking a Food Order

a) Encourage staff to ask consumers about any food allergies they might have.

b) When a consumer informs staff they have a food allergy, intolerance, or sensitivity, immediately notify the Person in Charge (PIC) or designated person (manager, chef, or key employees).

c) Provide a list of menu items and their ingredients for food handlers and consumers as a reference.

d) Help the consumer identify menu items that contain ingredients to which they are allergic and offer suggestions for alternative menu items.

e) If no alternative menu options are available, politely inform the consumer.

f) If it is possible to modify a menu item so that it does not include ingredients the consumer must avoid, inform the consumer, and ask if the modification would suit their needs.

g) Verify with the food handler that the proposed menu item modification is possible, feasible, and can be done safely for the consumer.

h) Make a note on the consumer's order that they have a food allergy/intolerance/sensitivity and which ingredients they must avoid so that other food handlers are aware.

4. Preparing a Food Order

a) Thoroughly clean all areas and equipment that will be used for preparing the allergic consumer's meal, even if those areas had already been cleaned for normal use.

b) Wash hands thoroughly before preparing the allergic consumer's meal. It is necessary to change apron/chef coat, if previously soiled with potential allergens.

c) Use dedicated equipment or physically separate products to prevent cross-contact.

   i. Use color-coded or specially marked supplies, uniforms, equipment, and utensils designated for preparing allergen-free meals.

   ii. Avoid using the same cooking medium (e.g., oil or water) and surface (e.g., grill, prep table) when handling ingredients with and without allergens.

d) Use ingredients that do not contain the allergen(s) to which the consumer is allergic. Check ingredient labels for packaged foods.

e) Prepare food in a manner that eliminates cross-contact. All preparation, including garnishes, should be done by only one food handler who is dedicated to ensuring the meal is allergen-free, and who is not preparing other consumers' meals at the same time.

   i. If a mistake is made, and an ingredient to which the consumer is allergic is accidentally included in the meal, it is not sufficient to simply remove the offending ingredient, because cross-contact will have occurred. In case this happens, re-make the consumer's meal.

   ii. Wash your hands with soap and water before continuing preparation to avoid potential, or additional, cross-contact.

f) Cover the meal with a clean lid to prevent cross-contact and mark the meal as "allergy" so other staff are aware.

g) Notify the PIC, or designated food handler once the allergen-free meal is prepared and ready for service.

h) Wash, rinse, and store special equipment for allergen-free meals to be ready for next use.

i) Wash your hands with soap and water before touching anything else if you have handled a food allergen.

5. Delivering a Food Order

a) Verify with the food handler who prepared the meal that it does not contain the allergen specified by the consumer.

b) Ensure no cross-contact with other meals occurs during transport of the meal to the consumer.

c) Use a separate meal tray to deliver the meal.

d) VERIFY with the consumer that the meal meets their needs.

e) Discard the meal and offer to re-make it for the consumer if the meal contains ingredients to which the consumer is allergic. Notify the PIC. Review procedures and retrain the food handler(s) who prepared and handled the meal on these procedures before allowing them to re-make the consumer's meal.

6. If someone reports an allergic reaction

*** When in doubt, call 911 ***

a) Clearly direct one person to dial 911 and report an allergic reaction.

b) Follow the directions of emergency services personnel and the food establishment's food allergy emergency response plan.

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Meeting Number	Meeting Date	Meeting Time
01	**11/12/21**	11:00 am EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair; Meeting Scribe Michelle Hill	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour	Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Rollcall	Michelle Hill
iii.	CFP Antitrust Statement	Amani Babekir
iv.	Identify a Committee Scribe	Michelle Hill (via Teams transcription service)
v.	Review CFP Timeline for Committee Work	Michelle Hill
vi.	Review of Committee Charges	Michelle Hill
vii.	Overview of Committee Plan of work	Amani Babekir
viii.	Action Items	Amani Babekir and Michelle Hill
ix.	Determine next meeting date	Tuesday, Nov 23, 2021, 2 pm EST
x.	Adjournment	Amani Babekir
xi.	Attachments to Minutes	Yes

MEETING MINUTES

i. Call to Order – Amani Babekir

This first meeting of the CFPs Council II Allergen Committee will now come to order at 11 am EST on November 12, 2021 … As this is our first meeting there are no minutes to approve.

ii. ROLLCALL – Michelle Hill - 15/19 Voting Members present [*9 required for quorum]*

iii. Conference for Food Protection, Inc. Antitrust Statement – Read out by Amani Babekir

This Antitrust Statement is to inform the Conference for Food Protection (CFP) Executive Board members and the general membership of CFP that whenever competitors within an industry gather together, appropriate care must be taken to ensure that violations of antitrust laws do not take place.

CFP functions, be they conferences, board or committee meetings, by their very nature, bring competitors together. To avoid antitrust allegations it is necessary to avoid discussions of sensitive topics. Agreements to engage in product boycotts, restrictive market allocations, refusal to deal with third parties and price-restraining activities are automatically illegal under antitrust laws.

An antitrust violation does not require proof of a formal agreement. There need not be written or verbal agreement to collude. Also, conversations regarding any of these sensitive areas may be construed as implicit violations. As a result, those attending CFP-sponsored functions should remember the importance of avoiding not only unlawful activities but even the appearance of unlawful activity.

The antitrust laws – the Sherman Act, Clayton Act, and the Federal Trade Commission Act – are intended to ensure free and open competition. Violations of these laws can have serious consequences for CFP and its members. Violations are felonies that can result in severe penalties and significant litigation expenses for CFP and its members. Even if a government or private suit is successfully defended, the cost and disruption of the litigation can be overwhelming. Taking antitrust precautions, therefore, is not only advisable but imperative.

For your protection, the Conference for Food Protection recommends that, should one of these subjects be brought up, it would be in your best interest to voice your objection and disassociate yourself from the discussion if it continues.

iv. Committee Scribe

Michelle Hill will vet meeting minutes and curate the file moving forward. Meeting minutes to be approved at the start of the next meeting.

v. Review CFP Timeline for Committee Work – Michelle Hill

This timeline was produced by the 2023 Biennium Executive Board. As we all are aware, we are operating on a condensed timeline for this biennium. We have just over 12-months to address and complete the charges assigned to this committee.

The EB has yet to publish a more specific timeline. As more information is made available, we will be sharing exact dates.

As you can see from this list, we have deadlines dictating the completion and submission of our work to our Council II Chairs, Co-Chairs, and EB.

Committee reports are due in March, July, September, and November.

2022	March	**Due: Committee Reports submitted to Council (14-days prior to EB-mtg)**
	April	EB Meeting – Westin Galleria - Houston TX
	May/June	Opens: 30-day period to apply online for Councils for 2023 Biennium
	July	**Due: Committee Reports submitted to Council** Review: Council Chairs review 2023 Council Applicants Due: Recommendations for Council - 30-days prior to EB Meeting
	August	EB Meeting: TBD EB Approve: Council Members for 2023 Biennium Due: 2023 *draft* Registration Packet for EB review Finalized: Registration Fees for 2023 Biennium Sponsorship categories, benefits, fees Consider: Workshop topics for 2023 Biennium
	September	Send: Notification to Council Applicants **Conference Call: Issue Chair hosts call with Council and Standing Committee Chairs and Co-Chairs** Site Visits: for future Biennial Meeting 2025/2026 Midwest Region TBD Due: Meeting venue contract negotiations for EB approval.
	October	Released: 2023 Issue Pre-submission form; Issue submission guidelines Distribute: Registration Packets
	November	Send: Delegate Letters – 150-days prior to Biennial Meeting (mandated) **Due to Council Chairs for Review: Final Committee Reports; Prospective Committee Issues** Send to EB for Review: Standing Committees Documents Due: Feedback to Committee Chairs from Conference Chair/EB/Council Chairs Submit: Revised Final Reports submitted to Issue Chairs for review and comment Submit: Revised Issues submitted to Issue Chairs for review and comment
	December	Opens online: 30-day submission period for 2023 Biennium
2023	January	Close: Issue submission mandated to close not less than 90-days prior to Biennial Meeting
	February	Deadline: Submit Official State Delegate Voting Form Finalize and Assign: Issue Committee completes review and assigns each to a Council for deliberation
	March	Available: Director produces Issue Packets, mandated at least 40-days prior to Biennial Meeting Due: Reports for EB due to Director
	April	21st -28th Biennial Meeting – Westin Galleria -Houston TX

vi. Review of Committee Charges – read out by Michelle Hill

1. Develop an operational framework for food allergy prevention and control using existing research and other evidence-based materials (for example: CDC guidance in schools and guidance developed by retail food industry) in retail food establishments including:
   a. A written template retail food establishments can use to reduce the risk of food allergy reactions and respond to any reactions that do occur. The template can incorporate findings, lessons, materials, etc. from items 2-6.
   b. Steps to take during a food allergy emergency and identify key components of food allergy emergency plans.
   c. Food allergy training for food workers and identify educational content and training needs based on employees' assigned duties.
   d. Findings, recommendations, and materials from the 2018 Allergen Committee to ensure retail food establishments have tools to notify customers when menu items contain major food allergens.
   e. Food-handling practices, policies, and procedures to prevent food allergens from unintentionally contacting another food.
   f. Equal considerations for alternate food sources, such as food pantries and food banks, to ensure equity and access.
2. Recommend changes to the Food Code that support retail food establishments to operationalize framework to prevent and control food allergic reactions.
3. Report back findings and recommendations to the next Biennial Meeting of the Conference for Food Protection.

vii. Overview of Committee Work Plan/Timeline – Amani Babekir

a) collect materials and resources … complete by the end of November.

b) sorting of collected materials

c) categorize it into categories and then we assign workgroups to these categories.

d) workgroups will evaluate resources and determine the materials … to construct framework.

e) Collection and analysis completed by end of March

f) April - write template to be used by … retail food … to manage the risk of allergy … template is also going to be part of the framework.

g) Framework to complete by … July the 30th.

h) Identify possible change to the food code by the end of October – clear Framework written and reviewed.

i) Finalize Committee work – by end of December 2022.

Steps to Completion	Completion Date
Collect materials/resources	November 30
Assign work groups	December 30
Evaluate materials/resources	March 30
Write a template	April 30
Written framework	July 30
Changes to the Food Code	October 30
Final Report	December 30

Amani Babekir: I'm opening the floor for discussion from all of you. So, if you have a point or suggestion or comments, please raise your hand.

Michelle Hill: Madam Chair, I don't see any hands raised.

Amani Babekir: I would like to have a motion to accept or decline the workplan. Can I get first and a second on this motion please?

Michelle Hill: I move to accept this workplan.

Vinson, Scott: Second … the motion.

Babekir, Amani: And let us proceed with the vote on the motion … To make it simple … voting YES for **non-acceptance**. …if anyone opposed to the motion please say no or raise your hand … Do we have any abstain … motion pass to accept the committee work plan. Thank you.

viii. Action Items – Amani Babekir

Amani Babekir: Per our work plan we need to complete the collection of the material and resources … by the end of this month. THANK YOU FOR CONTRIBUTING: James Baldwin, Jennifer Green, Ben Wagner. From the beginning of this committee work we are looking to add extra resources and materials to the research FDA and CDC, USDA … local regulatory … if you are aware of any resources, please send it to us. You could send the link or the PDF file.

Cartagena, Mary: clarification …. Is it any resource on allergens or is there something specific that you're looking for?

Amani Babekir: Yes … it's more about controlling allergy in education about allergen and managing allergy in public setting or in food service areas.

Michelle Hill: We have not yet been able to set up a collection point on … Teams … as soon as we're able … start pulling all those resources in one - we'll send out an email when completed - you can go and check it out and we don't repeat effort.

Resource	Completed
Previous CFP Committees	✓
Research	
FDA/CDC	
USDA	
Industry	
Food Retail	
Regulatory	

ix. Meetings Schedule for 2022 / 2023

- Bi-weekly meeting
- Thursday's
- 2 - 3 pm EST, 1 - 2 pm CST, 12 - 1 pm MST, 11 am – 12 pm PST
- Teams – configure access and data storage

Amani Babekir: [Opens Discussion around the proposed Committee Meeting Schedule]

Mortiz, Erin – makes suggestion regarding meeting times, alternating days of week so if you cannot attend one you may be able to attend another.

Amani Babekir: set up recurring meeting every Thursday … will monitor your emails and responses to every meeting and invitation as it approaches … those who cannot attend … could suggest a better time or day …. to move it. [Request for questions / discussion]

Thoma, Libby – Yes, I was wondering if it's possible to have a proxy attend in our place if we have a desk, one dedicated person to fill in as our backup. If we're not able to attend.

Courtney Halbrook – I serve as vice chair of Council 2 and … The correct answer is I'm not 100% certain … so we'll get back to you. But it's a great question. Will find an answer.

Babekir, Amani – That sounds good. Thank you, Courtney … we will send out an email once Courtney clarifies. Any further suggestions or a question? [silence] I would like to have a motion to accept or decline the timeline proposed here. Can I get first and second on this motion?

Vinson, Scott – I move to accept this schedule.

Baldwin, James – … I … second.

Babekir, Amani - Thank you, so let's proceed with the vote on this motion. Is there anyone opposed to the motion? Please say no or raise your hand? [silence] Do we have any abstaining? [silence] Thank you so Motion passes … we will accept this schedule and adjust it as it needed. Thank you. I would like have a motion … to accept or decline the next meeting Tuesday, November 23rd from 2:00 to 3:00. … Can I get a first and second on this motion?

Vinson, Scott – Moves the motion

Ben Wagner – Seconds the motion.

Babekir, Amani - Thank you, let's just proceed with the vote on the motion … anyone opposed motion, please say no. [silence] Do we have any abstaining? [silence] The motion passes - we will have our next meeting Tuesday, November 23rd from 2:00 to 3:00 Eastern Time. **ACTION** – Co-Chairs will send out email invites for meetings.

x. Meeting Adjourned – Amani Babekir

xi. ATTACHMENTS to Minutes

American College of Allergy, Asthma & Immunology, http://acaai.org/

Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II).

Food Allergy & Anaphylaxis Connection Team, http://www.foodallergyawareness.org/

Food Allergy Research & Education, http://www.foodallergy.org/

FDA 2017 Food Code https://www.fda.gov/media/110822/download

Retail Allergen Resource Document: https://www.fmi.org/docs/default-source/food-safety/retail-allergen-resource-document.pdf?sfvrsn=6

Asthma and Allergy Foundation of America: https://www.aafa.org/food-allergies/

Food Allergies / FDA: https://www.fda.gov/food/food-labeling-nutrition/food-allergies

Restaurant Food Allergy Practices – Six Selected Sites, United States, 2014: https://www.cdc.gov/mmwr/volumes/66/wr/mm6615a2.htm

McAdams, B., Deng, A., & MacLaurin, T. (2018). Food allergy knowledge, attitudes, and resources of restaurant employees. *British Food Journal, 120*(11), 2681-2694. http://dx.doi.org/10.1108/BFJ-01-2018-0028

FDA, Food Allergens, www.fda.gov/food/ingredientspackaginglabeling/foodallergens/default.htm FDA, Food Allergen Labeling and Consumer Protection Act of 2004, www.fda.gov/Food/GuidanceRegulation/ GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm

Food Standards Agency, Allergy and Intolerance, https://www.food.gov.uk/science/allergy-intolerance

IDDBA, Food Allergens in the Bakery, www.iddba.org/training-materials/pdfs/job-guides-food-allergens-bakery

Food Allergy Research & Education, Resources for Food Manufacturers, www.foodallergy.org/resources/food-manufacturers

https://www.foodstandards.gov.au/consumer/foodallergies/foodallergenportal/Pages/Allergy-information-for-the-food-service-industry.aspx

https://www.afgc.org.au/industry-resources/food-labelling-and-allergen-guide

https://info.allergenbureau.net/

https://allergenbureau.net/resources/

https://vital.allergenbureau.net/

https://allergyfacts.org.au/allergy-management/food-industry/food-service

FSIS Compliance Guidelines Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling

Food Allergies Webpage

Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common (BIG 8) Food Allergens - Revision 2

Allergens- Voluntary Labeling Statements

Availability of FSIS Compliance Guidelines for Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration Through Labeling (79 FR 22083)

Meeting Number 02	Meeting Date **11/23/21**	Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair; Meeting Scribe Michelle Hill	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour	Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Rollcall	Michelle Hill
iii.	CFP Antitrust Statement	Included via attachment to Meeting Invitation email.
iv.	Identify a Committee Scribe	Michelle Hill (via Teams transcription service)
v.	Meeting Minutes	Michelle Hill
vi.	Accessing Teams	Amani Babekir
vii.	Collect Resources	Michelle Hill
viii.	Action Items	Verify access to Teams and the Resources folder
ix.	Adjournment	Amani Babekir

MEETING MINUTES

i. Call to Order

ii. ROLLCALL - 16/19 Voting Members present {*9 required for quorum}*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Committee Scribe

Michelle Hill will vet meeting minutes and curate the file moving forward. Meeting minutes to be approved at the start of the next meeting.

v. Approve previous Meeting Minutes (11/12/21)

Motion passed via voice vote.

vi. Accessing the folder of Resources for evaluation – Amani Babekir

Showed the committee members how to access the Resource folder within Teams.

The FDA members are not able to access the Teams folders so have requested another method of distribution. We agreed to send documents, when needed, via email attachment, and also recommended that members access document via the SharePoint interface of Teams.

Two additional document repository services were recommended to try – Dropbox and Adobe Cloud.

vii. Overview of Collected Resources – Michelle Hill

Showed the committee members the folder of Resources that need to be reviewed. We opened the floor for discussion, and it was suggested that we choose an evaluation method to screen documents for further evaluation. Additional resources were shared by committee members via the Chat in Teams.

viii. Action Item

Co-chairs agreed to send out two options to access documents: Teams and SharePoint; requested members email the Co-Chairs with access issues so they can be addressed before the next meeting.

xi. Meeting Adjourned – Amani Babekir

Meeting Number 03	Meeting Date **12/09/21**	Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair; Meeting Scribe Michelle Hill	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour	Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Rollcall	Michelle Hill
iii.	CFP Antitrust Statement	Included via attachment to Meeting Invitation email.
iv.	Meeting Minutes	Michelle Hill (via Teams transcription service)
v.	Review Committee Work Plan	Amani Babekir
vi.	Access to Resources	Michelle Hill
vii.	Evaluate Collected Resources	Amani Babekir
viii.	Assign Documents for Evaluation	Michelle + Amani
ix.	Adjournment	Amani Babekir

MEETING MINUTES

i. Call to Order

ii. ROLLCALL

18/19 Voting Members present {*10 required for quorum}*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Meeting Minutes

Michelle Hill will vet meeting minutes and curate the file moving forward. Meeting minutes to be approved at the start of the next meeting.

Motion to approve Meeting Minutes made by NAME, seconded by NAME, approved via voice vote.

v. Review of Committee Work Plan

Steps to Completion	Completion Date
Collect materials/resources	November 30
Assign work	December 30
Evaluate materials/resources	March 30
Write a template	April 30
Written framework	July 30
Changes to the Food Code	October 30
Final Report	December 30

vi. Access to Resources

Three Ways to Access Documents

- CFP Teams > Files > Council II > Allergen Committee > Members > Collected Resources

- CFP SharePoint via Teams
- Email attachments

vii. Evaluate Collected Resources

Collected Resources

Folder Name	#
CDC related	2
CFP related	6
FDA related	20
International	39
Regulations	18
Regulatory – State and Local	21
Research 1. Allergen control 2. Allergen Labeling 3. Allergens educating about 4. Allergens general info	 28 14 20 133
USDA related	9

1. Co-chairs evaluate documents using the "Evaluating Information Source" form
2. Files that meet criteria will be assigned to reviewers

Deadline 12/30/21

Evaluation Form

Evaluating Information Sources

Criteria	(Yes/No)
Document Purpose	
Provide information, persuade or advocate	Yes
Intended audience	
Food retail, food service, food industry, public, researchers	Yes
Authority and credibility	
the resource has authority/credibility	Yes
Accuracy and reliability	
The information well researched?	Yes
Currency and timeliness	
The information is not outdated or updated/revised in another version?	Yes

If you answer "Yes" to all of the criteria items, please proceed to the information collection step using the "**Information Collection Form**"

Information Collection Form

Allergen Committee –Information Collection Form

Name: Amani Babekir	
Document Title/Date: Food Allergen Notifications: A Guidance for Industry / 2020	
Document Source: CFP 2020 – Allergen Committee	
Document Pass Information Criteria (Yes/No): Yes	
Allergy emergency	
Steps during allergy emergency	
Components of food allergy emergency plans	
Employee Training	
Education content	
Training per assigned duties	
Food-handling practices to prevent cross-contact	
Policy	
procedures	
Equity access	
Alternative food sources	
Tools for retails to notify customers about item containing allergen (CFP previous committee)	
• A combination of verbal and written allergen notifications. • Notifications should be specific to menu items and the major food allergens they contain, rather than generic warnings that may apply to the entire menu or food preparation environment. • Food allergen notifications should address all ingredients containing major food allergens, including "hidden ingredients," such as egg washes, sauces, garnishes, etc. • If food operation is not able to accommodate an allergen-free order. Be open and honest with the consumer about the limitations of the establishment in controlling food allergens. **More illustration/details in the documents**	

viii. Assign Documents for Evaluation

- Members will be notified by email of the documents to evaluate.
- The assigned document will be sent by email to each reviewer.
- Forms will be sent to each reviewer by email
- Forms and documents will be available in Teams
- Objections and Discussions – Darby's statement and request to just begin by writing a draft framework ….

ix. Meeting Adjourned

Next meeting: December 23, 2021 - 2:00 EST

Meeting Number 04	Meeting Date **12/23/21**	Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair; Meeting Scribe Michelle Hill	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour	Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Rollcall	Michelle Hill
iii.	CFP Antitrust Statement	Included via attachment to Meeting Invitation email.
iv.	Meeting Minutes	Michelle Hill (via Teams transcription service)
v.	Adjournment	Amani Babekir

MEETING MINUTES

i. Call to Order – Amani Babekir

ii. ROLLCALL – Michelle Hill

8/17 Voting Members present {*10 required for quorum}*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Meeting Minutes

Michelle Hill will vet meeting minutes and curate the file moving forward. Meeting minutes to be approved at the start of the next meeting.

- Assign Documents for Evaluation
- Objections and Discussions – Darby's statement and request to just begin by writing a draft framework ….

v. Meeting Adjourned

Next meeting: Jan 6, 2022 – 2:00 pm EST

Meeting Number	Meeting Date		Meeting Time
05	**01/06/2022**		2:00 pm EST
Co-Chair; Meeting Chair	Co-Chair	Scribe	Council II Chairs
Amani Babekir	Michelle Hill	Amber Potts	Jo DeFrancesco/Courtney Halbrook
Advisory - FDA	Advisory – FDA		Advisory - FDA
Greg Abel	Devin Dutilly		Mary Cartagena
Advisory - CDC	Advisory – CDC		
Erin Moritz	Jenna Seymour		
Advisory - USDA			
Jennifer Green			

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Rollcall	Michelle Hill
iii.	Meeting Scribe	Amber Potts
iv.	CFP Antitrust Statement	Amani Babekir
v.	Previous Meeting Minutes	Amani Babekir
vi.	Reconsider Work Plan	Amani Babekir and Michelle Hill
vii.	Adjournment	Amani Babekir

MEETING MINUTES

i. Call to Order

ii. ROLLCALL - 15/17 Voting Members present {*10 required for quorum}*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Previous Meeting Minutes

There were no meeting minutes for call held 12/23/2021 as there was not a quorum. Meeting minutes for 12/09/2021 were voted on. Motion to approve Meeting Minutes 12/09/2021 as is made by Scott Vinson, seconded by Ben Wagner, approved via voice vote. Today's meeting minutes scribed by Amber Potts.

v. Reconsider Work Plan

The original process was to use the form created to evaluate the documents and a form to collect information needed. The resources would be split into sections and assigned out.

Madam Chair *entertained a motion* regarding reviewing only the shared resources, attached to the email meeting invitation. The shared resources are those added by the committee only.

No motion to proceed. Motion dies.

Several committee members expressed issues with accessing the resource link on the shared resource document stating there are issues with security risks on the document, unable to open the link, some links were not working. Vy Goddard suggested all members to list the resources by charges and see if everyone's match.

Madam chair *entertained a motion* to proceed as Vy suggested.

Steven von Bodungen motioned to proceed. Amanda Garvin seconded.

Discussion opens. Michelle Hill asks Vy to repeat the suggestion. Vy clarifies that we would all review the shared resource document and assign links to specific charges, the groups would be assigned charges. This would negate the need for any collection forms Vote on motion: 0 opposed, 0 abstain. *Motion passes.*

Vy screen shared to show example. Groups would compile everything then vet resources at the next meeting. Vy would begin working on this.

Scott Vinson raises a question: For charges 1a, it states relating to items 2-6. There are no items 2-6.

Michelle Hill clarifies it means b-f, all items below 1a or the remaining part of the list. Charge 1 refers to SOPs and 1b are the steps to take. Looking at the Australia and New Zealand resources, they have implemented allergen training modules at the Federal level for specific retail establishments: hospitals, restaurants, schools, etc. They have methods and modules we can use to build our framework.

Amani mentions that we are vetting the resources because they are going to be the components of the framework.

Scott Vinson comments: Allergy training is one of *many* trainings for employees. Due to the high turnover and limited period for training Scott suggests that what ever materials we prepare should be concise and conveyed quickly.

Steven von Bodungen backs up the comment and agrees materials should be concise and to the point.

Amber Potts also agrees, and the materials should be in plain language. Vy suggests making flyers, stickers, and magnets. Cassandra Mitchell agrees with Vy, there are many languages spoken so pictures would be great.

Libby Thoma mentions to look in the ServSafe exam. There is limited information on allergens and ServSafe is not focused much on food production. ServSafe should be added to the resource page. ServSafe has an online allergen module.

Crystal Eisner says she would look into Responsible Training, link already on the shared resource page.

Scott Vinson suggests that the workers in food service ask if the consumer has any food allergies or to post a sign to encourage customers to let the server know of the allergy. For customers to take more responsibility. Several members agree and it is suggested that conversation happen with the PIC or the manager, not necessarily the server.

Amani Babekir asks if we should begin preparing the framework at the next meeting to add in these points made. Several members agree.

David Read raises a question if we should not just limit the allergen training and this framework to focus on worker but also for managers and even up to the corporate level?

> Scott suggests not bringing it to the corporate level and to focus on the workers. He recommends listing the most common allergens with graphics so they can quickly see them.
>
> Christine Sylvis says there are a lot of resources from SNHS we can use. She shares her screen so we can view the Big-8 infographic. The smaller 'Just Ask' infographic was not successful in their local campaign.

Amanda Garvin likes SNHD and states we should base our material on their resources; Suggests the dairy allergen graphic be something other than a glass of milk.

Scott Vinson also likes SNHD and proposes *to move a motion.*

Madam chair *entertains a motion* that on the next call we will review all the SNHD resources and decide which to incorporate into the work project.

> Michelle Hill motions to proceed. Amanda Garvin seconds.

Motion opens for discussion. Christine Sylvis is happy to share all the information in a format that we can utilize, Word document etc. Amber Potts mentions that NEHA has a Canva account and can make infographics.

Vote on motion: 0 opposed, 0 abstain. *Motion passes.*

vi. Next call

- We will look into SNHD resources. Christine to send resources in an email.
- Armani and Michelle will begin building out the framework.
- Vy clarifies that we will no longer be reviewing the shared resource document.

Amanda Garvin raises a question: Is our work directed toward industry and not inspectors and only to change the food code?

Greg Able answers yes. Reminds us that this is for all institution types in the retail setting: grocery, deli, restaurants, schools, food trucks etc.

Libby Thoma asks if we can see the work completed from the 2018 committee?

Amani answers work can be viewed from CFP website, ask for all issues and attachments.

vii. Meeting Adjourned - Next meeting January 20th 2022. .

Meeting Number	Meeting Date		Meeting Time
06	**01/20/2022**		2:00 pm EST
Co-Chair; Meeting Chair	Co-Chair	Scribe	Council II Chairs
Amani Babekir	Michelle Hill	Amber Potts	Jo DeFrancesco/Courtney Halbrook
Advisory - FDA	Advisory – FDA		Advisory - FDA
Greg Abel	Devin Dutilly		Mary Cartagena
Advisory - CDC	Advisory – CDC		
Erin Moritz	Jenna Seymour		
Advisory - USDA			
Jennifer Green			

AGENDA

i. Rollcall – Michelle Hill

ii. Scribe (Volunteer) – Amber Potts

iii. CFP Antitrust Statement – Amani Babekir

iv. Meeting Minutes Approval – Michelle Hill

v. Review SNHD Resources - Committee

vi. Framework Points - Committee

vii. Adjournment – Amani Babekir

MEETING MINUTES

i. Call to Order – Amani Babekir

ii. ROLLCALL – 13/17 Voting Members present [*10 required for quorum]*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Previous Meeting Minutes

Madam Chair *entertained a motion* to approve previous meeting minutes from 1/6/2022 meeting.

Scott Vinson moved to approve minutes.

Jim Baldwin seconded the motion.

Madam Chair opened the floor for discussion. Michelle Hill recognized Amber Potts for a god job on previous meeting minutes.

Vote on motion: 0 opposed, 0 abstained. *Motion passed* to accept previous meeting minutes as they were submitted.

Christine Sylvis asked about icons from the 2018 Allergen Committee. She is unable to find the icons and would like for us to see them

Madam Chair said she will look into finding the icons.

Amber Potts scribed today's meeting minutes.

v. Review SNHD Resources

Madam Chair screen shared SNHD resource page we received by email. We began reviewing links in resource page one at time. Question raised by Scott Vinson; should we click on the links in the documents? Madam chair answered yes.

Allergy Aware Poster:

Michelle Hill- the poster is an excellent resource and categorized correctly and associated with charges.

Michelle Hill – will SNHD be updating for sesame? Christine Sylvis answered, yes SNHD can update to include sesame.

Amber Potts – maybe we should change photos? Is this intended for food handlers? Answers is yes, it's for food handler. So, we could put in more specific photos to show the kinds of food these allergens are present in.

Jennifer Green – seconds changing photos to things we eat that have the allergen in them.

Michelle Hill – thirds. To look for alternative graphics.

James Baldwin – Recommends storing the poster with food as reminder and to create awareness and be used as a training tool [by inspectors] when on site to explain major allergens and what a food handler's role is. Will illicit awareness and quick reference and what to do, how to recognize a reaction.

Scott Vinson – Pictures aren't going to be the way those appear in a restaurant. Some are additives to food items that aren't able to be seen. We may have a hard time finding pictures to represent this.

Erin Moritz – agree with Scott. Unless we want an exhaustive list we may want to stick with them [current graphics]. If we make food specific photo it may be seen to the food worker as the only thing to worry about, example being bread.

Amanda Garvin– Answer will lie somewhere in the middle. Agree about changing milk picture as dairy, but maybe have a few more things. This will not work without some sort of training – combined with training. Answer of including (example dairy) has three main ingredients casein, whey, and lactose as proteins people are allergic to. List proteins people are allergic to.

Scott Vinson– Wheat is its own challenge. When customers say they have a wheat allergy they probably mean they have celiac disease, which is not the same as an allergen. Whey, barley, oats etc. Not sure how to visually depict wheat. What is our committee charge on gluten or related celiac disease, not an allergy?

Erin Moritz– agree simpler is better. End result is to not expose customers to what they can't eat. In training, it would be worth to introduce, at a very high level, that celiac is a different outcome than with someone with a food allergy. Allergy vs sensitivity vs celiac.

Vy Truong – keep things simple. Resources specific to PIC can be more thorough than with food worker. The PIC can narrow it down to what they have in their facility.

Amanda Garvin – We do need something simple, quick but where do we draw the line of simple? We need to take things forward before we know the line. Agree that we should define a few things to eliminate confusion. So we can help break myth that people who aren't allergic will not die if they are exposed.

Jenna Seymore – The problem is that within the restaurant world a lot of restaurant tell the customer to say you have an allergy so it alerts people and increases seriousness even if it's not an allergy.

James Baldwin – Referring back to a comment in last meeting by Scott regarding practicality and simplicity and competing training. Most food establishments don't have labs or scientist – recommend we be simplistic about 8 major allergens. Can't make it too complex or it will not work well.

Cassandra Mitchell – concur with Vy to keep it simple and training will be essential. Ask Cristine – how has this been received at SNHD establishments?

Christine Sylvis– Received really well. Did this as intervention strategy, the risk factor survey identified we weren't doing a good job about educating on allergens. Did include industry in creating strategy. Response always poster is a good idea. SOP good idea. Having a logo or something to say we are educated on allergens was not received well, thought there was liability on their part. Inspections talked about allergens and importance and things food hander could do. Promotional to handout purple marker to hand write allergen orders. Discussion about allergens – sees posters up, helps with PIC knowledge. Statistics show a significant improvement on allergy awareness on follow up study.

Madam Chair asked if we can more forward with using the poster as a resource. Several members said yes we want to use poster.

Allergy Awareness Video

Amber Potts – There may be an issue with using video for training due to language barrier.

Scott Vinson in chat: I think it's a great video and I watched nearly the whole thing, but I think it might be a bit long for our purposes.

James Baldwin – Is the intent to use the video as part of the process -or use ideas from the video in the frame work (recommend second)? There are states that require managers allergen cert requires food handlers to view video and take a test and completed annually.

Madam Chair proceeded to next resource.

Allergen Guide

Scott Vinson in comments: I think it's a useful resource and we should include it

Crystal Eisner agrees and says it's a good tool.

James Baldwin – Provides an allergen guides helps them make an informed decision on what to eat. Customer informs server and lets the cooks know to prepare item to spec using clean utensils. This is a good part of training. Not so much all on restaurant but gives guest a chance to talk – partnership.

Madam Chair proceeded to next resource.

Food Allergen Warning Sign

Amber Potts – This seems like a liability statement on restaurants, I don't think it would be helpful.

Scott Vinson agrees – not helpful and doesn't provide training. But we can use it if our charges require this kind of resource.

Christine Sylvis – agrees with Scott – not favorite thing but industry asked for it.

Crystal Eisner – Can be a tool in toolbox that most rest require them to post that. Can still be part of the tool box.

Vy Truong – good start to bring awareness to consumers – could reword it. Include cross contact to be aware that the other foods are in the establishment.

Madam Chair proceeded to next resource.

Logo for Allergy Awareness

Amber Potts- similar to previous and not sure how well it would be received. And to be used when the facility is certified in allergen training.

Scott Vinson in chat: I think it's fine. It's an efficient way of getting 8 words into a square shape.

Madam Chair proceeded to next resource.

SOP – Allery Free Meal Prep

Amber Potts and Vy Truong agree to use

Madam Chair proceeded to next two resources.

[Via Chat]

Vy Truong - I think this resource will be helpful. I think all three SOPs are great

Scott Vinson - Allergy is spelled incorrectly at top

Amber Potts - I love SOPs but I am not sure how useful they are in a restaurant setting.

Scott Vinson- I agree -- I frankly don't think the typical restaurant will use these last three documents

Cassandra Mitchell - I think the SOP are great. I like the break down of the instructions in different segments

Committee did not have time to discuss the Framework Points.

Madam chair asked for any final comments before we adjourn.

Libby Thoma asked if we can get access to SafeFood program's training on allergens to review.

Madam Chair said she would check to see if we have access to the resources, which should be listed on the resources page.

vi. Next call

We will discuss framework points and working groups and brainstorm to see how we can cover all the charges.

vii. Meeting Adjourned. - Next meeting February 3, 2022.

Meeting Number	Meeting Date		Meeting Time
07	**02/03/2022**		2:00 pm EST
Co-Chair; Meeting Chair	Co-Chair	Scribe	Council II Chairs
Amani Babekir	Michelle Hill	Amber Potts	Jo DeFrancesco/Courtney Halbrook
Advisory - FDA	Advisory – FDA		Advisory - FDA
Greg Abel	Devin Dutilly		Mary Cartagena
Advisory - CDC	Advisory – CDC		
Erin Moritz	Jenna Seymour		
Advisory - USDA			
Jennifer Green			

AGENDA

i. Call to Order – Amani Babekir
ii. Rollcall – Michelle Hill
iii. Scribe – Amber Potts
iv. CFP Antitrust Statement – Amani Babekir
v. Meeting Minutes Approval – Michelle Hill
vi. Framework Points – Committee
vii. Next call
viii. Adjournment – Amani Babekir

MEETING MINUTES

i. Call to Order – Amani Babekir

ii. ROLLCALL 11/17 Voting Members present [*10 required for quorum]*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Previous Meeting Minutes

Madam Chair *entertained a motion* to approve previous meeting minutes from 1/20/2022 meeting.

Cassandra Mitchell moved to approve minutes; Scott Vinson seconded the motion; Madam Chair opened the floor for discussion.

Vote on motion: 0 opposed, 0 abstained. *Motion passed* to accept previous meeting minutes as they were submitted. No other discussion ensued.

v. Framework Points

Madam Chair screen-shared the framework point document. At the requests of members, Amani emailed the document so we could follow along.

Amani gave a summary of this framework document:

Noted that the targeted timeline is July 2022.

She divided up the section into 6 workgroups to present draft work to the committee to frame out the final framework. These workgroups would meet separately then come together at the committee meetings to discuss progress. Workgroups will have leaders who decide on work and when to meet.

Ben Wagner asked to clarify the sequential due dates, does that mean workgroups cannot get started at the same time? Amani answered that it depends on the workgroup and suggested all workgroups begin work at once.

Erin Moritz commented that some workgroups will have more work than others and we may want to keep that in mind when we decide how many are in each group.

Emergency Plans Group:

Volunteers = Erin Moritz, Mary Cartagena, Libby Thoma, Crystal Eisner

Lead = Erin Moritz

Training:

Volunteers = Vy Goddard, Dave Reed, Nicole Lepore, Amber Potts, Jennifer Seymour, James Baldwin, Greg Abel

Lead = Amber Potts

Notification Tools:

Volunteers = Cristine Sylvis, Cassandra Mitchell, Erin Moritz, Mary Cartagena, Christina Meinhardt

Lead = No one volunteered so Amani will request more members through email and then we will come back to decide a leader.

Practices:

Volunteers = Ben Wagner, Scott Vinson, James O'Neil, Aubrey Noller, Greg Abel, Amani Babekir

Lead = Scott Vinson

Equal Consideration:

Unidentified member asked what this workgroup is. Amani explained that it is finding an alternative food source and to include this in your (the food establishment's) operational plan.

Discussion Ensued:

Scott Vinson and Erin Moritz disagreed with Amani and interpreted 'equal consideration' to mean we need to come up with allergen resources for entities that are not typical food establishments (not restaurants). Scott thought the charge should have read 'alternative' not 'alternate.' Food source means other food establishments such pantries and banks. So, our charge is to come up with allergy awareness resources used in food settings other than retail foods.

Mary Cartagena asked are food banks/pantries not considered retail food establishments? Scott Vinson answered that retail means they sell food. Amber Potts clarified that the Food Code says 'convey' and has nothing to do with if they charge or not.

Erin Moritz commented that whatever resources we develop can be adapted for locations other than restaurants and grocery stores. Scott Vinson agreed. Scott suggested eliminating this as a workgroup suggested the CFP included it to cover equity considerations. Jennifer Green (?) disagreed with the CFP equity statement and added that people who work in these alternate establishments are often volunteers, older and less aware of allergen issues. There is a difference so we should include different resources for them, it's important to think about this sector – donated food. Vy Truong agreed with Jennifer adding that workers are not trained and it is a good idea to have a few things on hand for them for the volunteers (basic allergen training).

Cassandra Mitchell suggested we come back to this workgroup. Erin agreed and added that we could consider developing other materials and come back. Or instead of forming a formal workgroup we designate individuals to keep this consideration in mind as work through our charges. Vy Truong and Jennifer Green volunteered as well. Amani agreed and asked the group if we can appoint them for this position. Group agrees.

Template (must include all sections we develop and to be used by the establishments):

Volunteers = Erin Moritz, Ben Wagner

Lead = Ben Wagner

No additional thought or comments were made about the workgroups or framework document.

Amani reminded everyone that we do have resources already approved in the Teams folders.

- SNHD resources
- Shared resources
- Collected resources

Amani asked about the ServSafe resources and if we are allowed to use them. There is a charge to access the platform. Jo DeFrancesco said she would meet with Amani separately about this.

Amani asked about the Responsible Training resources (generic allergen awareness training). There is also a charge. Crystal Eisner answered that she has emailed the owner and is awaiting an answer. But she would pay the cost to access the training.

Amani will send out email and contact list so workgroup members can start their work and begin scheduling meetings.

No final comments were made.

vi. Next call

Framework.

vii. Meeting Adjourned. - Next meeting February 17, 2022.

Meeting Number 08	Meeting Date **02/17/2022**	Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair and Scribe Michelle Hill	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour	

AGENDA

i. Call to Order – Amani Babekir

ii. Rollcall – Michelle Hill

iii. Scribe – Michelle Hill

iv. CFP Antitrust Statement – Amani Babekir

v. Meeting Minutes Approval – Amani Babekir

vi. Sub-committees – Progress Reports for groups b, c, d, e

vii. Adjournment – Amani Babekir

MEETING MINUTES

i. Call to Order – Amani Babekir

ii. ROLLCALL 13/17 Voting Members present [*10 required for quorum]*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Previous Meeting Minutes

Madam Chair *entertained a motion* to approve previous meeting minutes from 2/03/2022 meeting.

Crystal Eisner moved to approve minutes; David Read seconded the motion; Madam Chair opened the floor for discussion.

Vote on motion: 0 opposed, 0 abstained. *Motion passed* to accept previous meeting minutes as they were submitted.

No other discussion ensued.

v. Sub-Committees – Progress Reports

- During our previous meeting, we voted to:
- divide into 6 workgroups to present draft work to the committee to frame out the final framework. These workgroups would meet separately then come together at the committee meetings to discuss progress. Workgroups will have leaders who decide on work and when to meet.
- Madam Chair requested the leader of each sub-committee report on their progress.

Emergency Plans (Due date Feb 16, 2022):

- Members Erin Moritz, Mary Cartagena/Devin Dutilly, Libby Thoma, Crystal Eisner
- Lead Erin Moritz

Status report given by E. Mortiz – held 1st meeting last week, will meet again tomorrow.

- Currently group is tasked with gathering already-published Allergy - Emergency Control Plans.
- Will gather the documents, review, and use them to inform our plan creation.

b. Training (Due date March 2, 2022):

- Members Amber Potts, Vy Truong, David Read, Nicole Lapore, Amanda Garvin, Greg Abel, Jennifer Seymour, James Baldwin

- Lead Amber Potts

Status report given by V. Truong – held two meetings this week.

Defined 3 categories of training, organized as a tier system for amount and type of training for each tier.

1. PIC – most training. Will create/acquire Allergen awareness materials based on allergens on site; will train others on how allergens appear in the food being offered. Can use posters, printed materials, and video-learning for training. (Southern Nevada Allergy Materials; FAAN videos)
2. Food Handler/Prep – Must be able to name all major allergens and how they appear in the food being served; will learn safe-handling practices for allergens. Can use posters, printed materials, and video-learning for training. (Southern Nevada Allergy Materials; FAAN videos)
3. Wait Staff – Must know what allergens are present for menu items and if and how they can be excluded or replaced. Will use primarily video-based training (FAAN videos, etc.)

Vy Truong asked what the expectations are for sub-committees for work completion. Madam Chair declared that the sub-committees are expected to produce DRAFT framework around their charges.

c. Notification Tools (Due date March 16, 2022):

- Members Cristine Sylvis, Cassandra Mitchell, Erin Moritz, Mary Cartagena/Devin Dutilly, Christina Meinhardt, Michelle Hill, Scott Vinson, Amani Babekir
- Lead Amani Babekir

Status report – given by A. Babekir – held 1st meeting this week. The group acknowledges the hard work of previous Allergen Committees within the CFP. Selected the 2020 Allergen guidance as published on the CFP website as a base starting point to develop this part of the framework.

It was determined that the document has been well-prepared and will allow us to make informed decisions moving forward. The idea is to reduce words when able and move towards a shorter, more visual presentation for this information.

The use of ICONS to visually represent allergens was discussed. It was agreed that the ICONS included in the previous CFP work were acceptable to use and to encourage others to use.

Anne D – speaking as a Consumer, finds the ICONS very helpful in making decisions.

V. Truong – Agreed with Anne. Prefers visual over written words as it can reach all people. Visual ICONS are easily recalled later.

E. Moritz – Suggested the committee provide the ICONS as part of the Framework so that entities can choose to use those they find to be appropriate.

d. Practices (Due March 30, 2022):

- Members B Scott Vinson, Ben Wagner, James Baldwin, Aubrey Noller, Greg Abel, Amani Babekir, James O'Neal
- Lead Scott Vinson

Status report – given by A. Babekir – held 1st meeting yesterday. Group agreed to combine 2 SOPs from Southern NV Health District for clarity sake. Considering ICONS.

e. Template Group (Due date April 27, 2022):

- Members Ben Wagner, Michelle Hill, Erin Mortiz
- Lead Ben Wagner

Status report – given by A. Babekir – Has not met yet – will wait until work has been submitted by the other sub-groups and then begin the process of porting it all into the Framework.

vi. Next call - Subcommittee Status Reports - March 3, 2022.

vii. Meeting Adjourned. - Next meeting.

Meeting Number 09	Meeting Date **03/03/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Scribe Susan Algeo	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Devin Dutilly Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		

AGENDA

i. Call to Order – Amani Babekir

ii. Rollcall – Amani Babekir

iii. Scribe – Susan Algeo

iv. CFP Antitrust Statement – Amani Babekir

v. Meeting Minutes Approval – Amani Babekir

vi. Committee charges review - Amani Babekir

vii. Working group update – group leaders

viii. Adjournment – Amani Babekir

MEETING MINUTES

i. Call to Order – Amani Babekir

ii. ROLLCALL 9/16 Voting Members present [*9 required for quorum]*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Previous Meeting Minutes

David Read- Motion to accept previous meeting minutes, second James O'Neal, no discussion. Motion passed to accept last meeting minutes.

v. Discussion regarding questions that came up during sub-committee meetings

Questions about charge #2: Will the framework we create be referenced in the food code or will it act as guide for retail food establishments?

[Opens the floor for discussion]

James Baldwin- are we trying to determine the charge? Recommendation is guidance.

Amber Potts- agree they are very different things and if it was for the food code, we would need specific language. Recommend it is referenced as a guide but that the food code require sometime of framework.

Jo DeFrancesco- we can make a recommendation that the FDA includes it and offer language that can be modified.

Scott Vinson – are we supposed to recommend specific language?

David Read – recommend what we do could be included as guidance in the Food Code Annex, which does not change the codified Food Code language. The Annex is guidance

Greg Abel- support not recommended for food code and do it as a framework and/or annex. This is because it's about bringing awareness for allergens. Because if it's in the food code, can it/will it be enforced?

Scott Vinson- given what we heard about enforcement; are the guidance documents enforceable provisions?

Jo- talked about different ways to submit the documents (whitepapers, annexes, CFP website) without it being codified

James Baldwin- recommend whitepapers to be posted on CFP website.

- Subgroups
- Emergency Plans

Devin Dutilly- Continue to work, meeting every Friday. Things are going well and should meet the deadline.

Training

Amber Potts- shared document they are working with. They need an extension for deadline. They started questioning if we want an SOP for an allergen free meal based on the document they had started with.

Question for larger group: how in depth should we be going?

Scott Vinson suggested condensing the document (their group had used the same document) into one or two pages. To make it as simple as possible for food workers to understand and food managers to be able to train.

They will go back and make it a more generalized document about major allergens and symptoms.

James Baldwin cautioned the group on whatever is put together here applies to the retail industry across the board (supermarket vs. restaurant). Be careful to not make it very specific to table service.

Amanda Garvin- is there a different term for food handlers in grocery stores??

Greg Able- FDA refers to retail as anywhere the consumer gets their hands on the food. Recommended Food Employee (which would be consistent with the food code).

Discussion about definition of food employee and who will be trained on allergens.

Amber asked if the training group is supposed to recommending increased allergen training??

Erin Moritz- in general we want to provide as much as we can. Seems there are not a lot of training that are available.

C. Notification Tools

Amani Babekir- Making good progress. Prepared documents on previous committees work and added extra materials about how to check food allergens in menu items

They would like to add Spanish language icons/posters to the materials.

Practices

Scott Vinson- they are making good progress for the March 30th deadline

First draft is put together. They want the document to be readable and something that can be copied and displayed in food establishments. They have written about storage, taking the order, preparing, and serving the food. They are still working on pairing it down so it can be concise and fit on one page.

Greg Abel asked about how useful documents posted on the wall will work for visual learners? And mentioned many employees won't read something posted. Scott mentioned there are icons that IAFP had created that may be useful; they do plan on having graphics in addition to verbiage.

Question for the group: Should they be developing only visual?? And let the training group deal with the verbiage?

Scott made the point we need to make the documents understandable for everyday people, by using plain language and simplified documents.

Devin Dutilly suggested looking up plain language there are resources that can assist.

Templates

If other groups come across forms or tools that could be useful for the templates group, please send to the group. At the end of the month the Templates group should be able to start their work.

NRA/ServSafe

What exactly do we want to use their content for and what is the outcome of using them?

James Baldwin- the way allergens are currently covered in CFPM courses is very basic information.

Amani asked, do we need the materials?? James did say the materials have been vetted and accepted by stakeholders. Erin mentioned having them review our documents after they are completed?

Do we need to be coordinating more between the subgroups so we are all staying in our lane and not doing double work? Amani suggested that training starts sharing their work. But even if we do create extra materials, it will still all be put together and will be revised. It's better to start with too much information

vi. **Next call -** Subcommittee Status Reports - March 17, 2022.

vii. **Meeting Adjourned. -** Next meeting.

Meeting Number 10	Meeting Date **03/17/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Amber Potts	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Scribe	Amber Potts
iii.	CFP Antitrust Statement	Amani Babekir
iv.	Previous Meeting Minutes	Amani Babekir
v.	Framework Points	Amani Babekir
vi.	Subgroup Update	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

i. Call to Order – Amani Babekir

ii. ROLLCALL 09/17 Voting Members present [*10 required for quorum]*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Previous Meeting Minutes

David Reed made a correction in the minuets: page 23 comment from David Reed on the bottom of the page should say that what we do we include in the Food Code Annex, which does not change the Food Code. Annex is only guidance, where the framework would possibly live.

Amani asked for him to email the changes.

Devon from FDA thanks David for his comments and clarifies that the Food Code is the both annex and codified language, which cannot be changed.

Amani entertained a motion to approved previous meeting minuets. David Reed moved to approve minuets. Libby Thoma seconds the motion. Amani approved meeting minutes as amended by David.

No further discussion about the minutes.

Amani – proceed to vote on motion. Opposed = 0. Abstain = 0. *Motion passed* to accept minutes as amended.

v. Framework Points

Feedback from team members and FDA consultants about the framework.

Amani shared screen. We need to finalize first draft from each work group by the end of March. Training and Practices finalized draft. Working on notification and emergency team.

Discussion that framework to be a guidance for CFP website. We could reference or support the Food Code by referencing in the Annex of the Food Code. We may have to submit in a separate issue, Joe to check on that.

Comments/thoughts about framework? None.

Recommendation to look into FARE org has about allergens as resources and into different sections, similar to sections we are working on in subgroups. Each subgroup looks into their section through website and look into contents. Foodallergy.org/resources

- Consider adding anything missing.

- Add references to drafts (end section listing references used to create the draft). Then work later on how we will add it in the document.
- Need consistent terms throughout all drafts.
- Food Code defines some terms: Major Food Allergen, Food Employee, Food Establishment, …
- Which definition do we want used in the framework? Need volunteers to work on terms and intro section to framework.

Terms subgroup volunteers = None in chat.

Leaving to subgroup members to add more terms that need a definition. Feel free to add terms to list.

Recommendation to do a further review to review framework by FDA consultant and if we could get access to ServSafe/AllerTrain to look into framework to look at what we will create.

vi. Subgroup update:

Emergency – Erin Moritz Screen shared draft framework

Reviewed sections and key decisions.

7 sections:

- Section 1 poster/flyer posted where staff can see it
- Sections 2 - 3; learn more about allergic reactions, emphasized every allergic reaction and symptoms are different with different severities. Poster of potential symptoms of allergic reaction. Additional considerations
- Section 4 - dedicated to children
- Section 5 - procedural when customer reports a reaction
- Posters included as examples
- Section 6 - what is an epi-pen including pictures of examples and how to administer one with graphics

How does the larger group feel about using the brand name Epi-Pen? Other comments

Scott Vinson – comprehensive. Suggests we make sure this guidance remains ever green, so it does not have to be updated often, chances are it won't. Try to make them applicable and relevant for the longer term. Graphics may change, colors may change etc. Keep that in mind for lengthy descriptions of auto injectors.

Erin agrees. All from US other countries may have own brands. Good idea to add something about how not all Epi-pens will look like this.

Scott – maybe just include a brief section on the fact that these exist. No photos or maybe just one. Not really the food services role to be responsible for administering them, helpful to let staff know they exist. Not necessary to go into lengthy description of what they are and images. Document is very long and thought we agreed to keep them concise as possible, and this is just one subcommittee. Thinks to take a second look.

Erin – Establishment to decide if it's their role to administer the pen, they can disregard the entire section, but some establishments may want this information. It is our role to make the decision?

Libby – the first part says this is to be crafted to establishment own policies.

Erin – yes, we said that under purpose. Purpose to serve as a resource.

Libby read purpose. Erin – can add that you may not need all these materials based on situation. Libby – not meant to be 100% prescriptive.

Devin - any sections that are applicative in other workgroups? So, we can reduce document size.

Erin – to took entire framework and then shorten it.

Scott shortened document because they originally included emergency.

Amani – include everything and then reduce as a whole.

Mitchell, Cassandra - I have found that a couple of the training courses identify the epi pens generally as Auto-Injector Devices

Amani – any further questions?

Erin – would be interested if sections are not needed put those in the chat and we can discuss those. A draft is not ready to send out will send after the meeting tomorrow afternoon.

Amani – next section Training.

Amber went over the training draft.

Amani – please review all draft as they relate to their charges and make sure all components are covered.

Notification Tools Group – working on draft, received several comments and suggestions and also thank you Scott for making in plain language. Meeting tomorrow to finalize comments and draft and will send it out to larger committee.

Point about Icons and Spanish language – CFP does not have capability to offer this service, but we can explore if the committee members could provide this. Backup we can look for resources.

Amber – we have adobe stock we can use

Amani – no members who speak Spanish – ask larger council to see who speaks Spanish.

Move to Practices group

Scott Vinson – member companies said it's very important to have those for staff.

Already shared with full committee. Important that all staff members see this, so we added sentence to include that. Kept it concise and brief and plan language. One divergence from language – supposed to use term unpackaged food, did not include this term because we want to make sure not to forget food items made in the store. They won't be labeled from the manufacturer, avoided that term.

Should this group include signage to include in back of house? If so, another group may need to help. What font should we use?

Erin – regarding icons, Erin can help out with that. Would be helpful if there is which section you want an icon for.

Scott – we should use all the same icons. Color ones weren't as good. Choose at full committee level. Maybe Amani can provide those so we can all use the same ones.

Amani – add icons to draft and we can discuss to whole team.

Devon – clarify that definition of packaged in food code, under label section covers food packaged in a food establishment.

Amani – thank you and asking for volunteers for terms group.

vii. Meeting Adjourned.

Next meeting March 31, 2022.

Meeting Number 11	Meeting Date **03/31/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Previous Meeting Minutes	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Subgroup Update	Amani Babekir
viii.	Adjournment	Amani Babekir

MEETING MINUTES

Call to Order

Babekir, Amani: Hello everyone and thank you for giving us this time to join our meeting. This meeting will now come to order. We would like to do the roll call, Michelle.

Roll Call

Michelle: Yes, I would be happy to. Thank you, Madam Chair. <calls roll for voting members> OK, I will try to keep my eye out if any of these other people arrived that haven't said yes, I'll add them in Madam Chair. We have a quorum of ten.

Scribe – Michelle Hill agreed to take notes that will be verified via transcript issued by Teams.

CFP Antitrust Statement

Babekir, Amani: And I would like to remind you that it is the Conference for Food Protection. Antitrust statement is active in this call. And just keep it in mind. And if you want to reference it, please find it in the attachment of this meeting Invitation.

Previous Meeting Minutes

Babekir, Amani: I will entertain a motion regarding the minutes of our last meeting.

Mitchell, Cassandra: motion that we accept the Minutes as written.

Garvin, Amanda: I second..

Babekir, Amani: Is there any discussion or question about the Minutes? So now we could proceed to the vote on the motion … is there anyone opposed to the motion? Please say no or raise your hand. Do we have anyone abstain? Nay. The motion passes to accept the document as it is. Thank you.

Framework Points

Babekir, Amani: Now we could move to the second item in the agenda. Let me share my screen. I have a couple of points I wanted to bring to all of you to discuss and see if you have any suggestions about it. Those points came out of the review process. We have right now in the draft which we generated as part of our subgroups work on these drafts. I sent out drafts for your review, and we received some comments and really, we appreciate your review. If you did not get a chance to review these drafts, please try to do so. It is really very important to make sure that we covered all the essential components of this framework.

One of the questions is about research that looks into the icons which are used to notify consumers about the allergy - are those icons sufficient. Do they convey the right message? All of the issues that might be around the icons, has anyone evaluated them.

Michelle: The paper that I'm going to be referring to, Icon based digital food allergen labels is the shortened title. It is a conference paper that was published in June of 2020. It is particular to a device - a handheld device where you scan the barcode of food products and receive information about allergen content. The study was specific to Wheat.

People were more responsive to an icon for allergen representation versus it being written out, and the clear choice was for Icon, and they have good data to show that that's the most responsive way that people can - most recognizable way for people to view allergen on a label. And in this case, it was being displayed digitally. I would be happy to distribute this paper, after the meeting today and give you an idea of what we are looking for as far as research as well, if anybody else wants to look around to find good data on what is a better way to transmit information, pictographic, icon versus written language. It was particularly preferred by people that were traveling and not native to the country. That, or did not have the speech or language ability for the country that they were in. It is a study that was done in Germany, in German. People in Italy as well as Switzerland, using the tool as well. And they saw quite a substantial percentage of people that really preferred the iconography over the written word.

Babekir, Amani: Thank you, Michelle. And this is just one example of the studies. Yes, Scott.

Vinson, Scott: I really liked the icons that the previous Allergen Committee group had included in their document. Maybe it was Erin, but they shared it with - I think on our last full Committee call. I thought those icons were really good. To Michelle's research, I yeah, I think it's pretty obvious that if you're traveling in a foreign country and you don't read the language you would like to see icons. I know when I'm traveling in a foreign country and I don't speak the language, I always appreciate seeing icons on packaged food when I'm buying it at the grocery store because I have celiac disease so that stands to reason. But Erin, do you have the icons that you had included in your work group document that you could share? I thought they were really good.

Moritz, Erin: Yeah, I can pull it up. Is that alright, Amani?

Babekir, Amani: Yes, please.

Michelle: I just wanted to add here really quick, and I failed to mention that they also use color coding. Yellow was used for likely possibility of there being an allergen present and red was absolutely that allergen is present, so it helped to address the preferential allergen labeling question as well.

Moritz, Erin: Sounds like a really interesting study, Michelle. The icons in our particular section – are these ones you are referring to?

Vinson, Scott: Those are really great.

Moritz, Erin: These are just kind of cobbled together from - they're not from one specific source. I'd have to go back and find where I pulled the images from. But we could certainly develop our own set from existing sources as well, if that's something that the group feels would be beneficial.

Vinson, Scott: No, why? Why remake the wheel? I think the work is already done. I think these are perfect. They have both an icon and the words in English next to them. Why don't we just include these and use them across all of our subcommittee work products?

Michelle: Scott, I like your suggestion there. I do want to mention that the previous allergen committee did provide a set of icons and they were the standardized set from the International Association of Food Protection. And they're what are used across Europe. I don't know if that's something we care to match, but they do exist. They're very similar to these. They are triangle shaped and we wouldn't have to follow that necessarily, but very similar to these.

Vinson, Scott: Oh, the ones that were in the triangle. Yeah, I've seen those several times. I looked at the IAFP link when we were preparing our work product document and those are good. But whatever we choose, we should just use them across all of our subgroups and then - put them in our final work product at the committee level.

Michelle: Absolutely.

Babekir, Amani: And do we think that we need a requirement for those icons - just to give it to the food facility in case they did not use those specific icons?

Vinson, Scott: Remember, we're creating a guidance document. This is not regulation.

Michelle: I do agree with you, Amani, with the question that they should be provided as an optional set that could be used in the case that they are not already using a recognizable set.

Moritz, Erin: Yes, is that what you were asking, Amani?

Babekir, Amani: That is correct, and I would like to satisfy the question that came from our FDA consultant. Devin maybe will elaborate into his comments about the icons. In general, if we specify that the icons need to be word and image, the image needs to be colored or black and white. Devin, could you give us more details about your comments regarding the icons?

Dutilly, Devin: Yes. Thank you, Amani. Thank you everybody on the call for the discussion with the icons. It is really great to see that the work group is moving forward with highlighting and bringing awareness to the nine major food allergens … these are the most recognizable and the team members mentioned that the other ones were also recognizable. It begs the question from all of us, perhaps we should be considering, if we're looking at uniform use of allergen icons or notification systems. How is that going to be interpreted across the United States, from different parts, the United States, different cultures that are within the United States. It's just something to think about whether icons are chosen, the ones that are on the screen or any other ones. It's just something to think about - the uniform acknowledgement of one image representing the allergen of choice here. But this is something to consider. Thank you.

Vinson, Scott: What are you saying? Are these not universally recognized? What do you suggest?

Moritz, Erin: If I might jump in here, I think Devin is saying that specific images aren't going to be universally recognized across the US because we don't have one set that the US has all agreed on using. Is that what you were trying to say, Devin?

Dutilly, Devin: Yes, and that would likely require quite a bit of research and investigation to establish something like that.

Moritz, Erin: Yeah, I think that's way above kind of you know our charges. I feel like that would be an entire separate conference maybe.

Dutilly, Devin: Thank you.

Michelle: When I was doing research to try and find anything about allergen icon use and recognizability, the Codex Alimentarius had industry specific icons that it's been using for a long time and there's good research for that. And it says right on there that they're not meant to be used at the consumer level. And my question would be why not? They look very similar to these. I could see if I could pull those up, but are you guys involved with that at all with the Codex Alimentarius and the USA Codex? Or is that not in your purview?

Moritz, Erin: I doubt anybody at CDC is involved with that. Jenna, I don't know if you know if somebody, please feel free to jump in.

Seymour, Jennifer (Jenna): I don't.

davidread2861: I'm pretty sure FDA is a member of the Codex.

Dutilly, Devin: There's a number of folks that are involved with it. You're right. Jennifer and Erin from the FDA side of it. So those are good points you bring up - so it's been done before.

Michelle: I'm guessing the research would be there. They were presented at the official conference recently and like Scott was saying, if it's already existing, maybe we could just point to that and use that.

Dutilly, Devin - I guess just to take a step back - the Codex is internationally focused, you know, organization - FAO and WHO? The food code is going to be targeted towards domestic, right? So that would be those are two different populations within that scope. So that that would be the difference. FDA does have representation, as Jennifer and Erin had mentioned, on multiple Codex Panels and committees.

Michelle: To that point, are they available to be used? I know that we're speaking about the United States. However, parity across is not a bad idea. If within the larger world, and if it's already recognizable when people travel, perhaps it's a good set. That was just what I was thinking.

Dutilly, Devin:. Michelle sounds like a great suggestion to perhaps include that as an option or an example within the document. So great suggestions. I'm glad you were able to find that research and bring it up, so it's definitely a valuable comment for the group to discuss. So, thank you very much Michelle.

Babekir, Amani: Also, I have a question about the food industry. Sometimes they do use icons in their product. Are there standard icons or is it up to the manufacturer? Do you know anything about that? CDC or FDA?

Moritz, Erin: I do not know. If I had to guess, I would say that. It's probably, as Michelle said, industry specific, not standardized across all food sources and all food users.

Vinson, Scott: Speaking for industry, it is not, and I think that's kind of what we're doing with this document. We're trying to provide resources for industry.

Moritz, Erin: Yes.

Vinson, Scott: This is a guidance document for Food establishments, retail food establishments. So, we should probably ask people like me representing the industry. And I think that these icons here are pretty recognizable. And if you want to go ahead and include the icons that are used by the Codex Alimentarius, that would be fine too. For people who travel internationally a lot like me, that's probably not a huge part of the population, we throw it in there. Why not? But you know, giving more options, I suppose to industry is fine, but I don't see a problem with these unless somebody can point out something specific about these, then I don't think we need to do a lot of research about whether people can tell whether this is a fish or not.

Michelle: But to earlier points - there are concerns especially around the appearance of a milk bottle for that dairy allergy - it's casein that's the issue. It's a hard thing to represent and I guess what I was just really getting at is that if there's a standard that people are used to seeing already, whether its industry based or not, perhaps it's a good standard. I don't take issue with these icons. I think they're demonstrative of what they are. But I do know that discussion early on was about how representative are they? You know, do they actually transmit what we need to transmit?

Thoma,Libby: I would like to just pop in and say in our from retail, we also in H-E-B we use Boards across all of our departments within the store to communicate to our customers that anything made in store is going to have one of these top nine allergens and they're all listed. They are icons and then they have the verbiage and these are easily their placards. They're displayed throughout our stores - our goal is to make sure that our non-English speaking customers understand what those are as well because it has, you know the descriptions along with the icon and they're color coded but. Honestly, ours are color coded based on aesthetics - I wouldn't say that they're based on anything that has anything to do with the actual food itself.

Michelle: Are they similar to this icon set?

Thoma,Libby: I can. I'll send you one when I get home. I'm driving right now.

Michelle: Thank you.

Vinson, Scott: On the black and white versus color issues for the icons I we need to look at this from the perspective of an individual operator. So, in actual food service establishments, not all of them may have color printers on site. And if we're expecting people to print these off and post them in the back of the kitchen or the back of the house and the kitchen area, food prep areas, they may only have a black and white printer. I would suggest we not do color.

Michelle: Absolutely, I agree.

Thoma,Libby: I agree too.

Babekir, Amani: Hey, thank you very much for this discussion. Any extra points about the icons - I see Erin, you put your point in the chat. You made a very good point. Any extra comments?

Vinson, Scott: I have a question about Erin's question here. She writes in my mind there are two decisions we will have to make as a committee - which icons to use in our final document, and which to provide as resources to establishments. Shouldn't they be the same?

Moritz, Erin: There's multiple sources of icons available, and so we'll have to pick one to use within just our document that we're providing - if we include links to the last committees deliverable - it has three or four resources. I don't see anything wrong with that and that way the establishments can choose which ones they prefer. We'll just have to just decide on one set that we are going to use in this particular document and if it matches one of the resources we are providing, that's great.

Vinson, Scott: It isn't the document we're producing. We're presenting this document to the CFP.

Babekir, Amani: Yes, Scott, I think what Erin meant here, is to make it consistent through the whole document. What icons are we going to use on that document? Besides providing additional resources to the food facility for these icons.

Michelle: What I am hearing here is a difference between whether we're dictating an icon set to be used across industry versus an icon set that we're going to use within the CFP guidance.

Moritz, Erin: Yes. And I think deciding a set across industry is well beyond the charges for this committee.

Michelle: So perhaps we offer the icon set that we use as the standard within our document, and like we've said earlier, just giving references that link out, not necessarily including that icon set as a part of our document - just links to those icons.

Moritz, Erin: So an establishment might read our document and say these look great, this is good for us, we're going to use them. Another establishment might say, I don't like the milk bottle. I'm going to use something else, and we have provided those resources for them to look for other images.

Michelle: OK, so there should be a spot within the guidance documentation that says here's a source for other allergen icons and give the link, not necessarily depicting the icons within our document just for clarity's sake. Is that?

Moritz, Erin: That's a good question. I assumed that we would include those, but because those were from the previous committee, maybe that's beyond our group. Yeah, I didn't think of it that way, Michelle. That's a great question.

Babekir, Amani: Yes, we do have the notification sections and one of the main sections on that section is to provide various resources for these icons just to diversify the options for the food facility. Yes. Which option they would use.

Moritz, Erin: OK. Yes, that's right.

Babekir, Amani: And to make those icons consistent through the document. We are going to leave that to the template group because the template group is the one who's going to work on the format and finalize the look of the framework. So, whatever icons we are going to add to our drafts, we are going to send it over to the template team and then they will look over it and decide after they discuss it with the whole team which icons they're going to use through the whole document. Does that sound like a good suggestion? Scott, I see your hand.

Vinson, Scott: Yes. So, my understanding is that the document the Subgroups and the committee is producing that so will turn into CFP has one audience. Not two separate audiences. The one audience is retail food establishments. We are producing an operational framework for retail food establishments to help them with allergy awareness and so forth. We don't have a document that's audience is CFP and then stuff within the document that's audience is retail food establishments, the whole work product we are coming up with, the audience is retail food establishments.

Babekir, Amani: That is correct.

Vinson, Scott: OK. Thanks.

Garvin, Amanda: But we do turn in reports to CFP, correct?

Michelle: Correct. There are specific things that we need to talk about - it's basically benchmarking on how far we are within our charge.

Babekir, Amani: Yeah, we already submitted, we do submit Periodic reports to the CFP and we already send the second report to the progress of our work and then at the end of the whole work, we going to submit a final report and that's going to be approved by the CFP, and one of the components of that report is this framework. But the main objective of the framework is to address the control and prevention of the allergen within the food facilities. So, any extra points or suggestions before we move to the next point?

Subgroup Updates

The next thing is about training, and Amber is not with us, but I would assume there is a team member from her subgroup which could help with this question. Let me share my screen here one more time. OK, the question is about how to ensure proper training. How do we ensure the proper training? Is there any requirement, any kind of assessment we would like to suggest - Anything like that? I'm not sure if that is being covered in the training subgroup. During their discussions, I know at some point they were looking into a standard way to evaluate the components of a training. But I'm not sure how far they went through this discussion. So, I'm opening it for the whole team and also for the Members in the training subgroup if they have any comments about this one.

Michelle: Just to clarify, Madam Chair, are we looking for ideas around how to assess a person's knowledge, or are we looking at how to assess the material as it is presented?

Babekir, Amani: Yeah, it's either way, just we are looking for if there is a way we could add to this framework - to assess the knowledge, or to assess the quality of the training that is going to be provided. I would assume at the end its going to fall on the person who is trained, how we're going to assess his training - his knowledge. Do you have anyone from the training subgroup in our meeting today?

davidread2861: I'm on that committee - something has been mentioned is how do you assess whether the training is sufficient or not? But we didn't discuss any further details about that. I do know that if it's online training, often there are assessments included periodically and maybe a quiz or something at the end, but it's not like a proctored exam or anything. It's just to measure progress and knowledge as you go through, for example, an online course.

Michelle: Being part of that training Subcommittee, is there an element that you guys have introduced that would allow that opportunity or a recommendation for that to occur? Just maybe stating that that's necessary, that there be an assessment of knowledge in some way.

davidread2861: But it seems like there needs to be some sort of assessment, but that's just my opinion. I don't think we've gone into detail in the committee about that, which would be ideal because everyone could get the same type of training and then you could have an assessment process built into that training.

Michelle: Much like ServSafe does with their allergen certification.

davidread2861: Most online training has that and if you're doing in person training as well. Don't know if you need to be developing, you know, separate testing processes - I guess a lot of this could be done as online training.

Michelle: That and as opposed to what we could just ask for, is that there be an assessment that's done and leave it open to what they might think that could be. But the fact is that we need to assess how well trained that person, you know, if they've been trained properly.

davidread2861: Right.

Michelle: So maybe a framework of assessment, you know, please know these things.

davidread2861: I agree.

Michelle: Which is I guess is what our framework is maybe, already.

davidread2861: I know we were building online training for the regulatory community and it's based on competencies. So, you'll look at what competencies are needed to perform certain tasks and then you develop your training and assessment around those competencies.

Vinson, Scott: I'm sorry we are talking about creating test materials to include in this guidance document.

Michelle: I don't know that that's the intent of the conversation. I think that it's more centered around whether we recommend that there be an assessment of knowledge as part of the framework.

Vinson, Scott: I'm going to say I would say no. I think that's beyond the scope of our charge - we are supposed to create an operational framework that can be used in retail food establishments to help with allergy awareness. I don't think we need to be creating testing materials or you want to call them, assessments, whatever.

Michelle: We would advise that they perform an assessment - is what we would be talking about - not actually saying this is the assessment you must adhere to. Just advise that they assess that person's knowledge in whatever way they find would be applicable to their circumstance. It's so varied.

Vinson, Scott: Folks, I think we need to be a little bit realistic. We need just a reality check here for a moment. And I've talked about this before on other calls. The retail food industry is under tremendous pressure right now. Labor shortages supply chain. Ingredient shortages it it's a mess. We need to be very careful about layering on additional regulation. The devil to deal with, particularly medium and smaller sized establishments, so.

Michelle: I agree with you Scott.

Vinson, Scott: I would be against that. I would be against.

Michelle: It's a very valuable opinion that you're sharing, Scott, and the load is there for those people. However, just making sure that reminding them that they need to know if that person has understood what they've been told. What we're after here is just acknowledgement that they understand. Maybe it's they sign a document saying they've been trained; it could be as simple as that.

Vinson, Scott: And an additional document. And then that document would be kept where?

Michelle: It would be up to the Food establishment how they deal with that, like everything else, how you document and how you store it.

Vinson, Scott: Like storing documents on site, every single requirement has - there's a domino effect.

davidread2861: Well, I think the food code actually has some training requirements in it right now and I would assume there's some way that facility would have to track that. I mean, they have to show that people have been trained.

Michelle: It could be added to it.

Vinson, Scott: So, you have these things.

Michelle: Absolutely. It's part of your operating procedures typically. Standard operating procedures are. I've seen that most commonly, and it's usually one single form, and there's several items on that form you have been made aware that you need to inform about personal illness, then how that pertains to food production. It's knife work - that you understand how to use a knife, it's agreement to report illness within the home. It could be added to that - that I acknowledge that these are the nine allergens, and we deal with them … and you know I'm not trying to give language here, I'm just saying it could be part of that and they're already retaining that. Most likely so if they've got good procedures in place they would be.

Babekir, Amani: These are good discussions? I will collect all these points from our recording, and I will send it over to the training subgroup. And then they're going to discuss it and decide how they're going to address these comments, because the question about the training assessment is based on just the feedback we got after reviewing the draft of our documents, so that is the reason

for this question. Thank you everyone - and before I continue, just to the next step, I want to open the floor to the subgroups update. I know that you have done fantastic jobs on your drafts. Really, very good job combining and completing those drafts. I'm going to call the subgroups and give them the chance if they have any questions to the larger group - the emergency plan group - Erin, do you have any questions or any update?

Moritz, Erin: No, no questions. We got a few limited comments back and we've made changes based on those suggestions. And I think we need to go through and make sure the formatting makes sense, but other than that I think it's good to go. We are certainly open to other folks to still review it if you have a chance.

Babekir, Amani: And do you think you could send the draft?

Moritz, Erin: Yes, I think that's doable. We have a meeting tomorrow and I guess my plan at least was just to go through and make sure the formatting looks good and check spelling and all you know little stuff like that. And then I think it'll be good to go.

Babekir, Amani: Thank you, Erin, and uh, the emergency plan members. Now I'm going to move to the training subgroup. I know that is a draft being sent out for review from the training subgroup - Amber is not with us. Are there any comments from the group members about the progress of the draft?

Amber: Do you mean the draft itself - I sent the draft to you when we were done with it.

Babekir, Amani: OK. Thank you. So, I'm going to move to the notification tools group. We're going to have a meeting this Friday and we're going to go over some of the comments we received just to make further updates to our final draft. And then I'm going to move to the practice group. Scott, do you have any update?

Vinson, Scott: Yep, we finished our document and I sent it to you the other day.

Babekir, Amani: Thank you. I have all the drafts now ready and we still have a chance - if you want to review it and give us extra feedback, please feel free to do so. What our next step is going to be, let me just share my screen here one more time.

Michelle: Is there a central place that could we put those most up to date versions in our repository on Teams in the Teams folder for the allergen committee.

Babekir, Amani: Yes we could do that, thank you. What's our next step? My suggestion is to continue the subgroup meetings, just keep the block you have in your calendar for those meetings. Keep it on because what's going to happen? While we are reviewing it, we're going to come up with some questions, and we can receive comments and we are going to send it to the subgroups and you're going to work on addressing those comments or additions to your draft. So just keep those meetings in your calendar. If there is no request being sent to you, you could just cancel that meeting. But at least keep it on. We are going to compile all of these drafts together, put it in one draft, review it and validate it against ServSafe contents. Michelle has access to these contents, so she's going to review what we generate. It again is the components of the ServSafe allergy and training. Are we going to identify if there is anything we need to add? If there is anything we need to edit based on this review?

Also, we need to review it with FARE, so I'm going to go over the components of the FARE training and see if there are any additions we need to address in our drafts. The third one we suggested in our discussion is that we need to look at and also compare it to our documents is the AllerTrain. We don't have access to this training. If there is any member who has the contents of their training or materials and could help us to review and compare it to our draft.

Michelle: I'll reach out to Betsy Craig, the owner of AllerTrain and request access.

Babekir, Amani: Thank you, Michelle. And would you be able to do the review or?

Michelle: Most likely not, but I could put her in touch with whoever would be able to volunteer to do that.

Amber: Yeah, I can review that. That's our training.

Babekir, Amani: Thank you, Amber. So, do you have suggestions about any other materials to review and compare to our draft?

davidread2861: Are you looking for other online training?

Babekir, Amani: It could be online.

davidread2861: I know that FMI does have an allergen training course as well.

Michelle: I think we're looking for our hole, is what our goal here is.

Babekir, Amani: Yes - do you have access to the FMI training material?

davidread2861: I don't specifically. That training is available on the IFPTI website. I could inquire about its availability.

Babekir, Amani: OK. Thank you. Any extra points or suggestions about the review? We are hoping to complete the compilation and then the review within two to three weeks. And then we will send it over the template team to work on their charge. We're going to

work on the terms - and thank you very much to the notification subgroup members that agreed to continue working on the terms. We're going to be working on these and will provide it to the template team. If you want to volunteer to work with us on this term subgroup, please put your name on the chat or let me know through email. That is all I have, and I open it to all of you, if you have any extra suggestions or discussion?

Moritz, Erin: When you talk about terms, just to clarify, this is the group that will be deciding when we talk about and establish we're going to use the word food retail establishment or just establishment. When we talk about, you know, basically the definitions team, is that correct?

Babekir, Amani: That's correct, yeah.

Moritz, Erin: Ok, thank you.

Meeting Adjourned.

Babekir, Amani: Any extra suggestions or ideas? I think that concludes our meeting today and thank you, everyone, and I'm going to send any comments or feedback that I receive to the subgroup that is related to those comments and thank you very much for continuing to work on your drafts. Thank you. Have a nice afternoon.

Next meeting Thursday, April 14, 2022.

Meeting Number 12	Meeting Date **04/14/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Previous Meeting Minutes	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Subgroup Update	Amani Babekir
viii.	Adjournment	Amani Babekir

MEETING MINUTES

Call to Order

Babekir, Amani: Hello everyone and thank you for giving us this time to join our meeting. This meeting will now come to order. We would like to do the roll call, Michelle.

Roll Call

Michelle: Yes, I would be happy to. Thank you, Madam Chair. <calls roll for voting members> We have a quorum of eleven.

Scribe – Michelle Hill agreed to take notes that will be verified via transcript issued by Teams.

CFP Antitrust Statement

Babekir, Amani: And I would like to remind you that it is the Conference for Food Protection. Antitrust statement is active in this call. And just keep it in mind. And if you want to reference it, please find it in the attachment of this meeting Invitation.

Previous Meeting Minutes

Babekir, Amani: Now we could move to approving the Minutes. Could you please go to the version I sent out yesterday? To the end of the document, you will see our last meeting notes. I will give it 2 minutes for your review. And then we could entertain a motion. So I will entertain a motion regarding the minutes of our last meeting.

davidread2861: I just sent you some edits to the comments that I made to try to clarify at least what I thought I was saying.

Babekir, Amani: OK, that is great. Any other? To wait till we make the change on the minutes, and then we proceed with entertaining a motion on it or I will entertain a motion regarding the Minutes.

Michelle Hill: Madam Chair, perhaps somebody could make a motion to approve the amended minutes in our next meeting. So people have time to review that.

Babekir, Amani: OK.

Michelle Hill: What's the will of the committee?

Ben.Wagner: I motion to approve the amended meetings in the next meeting.

davidread2861: I second.

Babekir, Amani: Thank you. Any further suggestions? OK, so let's proceed to the vote on the motion. Is there any one opposed to the motion? Please say no or raise your hand. Thank you. Do we have anyone abstaining? Thank you. So the motion passes to approve the minutes next week, after amendment OK. Thank you.

Framework Points

Babekir, Amani: So now we could move to the second item in our agenda. Just they want to give you an update about the progress in the framework, and share my screen. What we did here, we put together all the sections we received from the subgroups. Thank you very much for your effort and the time you spent working on those documents. So as of now, we have the initial draft of the framework. So that is very good progress to our committee work. We put it all together. The first section is the training and then we added the handling piece. And here is the notification section. And then the third one is the allergic reaction.

We are also working on the definition section - the subgroup meets every Friday. We made good progress on listing all the possible terms that are commonly used in our draft and we are working on adding definitions to those terms. And thank you very much for Michelle and Devin and also for the subgroup members - they really put an effort and time into doing this. Another thing I want to say if you want to volunteer on the definitions of group, please send me an email. We are planning to conclude the work on those definitions within two weeks, so we will be able to send a draft to Devin. He volunteered to give it a revision on it from his side before we proceed with formatting the document and sending it out to the template team.

Any comments about the progress we have so far on the actual draft? And definitely we're gonna have a lot of discussion about it after this. I'm gonna hand off to Michelle and also I'm gonna tell you how I compare this document with the first sources by showing you all the sections in one draft. Do you have any questions, any comments about it?

Michelle Hill: Madam Chair, I see a hand raised - Jennifer.

Green, Jennifer - FSIS: I was able to review two or three sections - I'm not sure how many total sections it will be, but will we get a chance to review the entire document like this one, this version here that has everything included.

Babekir, Amani: That is for sure, Jennifer. After the end of this meeting, I will send out this version to all of the team members, so you will have a chance to review it and do comparison with whatever resource is available for you. So that is a good thing.

Green, Jennifer - FSIS: OK, awesome. Thank you.

Babekir, Amani: Any additional comments? Thank you. And I will give you an idea about how I compare it with the FARE resources. Let me share what I used here - I'm going to walk you through the FARE website and the resources I saw there.

I found a couple of resources - mainly for avoiding cross contact. They do have a portion for the emergency care plan. How to read a food label, and also they have Spanish versions. I tried to see if they have signage or icons in Spanish, and I did not see documents or procedures in Spanish, but we could reference it in our document. Going over these resources, I found that we covered everything in our draft. The only thing I added there is that they say to avoid the cross contact is to wash hands before preparing the allergen free meal - so I added that because I don't think we had it there in the best practices section. But other than that we are aligned with the FARE contents. Any discussion or note about this. OK. Thank you.

And now I'm gonna hand it to Michelle. Michelle has done a very good job - an awesome job on reviewing our contents against ServSafe. She added a lot of feedback and suggestions there and I will give her the floor to just walk us through our notes and discuss it with you.

Michelle Hill: I took some time and nitpicked through the ServSafe food allergen training modules that they offer on their website - it is a paid service. I teach this material frequently so it was fairly simple to go through and see how we matched up. I did not find any glaring omissions with the exception of defining anaphylaxis. I know that will be one of our definitions, but I think that we should probably say a little bit more about what anaphylaxis is, and I've made a note to that effect here on the right - That it's a serious allergic reaction that occurs rapidly and may cause death. That is how ServSafe defines it. And this is all up for debate. You don't have to use any of this or all of this. I'm just letting you know what I saw when I went through it. Any place you see A tag here, it's where I found actual language specific to those ideas addressed by the ServSafe curriculum. As I said, the biggest potion that was missing would be talking about anaphylaxis and then also the flow. We might consider changing the flow of this document. In particular, we start with the person in charge, which I think is appropriate. However, it seems like it flows much better if we go to the front of the House next and then the back of the House. And maybe it's because that's the experience that customer has that it makes more sense that way. But a lot of the trainings that I did observe all had the flow in that manner.

So it's just a how we feel about it, how it flows as far as the contents, everything looked really good. I didn't see, like I said, I didn't see anything that was a glaring omission. You are more than welcome to take time to look through this when you have time. And I was only able to complete this early this morning. So it's not a lot of time for people to be able to really walk through it. I'm not sure if you want me to go through each point here or if that's something we do offline. I'm open to any kind of questions or feedback regarding this. Madam Chair, is this what you were expecting for me to do, or would you like me to go through each comment I've made?

Babekir, Amani: Yeah, I think that is good. What is going to be our next move is I'm gonna send these documents to all of our committee members to comment on it, and definitely I encourage the subgroup leaders to talk to their group members to see if there is anything they need to address or make any change to their draft. Based on Michelle's comments, as far as she said, we don't need to add anything new. But if we see that we need to adjust some of the language, we need to do anything extra, we're gonna give the subgroup a chance to do that, and we are opening it for your suggestions also, If you have any.

Michelle Hill (Guest): Madam Chair, I guess the biggest thing I've noticed is that we don't really prescribe specific language and how these things should be spoken of. I don't know if that's something that is in our purview or if we just recommend that they obtain knowledge in that way - a framework for the knowledge is what I'm seeing it as. A lot of the comments that I've made give full blown descriptions of how it would be taught,, so I guess that's something we need to consider - how much of that do we actually include in the framework?

Babekir, Amani: Thank you. I'm opening it for discussion here. Michelle, could you go to the top of the document? Maybe we could go over some of the comments and see the feedback and then we could complete it if it is a definition.

Michelle Hill: Perhaps we do list symptoms, although this is addressed later on in this document, in the framework itself, it would fall under this area here how to recognize and respond - I think that that's cared for well in that latter part. I did break out each specific allergen from it just being an itemized list to being actual numbers to again reiterate that there are nine allergens.

Babekir, Amani: I see your comments about the guest - Keeping your guests safe starts before guests. Even walk through the door.

Michelle Hill (Guest): Yes.

Babekir, Amani: Could you walk us through this one?

Michelle Hill: This speaks to how to prevent cross contact and also to how to be more aware of what's gonna hit your door before it comes, especially if you're a facility that can take a reservation, this wouldn't necessarily be for retail food. And we're looking more at a sit down restaurant here. But either way having a clear policy ahead of time on what allergens are special requests that we can reasonably accommodate. And then having clear policies to communicate that information. Everybody in the operation should know what they can accommodate and not - within given reasoning. I mean, if you're making homemade bread on site, I don't think you're going to say you can accommodate gluten free. Or gluten sensitive.

Babekir, Amani: I know in our best practices section we did not address or we don't. We did not call out that there needs to be clear policy and communicated. Do we need to consider that point?

Michelle Hill: I think so. I think that maybe having a little bit more language using some of these ideas to fill in the blanks as far as specific things that we would like them to undertake - activities to undertake. I'd like feedback from the larger committee on this.

Babekir, Amani: Practice subgroup members, do you have any feedback or comments about this? You're gonna have some time to discuss it later - we have a very quiet team today.

Michelle Hill (Guest): I think it's a lot to process. You know, in our special ordering process, how do we actually handle these orders? Maybe being specific about how we do that? Although I believe that if you read our entire flow, it is addressed throughout each designation/segment of workers. I would like to see back of the house be third and front of the House to be second - I think the flow would be a lot better. That's something we could change right now if people agree to it - if they think it makes sense.

Babekir, Amani: Do we have any further discussion about the comparison with ServSafe? And how do we feel about the contents we produce and that we aligned with their content?

Eisner, Crystal (PHS): I feel it's aligned well.

Babekir, Amani: That's good. Thank you.

Michelle Hill: Are you speaking to the order of ideas here, or just overall that we've aligned well with ServSafe?

Eisner, Crystal (PHS): Overall with ServSafe.

Michelle Hill: OK. How do you feel about changing the order of how we talk about the training modules? Do you think it matters that we have a definite flow - maybe I'm the only one that thinks this flow is awkward.

Eisner, Crystal (PHS): Can you Scroll down? And so it's training and then you have person in charge and then what's the next?

Michelle Hill (Guest): The next one is back at the house and then it's followed up with front of the house. I would recommend that we do front of the House prior to back at the House. That's my only big idea.

Eisner, Crystal (PHS): You're doing it like the flow - as if you walk into a restaurant from the front door. Is that how you're doing it?

Michelle Hill: That's what I was thinking. It's the way a lot of other written material approaches this for training is that they go from the flow of a customer and so I think it makes sense, just for clarity sake, to have the two items swapped.

Eisner, Crystal (PHS): Yeah, that's the standard - why not stay with the standard?

Michelle Hill: Thank you. I do agree with that. Is that something we can just do or do we need to have this go back to the subgroup with that comment?

Babekir, Amani: We have Members from the training subgroup - in this portion of the training, that's right. Michelle, on the training section.

Michelle Hill: Correct. This is the training subgroup. If we'd like to take a, maybe somebody could make a motion to make this change. If you're comfortable as a group.

Eisner, Crystal (PHS): Is there anyone for that subgroup on the call right now? Maybe they had a certain reason why they did it in this order.

Babekir, Amani: Amber is not able to join us, but we welcome comments from other subgroup members.

Goddard, Vy (VDH): I'm on that sub group. I don't remember a specific reason for the flow that is really significant, so I'd be OK with changing the flow, but I'm only one person on that committee, so fine by me.

davidread2861: I was on that group as well, and I don't recall any specific reason for the way it was listed, so changing it would be fine.

Michelle Hill: Madame chair, how would you like to proceed? Do you think we need to have a vote on this or is this something that is a matter of course and I can just make the change and we'll move forward with this document for review?

Babekir, Amani: I think we could make the change and then we will leave it to the template team to work on the flow of the document, because this is gonna be their task. We have Amber with us, but she's not able to see the screen. But if you can hear us, Amber, just give us your feedback in the chat.

Michelle Hill (Guest): The change has been made, the flow is now within training. Number one, PIC, number two, front of House, number 3 back of house, and then the 4th recommended changes to the wording and this would be the food code Annex specifically - not the food code itself. I think this is good. I think it'll be important for people to really take some time and look at the comparisons that have been done. And you know, if we feel like there needs to be more language added in around certain ideas, just to flesh them out, if it's agreed that that's necessary, then we can do that.

Babekir, Amani: Yes, Scott.

Vinson, Scott: Michelle, can you scroll through the whole document so we can get a sense for the whole thing?

Michelle Hill: Absolutely. I'll start at the top. It's 19 pages.

Vinson, Scott: Is this a consolidation of all of the subgroups work?

Michelle Hill: It is. This is the training component that was produced by the training work group. This is the verbiage produced by the policies and Practices Group here. Here's the tools to notify, as provided by the subgroup. I did adjust this table - I recreated it because it was painful. And I did go through and drop in where the ServSafe material would align with the same ideas throughout the entire document - not just the beginning part. And then here's a blank example form they can use. The very last section is the emergency response guide and that includes several pictures or posters that people can print and use.

Here's the flow of what to do if something happens. And ServSafe is not very verbose on that - basically says make sure the person … it steps through exactly what we've done here for the most part, it's a lot lighter even than this, as far as what they tell people to do. This is more specific, which I think is good. And then here are the posters, with references of course.

How a child might describe it? I thought this was quite good. Actually this was a very nice graphic here - explanatory, and the references for each section - each part of the framework carries a references section.

Subgroup Updates

Vinson, Scott: Is there a section with sample Posters with icons - the notification group.

Michelle Hill: Yes. That is right here. It is part of the food allergy reactions - how to recognize and respond. So here's the 9 icons that we spoke of last meeting. These have not been adjusted in any way from the last meeting. They're intact as is.

Babekir, Amani: For the notification sections we have links, but we haven't added any actual icons there. I think Amber's team also gathered icons.

Michelle Hill: This is what we have right now is part of the framework. This is what it includes.

Babekir, Amani: Correct.

Michelle Hill: Did that answer your question, Scott?

Vinson, Scott: Yes - just scroll up to that page a minute ago - Symptoms of an allergic reaction. So this page here. You've got this section here. Symptoms of a severe allergic reaction. And then if you scroll down again on the next page, it's repeated.

Michelle Hill: It is - this would be intended to be hung separately. I think that the intention of this group was that it be found in both places? So just options I guess for people.

Vinson, Scott: And one is labeled symptoms of a severe allergic reaction and the other one is labeled symptoms of an allergic reaction. So is there a difference?

Michelle Hill: There can be - the severity matters. The question is, are they tipping into anaphylaxis or not?

Vinson, Scott: Well, I mean, but do we need the word severe - people are gonna notice that it's on one section and not the other. And they're gonna wonder why there's a difference. So maybe just make them the same.

Michelle Hill: I can make that as a note. Is that what I should be doing?

Babekir, Aman: Yes please.

Michelle Hill: OK.

Dutilly, Devin: To take a look at the number of work group members are on the call now. If you take a look at the each of those documents - I think some of the intent - like you had said Michelle very nicely - they will have them printed off and hung, and each of the documents can serve different purposes within the food establishment. Different locations that they are placed or hung. So that was kind of the intent for it. And so there's a little description above it. I believe that talks about that. Thank you.

Vinson, Scott: OK. So maybe somewhere on these pages if these are meant to be hung on the wall or posted somewhere maybe. Maybe that should be noted somewhere.

Michelle Hill: There is a list up here that calls out - it says below the below posters and Flyers are designed to be placed within your food establishment in locations such as, and then they give advice as to where each poster could appear that would make sense.

Vinson, Scott: Ah. Good.

Michelle Hill: So that's a good suggestion. They did a really good job on this, referring back out. In fact, any time that they had a spot that they could refer the user or the reader to a resource, they did so with this picture call out and then what it is - it was well done. The other part I liked about this is that they did layout examples of potential reactions and then what we do is that initial assessment of how severe is it? If they can talk or not, we do this. If they're unconscious, we do this, or semiconscious … and that in itself speaks to the severity and how we deal with it.

Vinson, Scott: I have one other suggestion. I've noticed that the word individual is used frequently in these pages. I would just suggest replacing the word individual with either person or people if it's plural. I find the word individual to be dehumanizing.

Michelle Hill: I can. I'll put that in absolutely as a suggestion to be considered as a Global change.

Babekir, Amani: Any additional thoughts or comments - and how do you feel about the length of the document? How many pages do we have, Michelle?

Michelle Hill: It's 19 pages in length, but we have to consider the fact that the final three or four pages, I believe 4 pages are posters - the cover page also wouldn't necessarily need to be always printed, so that would bring us down to 15 pages of actual framework.

Babekir, Amani: It's good. And we're gonna have the definition sections. So one of the ideas is are we going to have the introduction and then the definition section. The idea is do we need to put it in the front of the document or as an appendix? The end of the document - what are your thoughts on this? We're going to have around 15 Definitions. Do you think it's best to put it at the beginning or the end of the document as an appendix?

Michelle Hill: I typically see things like that defined ahead of time, but that's just me.

Goddard, Vy (VDH): I agree. I think up front would be great.

Babekir, Amani: At the beginning.

Michelle Hill: What I'm hearing is we would have an introduction page basically saying what we're doing, why we're doing it and then right after that the definitions, Correct?

Babekir, Amani: Yeah, that's correct. Yes, Scott.

Vinson, Scott: Normally I would agree. But in this instance, given our audience, and given the length of this document, I think having an introduction that is concise but approachable and maybe friendly and folksy in tone will be very good. But, then to have that

immediately followed by a lengthy definition section, I think it's going to be off putting if a person who's running a restaurant who's already stressed out, is immediately confronted with a very lengthy document like this, and then it has a page or two of definitions. They're going to - their eyes will glaze over and they'll just stop. So I would get right into the meat of the stuff first, and put the definitions at the end or in some other section. But to immediately start confronting people with a document that looks very technical in nature is going to be off putting.

Michelle Hill: To that, Scott, would it make more sense for us to call out the definitions as we flow through the document or would you just recommend that we have it be at the end and people can reference them as needed?

Vinson, Scott: Well, that's a good idea. Maybe having it woven in - maybe each time the word is used then you just put the definition in parentheses after it. Maybe that would be a better approach depending upon how long the definitions are.

Goddard, Vy (VDH): If I find a word no, I wanna be able to go to the beginning of the end and find that and not have to look through the documents and find the one place definition might be.

James O'Neal: Well, and we can continue this part of the conversation, I had a thought about the training piece. So however you wanna do that?

Babekir, Amani: Thank you, Jim.

Thoma,Libby: I agree with Scott - when we write our technical documents for our audiences, both in manufacturing and in our retail world, we put the definitions at the end. So let's just kind of a standard way that we do it in retail.

Babekir, Amani: Thank you. David?

davidread2861: I agree with that. I think it should be more like a glossary than maybe even calling it definitions. And that would be at the end.

Green, Jennifer - FSIS: At the end would be a good.

Babekir, Amani: Thank you. So the group of the template Ben - Ben you are the leader of the group. That correct? I don't have the list in front of me now.

Ben.Wagner: Yes, I am.

Babekir, Amani: Would you take the burden of Putting the document together and having. The option, it seems like we are leaning into putting the definitions by the end of the document, but it's hard to tell. Would you like to take the burden of Deciding on that with the team When you are working on the document, so you bring it here to our meeting and they could vote on it if they wanted this way or not.

Ben.Wagner: That works.

Babekir, Amani: Thank you.

Babekir, Amani: Yes, James.

James O'Neal: Looking at the training, it looks like a lot of it is a certain set of basic information that would be applicable to anybody that works there. Am I reading that correctly?

Michelle Hill: Absolutely, yes.

James O'Neal: And so just a thought. Would it be a good idea to say this is a training for anyone who works within the restaurant and then have it broken down into specific training for back of house front of house so it's not? I mean, it's really important, but it kind of looks repetitive. If I were to pick up this document and read through it the first time.

Babekir, Amani: Yes. Thank you - we could add a note, then we could refer it to the training subgroup to look into it.

Michelle Hill: If I can capture the essence - State that this is training for all who handle the food. Break out training.

James O'Neal: Yes, bullet Point C - list the major food allergies. It's the same for all of them. So if you could have just a section where kind of a general training and then if there's anything different for a backup House employee that they would need to know kind of the gist of what I was looking at.

Babekir, Amani: That's good.

Michelle Hill: I see. So we could say this is for instance, we could talk about there being general knowledge that everybody should have. And then specific knowledge of the job duty. Is that right?

James O'Neal: Yeah, exactly. Yeah.

Michelle Hill: I think that's a really good suggestion. I too found it repetitive. But I think that the intent here- I'm not on this subcommittee, so correct me if I'm wrong - the intent here was to be specific about what each segment of duties these people need, what they need to know to do their job correctly, as far as allergen control.

Goddard, Vy (VDH): Yeah, yeah, that was the intent. And there was like, if it were gonna be separated out, then they would have all the parts - we can talk about it within our group.

Michelle Hill: Yes, that's a good place for that, yes.

Babekir, Amani: It's good. Any further suggestions? I'm going to send out this document. Michelle, could you please send it out to the whole team members?

Michelle Hill: Yes.

Babekir, Amani: Please feel free to work with your subgroup on your section and just address the comments or anything that's added in the document. And we are gonna work on the definitions. And also if you are not even a member of any of the subgroups, if you have any additional thoughts, please send it to us. I'm going to give it like 2 weeks before we send the document to Ben. So if you feel like the change needs to be addressed by the template team, you could leave it and just leave a note - and they will handle it. Yes, Scott.

Vinson, Scott: Amani so now that the document is consolidated into one, is the work of the individual subgroups completed and we no longer need to have our subgroup meetings.

Babekir, Amani: Yes, I am going to send it to you. So we are still gonna have - from now and then - some meetings because it's gonna be a continuous process of editing the document. And I don't like to do all the work just in our general meeting. Just probably the subgroups will be better. To focus on each section individually and make the changes needed. I would say for example when I send out the documents, you probably need to call a meeting with your subgroup members to just go over the comments which are placed in your section.

Vinson, Scott: OK, alright. So someone will either Michelle or you will be sending this out to everyone and then the subgroup chairs should look at our sections and address any comments made in our section.

Babekir, Amani: That is correct. I would expect to receive four versions of the document - one from each subgroup after they address the comments that were placed on the document.

Vinson, Scott: OK.

Babekir, Amani: Within two weeks before our next meeting.

Michelle Hill: If I may mention - it might be useful - don't just spend time on your own section. It's very important that that section be right of course, to your subgroups liking, but comments are also welcome throughout the document, especially if you feel like it would add to the clarity and the conciseness of the information as it's presented.

Meeting Adjourned - Next meeting is April 28, 2022.

Babekir, Amani :That's correct, yeah. So any additional points or suggestions before we conclude our meeting today. So thank you everyone for joining us today. Have a very nice rest of the day.

Meeting Number 13	Meeting Date **04/28/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Framework Points	Amani Babekir
vi.	Previous Meeting Minutes	Amani Babekir
vii.	Adjournment	Michelle Hill

MEETING MINUTES

Meeting Call to Order

Amani Babekir: This meeting will now come to order. Michelle could you please take the roll call and see if we have quorum?

Roll Call

Michelle Hill: [takes roll call of voting members]. Madame chair, we have a quorum.

Scribe – Michelle Hill agreed to take notes that will be verified via transcript issued by Teams.

This meeting is now being recorded.

CFP Antitrust Statement

Amani Babekir: I'll just remind you the conference for food protection antitrust statement is active in this call, so just keep that in mind and for your reference, it's attached to all our meeting invitations.

Framework Points

Amani Babekir: The first topic here we wanted to discuss is the draft of the Equal Consideration Section. They really took their time to write down this draft and I would like to get your opinion on it and see if we need to make any changes to it before we add it to the framework draft. I'm going to share my screen and if you have an issue following on the screen – you could open the documents I sent out. Can you see my screen?

Michelle Hill: Yes.

Amani Babekir: You can see here the documents – Vy is not able to join us today for this meeting, but you could provide your comments about this document. Please let anyone into the meeting as I'm not able to do that while I'm sharing my screen.

First, a summary about the allergens. And then in the knowledge section, just pointing out the sections we have in the framework. Here's handling the cross contact. And then food preparation and understanding the label - it's More like a generic thing, but that which could be used in food pantries and food banks. Just open it for your discussions if you have any comments. Any suggestions? And do you think this is sufficient to meet the charge? Consider this section: Equal Consideration

Devin Dutilly: Thank you again for welcoming me and thank you for all the hard work that everybody has put into this document and all the other work. I really appreciate it. And I think everybody on the call does as well. Could you just give a little background for the equal consideration in this document and how it's going to fit in with the rest of the framework?

Amani Babekir: I can - let me share the charges.

Devin Dutilly: Yeah, that would be great. Thank you very much, Amani.

Amani Babekir: Here is the first charge which is talking about developing a framework for the food facility and they said that they needed to consider several points and one of these points is F. And on that one, it says equal considerations for alternate food sources such as food pantries, food banks to ensure equity and access. And during our initial discussions, we felt like we needed separate subgroups to develop contents for each point. But for this one, one or two of us could just compile a couple of graphs and couple of sentences that will address these equal considerations.

Erin Moritz: If I'm remembering correctly, the purpose of subsection F was really to make sure that what we end up submitting is helpful not just for retail food establishments, but for also these other kinds of establishments. Is that correct, Amani?

Amani Babekir: That is what I understood, yeah.

Erin Moritz: Through the lens of knowing that a food pantry or a food bank might experience additional challenges beyond what a retail food establishment experiences or maybe just different challenges, not necessarily more.

Amani Babekir: Any additional point about the understanding of the f part of the charge?

Devin Dutilly: That's helpful. Thank you.

Amani Babekir: Based on this we felt the need to have just a separate minor section that addresses these facilities.

Devin Dutilly: If we go back to the definitions that we used, and if we do choose to use the definition from the food Code on food establishments, the facilities that are mentioned above would be encompassed in that definition. It depends on the definition this document chooses to go with, but if we are using the food code definition, the FDA would likely have comments on that, making a distinction between this type of establishment having different needs than another type of establishment. Although there is a distinction between the establishments I think when it comes to the requirements within the food code, the requirements would hold for both of those types of establishments because they all fall underneath through establishment, and if we could apply it to all food establishments So I don't think there's an objection to creating this, but just a just as a note, the food code covers to all of these, and so anything that would apply to one would also apply to the other.

Amani Babekir: And it seems from the developed draft here, most of the components refer to specific pages of the framework which we already developed, so other than understanding labels, seems like this is a different section here. Do we think that when it comes into the preparation and the training and knowledge and handling, the cross contact, do we need a section, a separate section? What are the equal considerations?

Ben Wagner: I'm not sure that we do. Looking at this - the understanding labels - is that to train the staff members to understand labels and if so, would we not use that elsewhere for retail food establishments to understand the labels of their ingredients? I don't know. To me this seems like we're reiterating, just to reiterate. Is there anything in here that is novel to food pantries, food banks, etcetera?

Erin Moritz: I think when we very first started discussing this, two of the main points were, just concerns, maybe additional difficulty communicating with the patrons, and then also having volunteers who maybe have less of a background in food safety. Someone will have to remind me if there were other concerns. I think what we have probably covers it technically, but I'm wondering if It may be good to call out those considerations at the beginning of this particular document, and I like the idea of pointing out specifically where they can go in the document to address those issues. And I don't - is there anybody from the group who worked on this document on the call?

Amani Babekir: We don't have an actual subgroup for this part of the charge.

Erin Moritz: OK.

Amani Babekir: I think there was Jennifer with her, but we couldn't recognize which Jennifer. Not sure if there is anyone who volunteers on that subgroup or that team …

Erin Moritz: It'd be interesting to me to see if she found some sort of resources pointing out specifically additional or different challenges within the food banks, and maybe there's not, but if there are additional or different challenges than it may be worth pointing those out at the beginning of this section

Amani Babekir: OK. Any additional points on this?

Ben Wagner: It's minor, but where it says for food is prepared on site I would say for foods prepared or repackaged on site.

Erin Moritz: Yes. This reminds me - that was another comment made way back - that a lot of these types of facilities will have a package of crackers or something that they'll open and repackage for distribution.

Crystal Eisner: Understanding labels from manufacturers of packaged food. And then are required by that too -

Amani Babekir: OK. And do you think understanding the label is it an important piece to add to our framework – should be considering adding it to the whole framework? Seems like it's ...

Crystal Eisner: It's general information. I think it's good to understand the label. As far as may contain or production facility – this is maybe, overall concern, not just this area - is this anywhere in our framework?

Amani Babekir: Yes - it's not. I don't think we have detailed information about understanding the labels.

Erin Moritz: I think if we did want to keep the section, we'd have to tie it back to specific challenges in in food banks or food pantries.

Amani Babekir: But would it be worth adding it to the whole document? Especially this program just understanding the labels?

Crystal Eisner: Alright.

Erin Moritz: I do like the that bullet. Eat all that differentiates. Contains versus may contain. I think that's worth putting in the main body of the document

Crystal Eisner: And just like the common allergies can have other names, for example. But for the dairy, the casein and so forth, unfortunately, we had a little girl where my daughter goes to school. Her grandmother bought her something online - juice that said dairy free, but it can't contain casein - and she actually passed away from a severe allergy. Yes, I think that's a good. Sorry, I haven't gone through all the bullets, but if we have not stated that elsewhere, I think that it is a good idea to.

Amani Babekir: OK.

Michelle Hill: I just wanted to mention I'm back finally. FYI and, if you were speaking about casein being listed, I'm all for it. It's necessary

Amani Babekir: That's good.

Devin Dutilly: And just as a general comment - we would, the cautionary, the PALs, the cautionary allergen labeling that is listed here - this is not something that we have issued a specific guidance on. It's not something that we would comment on or you use it, something that could be in lieu of good manufacturing practices or cleaning sanitation practices within a retail establishment Thank you.

Amani Babekir: Thank you.

Erin Moritz: I'm wondering if it's worth adding something? Another bullet, - something to the extent that Devin just said, note that simply saying something may contain an allergen is not an acceptable alternative when trying prevent cross contact.

Ben Wagner: So, was the concern that a food shelf would be labeling something themselves? Is that the concern?

Erin Moritz: I just don't know enough about food pantries and food banks to really know the best content for this section.

Devin Dutilly: We have a representative on the call here that is part of one of those groups or a represents one of those groups, I think Vincent, Scott - he represents a lot of large facilities - is he on the call? I think he had some comments about other groups he represents and I think you captured a lot of different groups that are in his organization as he happened to be on the call.

Amani Babekir: He's not able to attend.

Devin Dutilly: Probably valuable. OK. Any anybody else who represents those groups or have a large of volume?

Michelle Hill: I can speak from a person that's worked in the food bank before and it's not that we would label necessarily on the shelf that something has an allergen, but we would definitely be wanting to help assist them to determine if a packaged food did. And in this case, I believe we're talking to the presence of casein and not dairy or not lactose. You know, understanding what the true allergen is. And I think that's what we're trying to get at here is that. Does that answer part of your question?

Ben Wagner: I think quite honestly, we're all over the board on this. There's been comments about the fact that it may contain statement does not give a production facility a get out of jail free card for doing proper GMP, which production facilities understand. I don't know if food shelves do - I don't know if food shelves – that if they break something down and repack it, put their own labels on it or not. I think this is good information for anybody working in the Food service side of things, whether it's a food bank or a restaurant. Well, the question is, Is this information good information that should be for anybody reading the document and then we can refer back to it when we're talking to food service or not food banks specifically, or this equal considerations portion? Specifically.

I have an additional question. The bolded statement above – The understanding labels says have a staff member that's knowledgeable about allergens. Review the ingredients on the label with the customer to ensure … You wouldn't expect somebody to do that in a grocery store? Would you expect somebody to do that in a food bank?

Amani Babekir: OK, so I'm going to highlight this section here to discuss it later. Michelle, would you like to proceed - if there is any extra discussion on this and then move to voting on approving the Minutes.

Michelle Hill: Absolutely. I'd be happy to, Madam Chair.

Amani Babekir: OK, so please continue the discussion if there are any extra points regarding this part. And just to give you an update about the framework right now, we are in the process of sending it out to the template team and the target date is May 4 - we will compile it send it to the template team after we review it with the ServSafe comments.

Michelle Hill: Thank you, Amani. One quick question, Amani, what we have remaining then is to decide about this document, as far as closing discussion, and then voting on the previous two meeting minutes and then we adjourn.

Amani Babekir: That's correct, yes.

Previous Meeting Minutes

Michelle Hill: What is the will of the people present here? Would you like to continue the discussion on this document? I'd like to entertain a motion to either continue to discuss or to table it until we have more information about this particular section.

Ben Wagner: I put out a motion to table it until we have more information.

Michelle Hill: Thank you. Ben, do I have a second?

Darby Greco: This is Darby. I'll second that.

Michelle Hill: Thank you, Darby, so noted. We will reach out to Vy, and perhaps the next time we come around to this, we'll have her on the call. Thank you for your patience on this, everyone. I apologize for my absence from the meeting. I don't really know what happened, but that's what the transcript is for, right? At this point, if you could please pull up, and if need be, review the minutes from the previous two meetings. We had a request to make a correction to the document. What we would like to do now is take a moment to review those and then we'll come back. And I'd like a motion to be made possibly for us to approve those minutes as they appear or whatever discussion needs to ensue about the Minutes. So let's take 2 minutes to review those documents and hopefully everybody got them – Amani sent them out pre meeting.

Michelle Hill: The meetings that the Minutes that we need to approve start on page 33, this is meeting number 11 and it was held on March 31st and there were edits. There were a couple words that were edited, and corrections made. We were asked to hold off on approving these minutes until people could see those updates. And so that's what this document is. It runs through page 40.

Michelle Hill: And then the next set that we need to approve are from the meeting we had two weeks ago, April 14th, and this is the first time we were attempting to approve these minutes. they're quite long. These meaning there's got to page 49, 41 to 49. When you feel comfortable, if you'd like to make a motion to either table or to approve or whatever …

Ben Wagner: I motioned to accept both sets of the meeting minutes

Michelle Hill: Thank you, Ben.

Ben Wagner: As written.

Michelle Hill: So noted. Thank you, Ben.

Crystal Eisner: Then what was your motion? Sorry, I missed it – was reading.

Ben Wagner: I was moving to accept both sets of meeting minutes as written

Crystal Eisner: I second that.

Michelle Hill: Crystal, Ben, thank you. We have a motion on the floor if you would like to vote.

Michelle Hill: Unless I see or hear a number or an abstain. I will say that this motion passes to approve minutes. From both meetings as written Alright, I appreciate that. Thank you so much.

Meeting Adjourned

Michelle Hill: As usual, you guys are a great team. I really enjoy being part of this committee and I'm really very pleased to see the level of attendance at today's meeting and I look forward to seeing everybody again in the next two weeks when we meet again. Please feel free to reach out with any questions, comments, and concerns, and when you do send communication, please make sure you include both Amani and I on that email message If there's nothing else, I would like to adjourn this meeting.

Next Meeting set for Thursday, May 12, 2022.

Erin Moritz: Hey, thanks everyone!

Meeting Number	Meeting Date		Meeting Time
14	**05/12/2022**		2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Amani Babekir
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iv.	CFP Antitrust Statement	Amani Babekir
v.	Framework Points	Amani Babekir
vi.	Previous Meeting Minutes	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

Meeting Call to Order

Babekir, Amani: I now call this meeting to order. I will proceed with the roll call.

Roll Call

Babekir, Amani: [takes roll call of voting members] Let me count – So we have 8, missing one for the quorum.

Hill, Michelle: I see a Wendy Bell on the call - do we know you? I'm sorry. I don't mean to be rude. I don't recognize your name.

Bell, Wendy: Hi yes, I don't know if you saw Courtney's email, but I was moved into the vice chair role.

Hill, Michelle: Oh! Welcome!

Babekir, Amani: Welcome to the Committee, Wendy, we're glad to have you with us.

Hill, Michelle: Can we count her towards our quorum?

Babekir, Amani: Yeah, I don't think so. I wish we could do that.

Bell, Wendy: No, no.

Babekir, Amani: We can proceed with the with the agenda and then by the end of the meeting, if we have a quorum, Michelle if you see voting Members waiting to join our meeting that might help meet our quorum.

Hill, Michelle: Good.

Scribe – Michelle Hill agreed to take notes that will be verified via transcript issued by Teams.

This meeting is now being recorded.

CFP Antitrust Statement

Babekir, Amani: Thank you. And just I would like to remind you that the Conference for Food Protection Antitrust statement is active in this call. So just please keep that in mind during the discussions and the activity in this call.

Framework Points

Babekir, Amani: The next thing here in our agenda is to give you an update about the framework.

Babekir, Amani: I sent out the framework to the templates team along with the definitions, and I am so glad that we have Ben us today. I wasn't able to join the initial meeting, so hopefully Ben will be able to give us an update of the progress.

Wagner, Ben: You want that now, OK. So the team has met, we took the three documents that were provided by the larger committee.

The main framework, the definitions and the additional thoughts for food banks, etcetera. Sorry, I'm not thinking of the official titles. Anyway. We started to put everything together. We're going to place the definitions at the end of the document. We are currently working with pulling information throughout the document for the purpose and scope of the overall document as well as an introductory paragraph to the rest of the work.

We'll continue to meet on this about once a week through the rest of the month and then we're hoping to have some progress that we can show back to the group.

Babekir, Amani: Do you have any questions or do you need any extra volunteers to help with the work?

Wagner, Ben: I feel like the group that we have is pretty good. We will probably be bringing things, as we as we look at what we can clean up in the document, one thing that we did note is that nine major allergens are listed repeatedly throughout the document. Now we are thinking we can make the document shorter by having that laid out in the beginning of the document and then referencing back to it.

But we wanted to bring that to the various groups that had created their portions just to verify that they are with that they didn't have a reason for calling them out again in full list.

Babekir, Amani: Thank you. Thank you, Ben. There is any questions or comments to them?

Babekir, Amani: We can proceed to the next item on the agenda, which is the equal considerations document.

I know in our previous meeting we did not complete the discussion on this topic; we wanted to get more information from Vy Truong.

The information she gathered on the document – if she sees something that is different than the larger scope of the document we created, which related to them Equal consideration and the food banks. So that is one of the questions we had for you. What's your thought on it?

Truong, Vy (VDH): Hi - I tried to skim through the meeting notes right beforehand and I see that you guys made some good suggestions. Thank you. I don't have a lot to add, I'm not actually very familiar with food banks. I just wanted to make sure that this topic wasn't dropped, so I volunteered to get something drafted. And yeah, I noticed that I do reference the document a lot because I didn't want to be repetitive and so I felt like the only new thing to really add would be reading labels - however you guys want to incorporate that.

And I was thinking that for food banks, they might not want to read the whole document depending on how long it ends up being - that maybe they could pull just that portion.

I guess I'm still not sure exactly how the framework's going to end up working at the end; if it'll be like pullable sections like that could just be dedicated to other types of food service, or food banks for example, and they could pull those couple of pages and not have to sort through everything. So however, you guys want to put it together in the final stages of this, is perfectly fine with me. I'm not committed to anything in particular. I do think that some food banks prepare food on site, so a lot of the stuff that we had already created was great for that. And then the only new thing I thought that was really important was to understand those labels. So, if you guys have suggestions on rewording that or things that take away or add, feel free to do whatever you guys want with that draft.

Babekir, Amani: Thank you. Michelle collected very good suggestions about this section – Michelle?

Hill, Michelle: Thank you, Amani. I have a compatriot here in Minnesota - his name is John Carrillo, and he just retired from Aramark. He's been in food for a long time. He's been dealing with food banks in and out throughout his career. I did just speak with him briefly about what we had in our framework. And he responded very nicely to me. He pointed out that the best time to give allergen information would be when the person is picking up their food and it could be as simple as a slip of paper mentioning that the food they're received may or can contain food allergens, and that it may cause an allergic response, and again that could be based on what's in the actual container or box or bag, whatever they're collecting it in. In particular he deals with Second Harvest, which is a big outfit here locally. I don't know. I think their nationwide, but he says that they as an entity, they do a good job letting volunteers who sign up for corporate community days or general volunteering, where they pack bulk foods, they repack bulk foods. They're very open about the fact that they may contain allergens and ask people that have known allergens to do something else, so they enforce strict hand washing. They change aprons and gloves between tasks. People who may have an allergic reaction are given tasks away from handling that bulk food. So the big piece that I think we may want to add to this would be like what Vy said, maybe it's a simple sheet of paper that would tell them real quick. These are the allergens in your box. I don't know. Maybe that's too specific, but that's the feedback I got. I know it's one person, but that's what I have. Thank you.

Babekir, Amani: Thank you, Michelle. Any comments from the team?

Truong, Vy (VDH): Yeah, I think that that's great, because if we make it too complicated, it's just going to get lost. Some sort of handout? And I don't know how to do that because food banks are so varied. If it is one sheet of paper - should we list all the allergens? Because, it's not going to be able to be specific to a box because we don't know what is going to be in each of the boxes. I'm not really sure I haven't handle that.

Hill, Michelle: If I may - what he suggested - it would be as simple as, we provide them the nine allergens like as a grid and they would just check the box if they know that there's a known allergen. And so it would be really be a simple sheet that would say, here's the nine allergens check which ones are present and maybe even a half sheet that they just throw in the box and say be aware. That doesn't have to be what it is, but that's what he recommended.

Truong, Vy (VDH): I think that's a really good idea, but it's also really important to remember that some food banks like his are really big and really well organized, and some are a lot smaller. And what if they miss one of the allergens? Just because they're not aware, that could be pretty dangerous if someone was like, oh, there's no wheat, and there is.

So, I don't know somehow whatever we create, just making sure that we address - maybe giving them a checklist, but also addressing that there could be unknown allergens.

Hill, Michelle: I think that's excellent - that they, we, would note that the other thing he said is that when they do break out the bulk food, if it is allergy, they label it for allergens and again, like you're saying, this is Second Harvest, so big dog, but it's good advice.

Babekir, Amani: So are we good with having a section for the equal consideration in the Framework?

Wagner, Ben: I feel like it it's a good idea.

Hill, Michelle: I do too, yes.

Truong, Vy (VDH): I agree.

Babekir, Amani: Ben, would you like to take the effort of adding this section , with your team, to the framework?

Wagner, Ben: I think we already had decided that we were going to do something like that. Yes, with the information that we already have, plus if we get any other Experts that we can talk to that might have further information we want to incorporate and then we can bring that back to the larger group to approve.

Babekir, Amani: OK. Vy, would you like to join to join these efforts?

Truong, Vy (VDH): Sure ,I can. Or, if you just need anything from me, just feel free to reach out.

Wagner, Ben: I think we'll reach out if we need you. How's that sound?

Truong, Vy (VDH): Sounds perfect.

Babekir, Amani: That sounds good. Thank you very much

Babekir, Amani: Michelle, you could forward those comments to Ben so he will have it in his records?

Hill, Michelle: Yes, I am also on the template committee with Ben. So yes, will do.

Previous Meeting Minutes

Babekir, Amani: I think that is all the items I have in the agenda today. We are going to postpone the voting for approving the Minutes until our next meeting. Are there any additional thoughts or questions about the progress of the work, or any other thing?

Hill, Michelle: Amani, if I may - please take the time to review the meeting minutes and if you do have changes let me know prior to our next meeting and we can get those put in so that we can approve, you know have an easier time of approval if there are needed changes.

Meeting Adjourned

Babekir, Amani: OK. I think that's it. We made a very good progress and I think we're going to make our deadline, which is the end of this month, so we can send it out for the FDA to review, and hopefully by July we'll have our framework complete, and then we will proceed with what suggestions we have for changes to the Annex to the FDA Model Food Code. Thank you everyone. Hopefully see you in our next meeting. Next Meeting is set for Thursday, May 26, 2022.

Meeting Number	Meeting Date		Meeting Time
15	**06/09/2022**		2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

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vii.	Adjournment	Amani Babekir

MEETING MINUTES

Call to Order

Babekir, Amani: This meeting will now come to order. Michelle, would you like to do the roll call today.

Roll Call

Michelle Hill (Co-Chair): Certainly. Thank you. Madam Chair, we have a quorum of nine.

CFP Antitrust Statement

Babekir, Amani: OK, that's great. Thank you, Michelle. We just want to remind you that the Conference for Food Protection antitrust statement is active during this call, so let's just keep it in mind and we can proceed to the first item in the agenda, which is approving the last meetings minutes.

Previous Meeting Minutes

Michelle Hill (Co-Chair): Madam Chair, I cancelled the May 26th meeting we would have had two weeks ago because it was the day before Memorial Day weekend, and it was not a date that was listed on our master schedule. Today we need to approve two sets of previous meeting minutes.

Babekir, Amani: Two sets, OK.

Michelle Hill (Co-Chair): I do believe so, as we did not have quorum for the most-recently held meeting, and we couldn't vote on the previous meeting because there had been edits to that set of minutes that needed to be reviewed and approved.

Babekir, Amani: OK. Thank you, Michelle, for reminding us of this. Let's review the last two sets of meeting minutes as part of the documents which I sent out yesterday. I will give it 2 minutes so you can go over it before we vote.

Michelle Hill (Co-Chair): Madam Chair, just for clarity's sake, we will be voting on minutes from the meeting from April 28th meeting #13, which beings on page 47. The second set of meeting minutes is for the May 12th meeting #14, begin on page 53.

Babekir, Amani: Thank you, Michelle. OK. I will entertain a motion regarding the minutes of the last two meetings.

Michelle Hill (Co-Chair): Madam Chair, shall we entertain a motion for just the meeting minutes from April 28th to start?

Babekir, Amani: OK, let's do that.

Ben.Wagner: This is Ben. I motion to approve the meeting minutes from April 28th. Thank you.

Michelle Hill (Co-Chair): So noted. Thank you, Ben.

James O'Neal: And this is James. I'll second the motion.

Michelle Hill (Co-Chair): Thank you, James O'Neal, so noted.

Babekir, Amani: Thank you. Is there any discussion on the Minutes, any questions? No? Let's proceed to the vote on the motion. Is there anyone opposed to the motion? Please raise your hand. Do we have anyone abstaining? The motion passes to accept the Minutes as is. Thank you. So now I will entertain a motion regarding the minutes of the last meeting.

Ben.Wagner: This is Ben again. I move to approve the meeting minutes from the last meeting.

Michelle Hill (Co-Chair): Thank you, Ben, so noted. The meeting date is May 12th that we're speaking about.

Vinson, Scott: I second the motion.

Babekir, Amani: Thank you, Scott.

Michelle Hill (Co-Chair): So noted.

Babekir, Amani: Is there any discussion on the Minutes? Any questions? Thank you. Let's proceed to the vote on the motion. Is there anyone opposed to the motion? Please say no or raise your hand. Do we have anyone abstaining? The motion passes.

Framework Points

Babekir, Amani: OK, so now we will move to the second agenda item. I would like first to start by thanking the template team. They put together the framework, the different sections in just one document and they went over it and investigated creating additional sections, like the Introduction and the Table of Contents.

Devin Dutilly (FDA) is going to lead the comments regarding reviewing this document. He will have an internal review of the document and we are hoping that we're going to get FDAs comments by July 15. I'm going to give the floor to Ben, and all of you, to discuss the framework piece by piece. But I would like to bring up to you one of the suggestions which I received. Amber suggested that the document is very long. It might be very useful to small restaurants. And we probably need to create a kind of handout or more concise document than this one.

So first we want to discuss this point before we go into discussing all the sections of the unified document. What do you think about this suggestion? Yes, Michelle.

Michelle Hill (Co-Chair): Thank you, Madam Chair. I think it's an incredibly good point. I personally would recommend that we keep our long document but develop something that maybe is a single sided or a double-sided sheet of paper and perhaps it's as simple as we have a nice set of icons or pictographic representation of symptoms of allergy, as well as icons for representing allergens. Thank you.

Babekir, Amani: Thank you, Michelle. Yes, Erin?

Mortiz, Erin: I'm a big fan of more pictures and fewer words. Before we get started on that, it would be good to formalize what perspective we want this document to be from. We kind of ran into some of this when we were formatting it, but right now I think it's sort of written as an educational document. In some sections I think the original idea was to make it a template that an establishment could either print out or use or fill in their own information if they wanted to do something different than what's already in the document. And I think some sections are a very high-level list of, we should be including this in an establishment's plan. I think nailing down what perspective we're coming from and exactly how we want the establishments to be able to use this. We might want to establish that first before we do anything else.

Babekir, Amani: Thank you. Yes, Amber?

Amber Potts: Hello. So let me explain what I'm meaning. I like the framework and I think we should keep that document, but in addition, a smaller like pamphlet-type thing and I'll show you something I did to give you a visual, but just from experience – for the majority of small businesses, English isn't the first language. These second-language speakers may have a very difficult time implementing this or even understanding it.

Just even personally, I got about 14 pages in, and I had to stop and do something else, then come back to it because it's just a lot of information. I do think that the document could be trimmed down a little bit. I think there's some repetitive spots. Can I share my screen and give you an example of what I was thinking about?

Babekir, Amani: Yes, please.

Amber Potts: OK, so you may have seen these business plan type things, but just a quick flip through pamphlet of what this document says on a high level, of course, this isn't the final one, but I put together a flip book.

We could list everything here. You could see the major food allergens, and then some of them I put like casein for milk, and stuff like that.

Kind of just a more fun document, I guess to read and something that maybe is more digestible and could be easily translated into another language.

Babekir, Amani: Thank you. Yes, Scott?

Vinson, Scott: I think that's a neat and generous offer. I think it would be useful to some of the smaller establishments than even not so small. If Amber is generous enough to make the offer to create something like that, I would be in support of it.

Babekir, Amani: Thank you, Scott. Yes, Michelle?

Michelle Hill (Co-Chair): I think it's a great idea and it's I like the idea of it kind of pulling it out of being such a formal, serious presentation, not that it's not serious, but kind of like fun facts. You know, so really neat! Is that a template, Amber, that you developed that we could just plug into?

Amber Potts: Yeah. So here at NEHA and personally I use Canva. It's a website that they give you templates and then you just plug and play.

This was the one I found. It was in red. I turned it all into purple because I felt like that was food allergy, and then it popped up yellow to kind of bring attention to certain areas. Once the framework is more finalized and more final, I can basically plug and play on this document, and then send it over for review, definitely. By December this is doable, sure.

Mortiz, Erin: The goal for, we'll call it Amber's document, may be just for ease, especially like smaller establishments. Print it out and have it as a resource without doing anything to it. Is that kind of the goal with that?

Amber Potts: Yeah, that that was my goal.

Mortiz, Erin: OK.

Amber Potts: And then not necessarily even printing. It could be something digital. People could have easy access to.

Mortiz, Erin: Sure. OK.

Amber Potts: What is the access? It would be nice if we could have it translated into other languages – that would be pretty neat too.

Mortiz, Erin: Definitely agree.

Babekir, Amani: Right, thank you. And Amber, do you think you're going to need any help at any point?

Do you need an extra volunteer with you? Or you could handle it by yourself.

Amber Potts: Yeah, it would be nice to have one other person to kind of go back and forth with.

Babekir, Amani: OK.

Amber Potts: I'm not sure how to give them access into the NEHA Canva account, but it's as simple as me downloading it and doing it that way is fine too. It's going to be really relatively simple for me to just basically copying and pasting what's already in the framework. I'm not adding anything. And then Canva has a wide variety of stock photos to use, and then of course if we have any photos we could put in there, but just someone else to look at it and make sure I didn’t install anything wrong or miss copy or anything like that would be nice.

Babekir, Amani: That is cool. Yes, Scott.

Vinson, Scott: I'm happy to help with that Amber, if you like.

Amber Potts: Oh yeah, sure.

Babekir, Amani: Those great thank you, Scott. OK. Yes, Michelle.

Michelle Hill (Co-Chair): And if you wouldn't mind having a third, I am happy to help out with that as well.

Amber Potts: Yes, awesome.

Babekir, Amani: Thank you, Michelle. So that's great. We can proceed with working on our original documents and while Amber is getting ready to prepare her template for the other document and also, I think beside Amber's document, if we feel down the road, that we might need to add extra handout. Any additional documents also feel free to suggest as we could add it as an attachment to our original document.

I think now we could proceed to the second point in our agenda, which is reviewing the framework draft. Ben, would you like to lead this one?

Ben.Wagner: If you wish, so is the expectation that we're going to go through and make comments as a group or just an overview, or what are we looking for here?

Babekir, Amani: Yeah, if you could walk us through the changes you made to the document and if you have any comments or question or suggestion about a specific section, feel free to ask it to the team and then to discuss it, and then proceed to the second point on the document.

Ben.Wagner: High level, we did put a table of contents together for the document. We also put together an introduction section with a purpose and scope for the entire document.

This symbol means that there's an image available within the document that can be used. And then it goes immediately into the various sections for the charges we were given. The only changes we tried to do is to put a purpose in where it seemed appropriate. Other than that, not much has changed. I guess I was hoping the larger group would take a look at the overall flow of the document and see if, once again, like we've mentioned, if it's too wordy in spots, or if it seems not wordy enough in other spots. I don't have all the mark-up language showing here just because it is really chaotic. When you show all the markup, but the data is still there. If you want to look on Word for what markup is happened. Some of these notes that remain from me could probably be deleted. I didn't realize this version was going to go out to the whole group immediately without those being deleted. I don't have much else to say at this point, except at the bottom of the entire document we get into a short paragraph about equal consideration for alternative community food sources. I don't know if that needs to be beefed up. I would love for that group to look at this and make suggestions as to how that can be edited or changed or added to a lot of the information we were originally provided was also provided elsewhere in the documents. We kind of referred back to that. And we actually included it in another section. There was a part about reading labels. And we included that in a previous section where we thought it would fit. If that doesn't work for the entire group, please speak out. We have this Definitions Section. And then we go down to references and these were just references pulled from the various sections and concatenated, and I tried to put them in. A format that I thought looked appropriate once again, not an expert at that, so somebody else wants to take a crack at it, feel free. I'm open to any feedback people have. If you just want to let me know where you want me to focus on the document while I'm sharing, or I can stop sharing my screen.

Babekir, Amani: Thank you, Ben. Yes, Scott.

Vinson, Scott: It's been a while since I've looked at this document and now, I'm looking at it with fresh eyes again and in the food handling policies and practices section starting on page.

6, scroll down to page 7. There's a section at the top under 22D, I guess it's just new section D use ingredients that have been designated as allergen free on their packages, or otherwise determined to be safe for allergen free meals. So, in looking at this section again, I'm wondering if that should be included. If the person is preparing, you know, food service workers, preparing someone's meal they're trying to exclude specific allergens that the customers told them they need to avoid. So, if we're directing the Food service worker to do what is written in line D, does that mean they're going to be maybe confused and exclude any type of allergen, even though the customer might not be allergic to that particular ingredient? The way this reads in section D, it looks like we're telling the food service worker to just make the food, free of every major food allergen. I'm not sure that's what we're intending to say here.

Abel, Greg: No, you're intending to say, uh, not to use the offending proteins for that particular order.

Vinson, Scott: Well, that's not what it says.

Abel, Greg: Yeah, we have to somehow fix that, I think.

Vinson, Scott: Yeah, because it makes it look like they're supposed to only use ingredients that are labeled allergen free.

Mortiz, Erin: And is there such a thing as allergen free?

Abel, Greg: No.

Michelle Hill (Co-Chair): No.

Abel, Greg A: Yeah, we don't want to be making up a term here that's doesn't exist.

Vinson, Scott: Yeah, I think that section is really confusing and is going to confuse food service workers.

Michelle Hill (Co-Chair): Can we just delete it? I mean because the next statement I think is pretty clear.

Vinson, Scott: Yeah, yeah. I think we should just delete it.

Mortiz, Erin: And just for reference, this you know sort of the formatting group. Our charge was not to actually look at content. It was more just to make it flow a little bit better.

Abel, Greg: I would recommend not removing it at this point, but rather maybe rewriting it, because I think that's an important piece - using correct ingredients. I'm trying to think of what would work better there.

Vinson, Scott: Just say something like don't put anything the customers are allergic to in the meal.

Abel, Greg: Right, or maybe something like ensuring ingredients do not contain …

Dutilly, Devin: You could put free. You could put free from.

Abel, Greg: Yeah, and certainly.

Ben.Wagner: So, does the group want to bring suggestions to Scott on how that could be altered? And then Scott, do you want to take that? And once you have something you think is sufficient, bring it back and we can insert it, and change it.

Vinson, Scott: Sure. But frankly, I don't think we need specific instructions because it's superfluous.

Michelle Hill (Co-Chair): I think so too. Brevity is our friend.

Vinson, Scott: Yeah, somebody's earlier in the call said that the documents too long. I don't know, but we should be looking at parts to omit.

Michelle Hill (Co-Chair): Or that are redundant or obvious.

Vinson, Scott: Yes.

Babekir, Amani: I think here this piece is about ingredients. Have we covered anything related to the ingredients in the upper sections? You could scroll up here.

Vinson, Scott: Yeah, but I mean, it's just common sense. They've been told to avoid a certain ingredient because the customer is allergic to it. They're not going to put that ingredient in the meal, and you don't need to write it out. This is common sense. It doesn't need to be set.

Michelle Hill (Co-Chair): Maybe the intention of the statement originally was that you make sure that the ingredient you're going to use doesn't have that allergen.

Mortiz, Erin: Yeah, I was going to say if, let's say you use you use like a store-bought salsa or something. That's kind of how I took the purpose of that particular statement, although I was confused by it as well. Do we say any place else in this section to check the ingredients of the ingredients, so to speak? Or let's say there's like a sauce that goes into a recipe you have the ingredients of the recipe, but then if there's a sauce that's premade or something you also need to make sure that this sauce does not have the food allergen in it as well.

Vinson, Scott: Ohh, I think I see what you're trying to get at. So, I think the issue here is processed foods. So, if the food preparer is using an ingredient that is processed and might have its own set of ingredients, they should check them too.

Michelle Hill (Co-Chair): Isn't it two or more ingredients you must label?

Abel, Greg: That's it - yes.

Thoma,Libby: Hi, this is Libby. I just want to say, as common sense as it seems to be, I do think we need to make a statement that says, don't put allergens in the food.

Michelle Hill (Co-Chair): Yes.

Susan Algeo: Great.

Thoma, Libby: Today I went to a Taco restaurant. I ordered a Taco that is described on their menu board as being prepared on a corn tortilla. And when it came to me, it was on a flour tortilla. So, I said this is on a flower tortilla and he goes, Yes, ma'am, it is. Do you want it on corn? And I said, I do because that's how it's described on your menu board.

And he was like, Oh, OK, well, we'll fix it. But they intentionally made it not according to their advertised. recipe. So as basic as that is, I do think we need to make sure that they are following their procedures, so that the customer isn't misled.

Abel, Greg: So, what you're saying there for D is ensuring the foods and ingredients used are free of that offending protein.

Michelle Hill (Co-Chair): Correct. I like that.

Susan Algeo: Yeah.

Dutilly, Devin: You might want to consider using a term like, unexpected sources of food allergens

Vinson, Scott: I just put something in the chat that's concise and to the point.

Babekir, Amani: Thank you. Any other suggestion or comments about this point? Ben, would you like to scroll up to the beginning of the document and then we could go over the comments with the team. See their suggestions – I left peoples because I thought maybe we just need to bring them here to the team and see if they have any additional thoughts.

If any of your comments are not needed, please delete.

Ben.Wagner: Is everybody happy with that phrasing of what the term Food Service employees?

Michelle Hill (Co-Chair): I would recommend food workers because then you're including people that are volunteering.

Vinson, Scott: I agree.

Susan Algeo: I think we talked about this before. Doesn't the Food Code define a food employee versus an employee, and food employee encompasses all that food service. I can check but I think that I mean the food could have the definition, so I just didn't know if we want to get confusing.

Michelle Hill (Co-Chair): No, that's an important point.

Babekir, Amani: What do we have in the definition section then? We have one. As in food service or food employ.

Susan Algeo: I was just looking at, didn't see we have food employee. It's food employee this food handler in there.

Babekir, Amani: So do we want to keep it food employee on the whole document?

Michelle Hill (Co-Chair): Could we add a definition that's food worker that combines the employee and handler ideas? Where were these pulled from? Is this from the food code from the Model Food code?

Babekir, Amani: Yeah, that's from the Food Code.

Babekir, Amani: And we previously discussed this one as Susan said and we agreed to use the food employee.

Michelle Hill (Co-Chair): Oh, OK.

Mortiz, Erin: And do we? What was the objection to food worker? Did we? Talk about that at all. I can't remember.

Babekir, Amani: I think because it was listed under the definitions, the food employee and also, we had, I think, the food workers and then we said, it's a difference in the Food Code to make it consistent with the language of the Food Code. Let's just stick to the food employee.

Mortiz, Erin: OK. I do like food worker better at sounds a little bit more plain language but being consistent with the Food Code is also beneficial.

Babekir, Amani: Thank you.

Susan Algeo: The Food Code only has, from what I can see, food employee. They don't define food handler that I see in here, so that might have been from another source.

Michelle Hill (Co-Chair): Well, and what's highlighted on our working document here is Food service employee, so.

Susan Algeo: Right, so we show.

Michelle Hill (Co-Chair): We would move that, yeah, OK.

Susan Algeo: Probably swap that to food employee, right?

Michelle Hill (Co-Chair): Correct. Yeah, that's my assumption too.

Susan Algeo: OK.

Babekir, Amani: Yes, Amber.

Amber Potts: The question under scope right here, isn't all of this covered in the table of contents? Do we need to say it again?

Ben.Wagner: I'm sorry, what's covered in the table of contents.

Amber Potts: Uh, where it says scope. The document covers these topics. You go to the table of contents. You can see what the document covers. I don't know if we need to say it twice.

Susan Algeo: I think when we put it together, Ben and Erin, correct me if wrong. I think we were just trying to match other pages that had the purpose, scope and intro, so I think we're just following that concept.

Amber Potts: Ah, I see.

Mortiz, Erin: I'm fine with deleting it.

Susan Algeo: I mean, I am too, except for just keep in mind, I don't think most people read a table of contents. They might just jump into it. But agreed there's some repetition in here.

Mortiz, Erin: And I'm not sure lay audience is going to understand the difference even between a purpose and a scope.

Vinson, Scott: I don't understand the difference.

Amber Potts: Yeah, I think we need to be cognizant of our audience. I mean, high up corporate food safety, they're going to understand this. But that's not the majority of restaurants. But then again, the additional pamphlet we're going to put together may alleviate that. I don't know what the best thing to do is.

Mortiz, Erin: And I vote for deleting the scope from the introduction, with my non-voting member vote.

Vinson, Scott: I support that.

Michelle Hill (Co-Chair): I do as well.

Susan Algeo: Amani. Did you say that FDA was going to look this over? Once we've completed stuff and they're going to give us feedback or they have a current document?

Babekir, Amani: They have the current document, is that correct, Devin?

Dutilly, Devin: Yes, the document that was sent out on 6/6. So that document is the one that's been used for comments? That's what we're currently using.

Susan Algeo: We just want to be careful if we change too much, then uh, we might need to wait for that feedback.

Babekir, Amani: Yes.

Amber Potts: So I guess I wasn't here for that meeting. We sent this to the FDA to review. OK.

Dutilly, Devin: Sorry I didn't announce myself – I am Devin Dutilly with the FDA, with the with staff here. I've been one of the consultants along with Greg Abel. And then we also have CDC consultants on the call and then USDA representative as well. So we've all been kind of participating with and engaging actively across the board here so I think, we're just taking some time to provide some comments from other individuals within our agencies as well as just looking at the document now that's been put together in a complete framework.

Amber Potts: Yeah, that just makes me nervous cause it's I don't think it's written to the level that the FDA would - if the FDA was our audience, this would not be sufficient. It's not written like code language either, which I know it's not code, but it's OK. I'll just wait for the comments.

Dutilly, Devin: I think these comments are helpful, right. So I think it's great to work through questions, concerns within the group, so I think that's been fruitful discussion right now. I don't think that you should be discouraged from commenting right now.

Michelle Hill (Co-Chair): We actually might be like minded on what we want to change.

Susan Algeo: Umm.

Amber Potts: I think one other quick comment I had is just an editing thing. When we say major food allergens, sometimes we capitalize all the M and the F and the A and sometimes we don't. I just think we need to be consistent throughout.

Abel, Greg: Agree.

Vinson, Scott: Makes sense?

Babekir, Amani: Thank you.

Michelle Hill (Co-Chair): I did want to ask the larger group here under the intro, the first statement declaring that it's an immune system overreaction to a food protein isn't the fact that the immune system is reacting at all the problem? It doesn't necessarily indicate overreaction, it just means it's reacted. And it maybe it doesn't matter, but it did bother me …

Abel, Greg: Where are you? At what paragraph?

Michelle Hill (Co-Chair): There you go, you've highlighted it – Overreacts. It's the fact that it's reacting at all, that is the problem is it's not an overreaction, it's just a reaction.

Mortiz, Erin: Well, it's.

Amber Potts: Yeah. And it's written differently down in the emergency section, the sentence is written twice in different ways. I notice that as well.

Mortiz, Erin: So I think. In in my mind it it's an overreaction because it is reacting to something that's harmless.

Michelle Hill (Co-Chair): I see.

Mortiz, Erin: I can't remember if I was involved in writing this sentence or not. I do kind of like the overreacts because it adds a little bit more urgency.

Babekir, Amani: So what do we have?

Vinson, Scott: Given our intended audience is food service workers, maybe we can just avoid the issue altogether by just saying, People who have allergies to certain foods must avoid those foods in order to avoid getting very sick. Something like that. You don't really need to explain the medical issue, they just need to know that it that it makes him sick.

Babekir, Amani: I agree with that, and we already have a definition for food allergy in the definitions or technical definition. So you could use a simple term here.

Michelle Hill (Co-Chair): We could say something such as a food allergy happens when a person consumes a food they're allergic to.

Mortiz, Erin: That to me is kind of circular.

Michelle Hill (Co-Chair): It is.

Abel, Greg: Right, I think you want to be kind of prescriptive of what it actually is because you know, people need to get educated at some point to actually know what it is to so they can react properly. You know to make it so simple, might belittle the importance of it maybe.

Mortiz, Erin: Yeah, I remember having jobs as a teenager and a young adult. You know, there's always that little voice in the back of my head, at least where I just wanted to know why, otherwise I wasn't going to take it seriously. I think having a medical line about it is helpful, because otherwise it's just like, well, now you're just telling me what to do by saying they can't be exposed.

Michelle Hill (Co-Chair): To speak to that point too, Erin, I think that also it's such a muddy play, the definition food allergy is - people don't all agree on what it means. We have people tell us all the time they got an allergy, when really it's an intolerance.

Mortiz, Erin: Yeah.

Michelle Hill (Co-Chair): So I do like having clarity around the terminology because it it's a big difference between.

Mortiz, Erin: Right.

Michelle Hill (Co-Chair): You're not going to drop dead if you have an intolerance, so.

Babekir, Amani: So we have in the definition section, we have like two long sentences explaining the food allergy. Maybe we need just to look at it and see exactly how we want to rebuild it and bring it there - the section which we are discussing now.

Michelle Hill (Co-Chair): If I may real quick, I just realized we could delete that entire first sentence and still have a very good introduction.

Mortiz, Erin: Yeah. I mean, if we define it elsewhere in the document. Yeah, we could just start the intro at approximately … We just have to define it somewhere in the document, which I think it should be in the definitions table.

Vinson, Scott: Yeah, I have to jump off in just a few minutes and I'm I wanted to ask the group about a couple other things I found in on page 7. Before I have to jump off, I'm wondering if we've included things that maybe shouldn't be there on page 7, at the end of Section 4. It's right above taking food to the customer. That line, wash your hands with soap and water before touching anything else if you have handled a food allergen. Wondering if that is needed there, because presumably the food worker has just finished preparing and allergen free meal so do we need to direct them to wash their hands again?

Babekir, Amani: Before.

Vinson, Scott: Right after they just washed the equipment. It seems like an extra repetitive step that might annoy people and be unnecessary. What do you think?

Michelle Hill (Co-Chair): I would strike it, I don't see that it has a purpose either. It's not logical flow.

Vinson, Scott: Yeah.

Susan Algeo: Yeah, we're saying the meals complete then, yeah. They would move on to the next one and that step wash their hands.

Vinson, Scott: I don't know how it ended up, but it ended up there if I if I put it there, it was my mistake.

Susan Algeo: And we love encouraging people to wash their hands!

Babekir, Amani: Have we mentioned washing hands before preparing the meal on step number one?

Abel, Greg: Yes, that's the problem.

Michelle Hill (Co-Chair): Yes, it's always the first thing, hopefully.

Vinson, Scott: Yes, it's 4B.

Vinson, Scott: It looks like we can just get rid of 4 (i) and then my next question before I have to run. In Section 5, taking food to the customer, 5E, Review procedures and retrain the staff who prepared and handled the meal on these procedures before allowing them to remake the customers meal. OK, so I'm just seeing I've been in these situations before where I've been the customer. I've been very diligent about telling the person who took my order about my gluten intolerance and the meal comes out and it has gluten in it and I get the waiter's attention, or take it back to the counter and tell them about it. If they must, it's already taken a lot of time, and if I'm eating with other people, they're like halfway through the meals by this point, if the person who has to prepare the meal has to review the procedures and be retrained by someone. Again, before remaking my meal, it's going to take forever. And at that point, I mean, I've been in these situations where I've they bring out the meal, it takes them so long. By the time they get it to me, everybody else in my dining party is already done. And I just say sorry, you know. Thanks, but no thanks. We're going to leave. So I'm wondering if that should be omitted there and or saved for a later step because you want to get the meal by this time you've annoyed the customer because you've brought out a meal that has the allergen. So you want to remake it quickly. Of course, it's important not to screw it up again, but reviewing procedures and retraining that seems a little time consuming.

Michelle Hill (Co-Chair): Perhaps, Scott, we could say something such as corrective action must be employed and that corrective action phrase to a CFPM would be I'm retraining as I go. We teach to correct as you go, and maybe that's the intention of that part of the statement.

Vinson, Scott: Or yeah, or you could just put something in the preceding clause from in the previous sentence. Offered to remake the meal, allergen free, for the customer or something like that. But if I'm the customer, I don't want to wait until the person gets retrained, you know? Or it'll. It'll take too long.

Michelle Hill (Co-Chair): That or if you go to a sub shop and ask for gluten free bread in the middle of lunch and they break the machine down so they'll clean the slicer ...

Baldwin, James: Should not be referred to as a follow up corrective action.

Michelle Hill (Co-Chair): I beg your pardon. I think that's how we teach it.

Baldwin, James: Should that be referred to as a follow up corrective action? So not scarily good in process, but doing it as a corrective action after.

Vinson, Scott: Yeah.

Vinson, Scott: Yeah, I wouldn't use the words corrective action cause it sounds too formal and again we need to remember our audience here. I would put it in conversational language. Umm, but you know it can be added as a step.

Vinson, Scott: If after you deliver the allergen free meal, remade allergen free meal to the customer, then make sure that everyone knows the proper procedures.

Babekir, Amani: Or maybe we just need to delete before allowing them to remake the customers meal?

Michelle Hill (Co-Chair): That's exactly what should happen.

Vinson, Scott: Yeah. OK, thanks everyone for indulging me. By jumping ahead. I've got to run. Good luck.

Babekir, Amani: Thank you, Scott.

Michelle Hill (Co-Chair): I suspect that that whoever worked on this phrase was hoping that we would have this be a teachable moment, is probably the intention there.

Babekir, Amani: That is true. So, Ben, are you good with this one? Do you like to remove just Before allowing them to remake the customer meal, maybe you could add that on your comments there.

Ben.Wagner: I'm sorry. Can you send me the language you would like? I'm not making any changes on this right now. I'm just putting everything in comments. Initially, when our team went through this, the content we weren't concerned about it. So I feel like, if you guys want contact me, the groups that created the individual section content can make the changes.

Michelle Hill (Co-Chair): It's a good point, Ben.

Mortiz, Erin: Yeah, I would rather have the groups review their own sections again and send us the changes - like I said, we really did not look at content in the formatting group.

Michelle Hill (Co-Chair): Not at all, Ben. I think that what we could set how to satisfy this possibly would be to state in your comment strike before allowing them to remake the customers meal. That's the recommendation currently is what's in front of us.

Babekir, Amani: OK, so it seems. Thank you, Ben. It seems we are running out of time. So what we could do? I'm going to give it extra one week for you to review. And if you have any comments to add it to the document. And then I could send it out to the teams so they could go over their sections and make the needed changes. Does that sound like a good plan to all of you?

Michelle Hill (Co-Chair): Amani, just for clarity, does that mean when you say extra week, can you clarify?

Babekir, Amani: Yes, because I haven't received a lot of comments on the document. So I'm going to give it extra week or maybe two weeks. By then we will also have the comments from Devin and his colleagues. And please try to give it some time to go over the documents and make any comments about any suggested changes or any formatting we need to consider. After two weeks, I will send it out to the original subgroups so they could work on their sections and addressing those comments. That sounds like a good plan.

Michelle Hill (Co-Chair): Thank you. Yes.

Babekir, Amani: I'm going to give you one week for you to go over it, add your comments and suggestions before I send it out to the subgroups to work on editing.

Michelle Hill (Co-Chair): Our directive at this point is to provide you with our comments on the document as it is and then they'll be compiled and then we'll return it to committees, subcommittees to discuss and change.

Babekir, Amani: Yes. OK.

Thoma,Libby: Thank you.

Adjournment

Babekir, Amani: So thank you everyone. Thank you and have a good rest of the week and nice weekend.

Meeting Number	Meeting Date		Meeting Time
16	**06/23/2022**		2:00 pm EST
Co-Chair; Meeting Chair	Co-Chair	Meeting Scribe	Council II Chairs
Amani Babekir	Michelle Hill	via Teams Transcript	Wendy Bell/Courtney Halbrook
Advisory - FDA	Advisory – FDA		Advisory - FDA
Greg Abel	Devin Dutilly		Mary Cartagena
Advisory - CDC	Advisory – CDC		
Erin Moritz	Jenna Seymour		
Advisory - USDA			
Jennifer Green			

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Amani Babekir
iii.	Scribe	
iv.	CFP Antitrust Statement	Amani Babekir
v.	Previous Meeting Minutes	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

1. Roll call
2. Framework update
3. Proposed issues
4. Proposed Food Code addition
5. Adjourn

Meeting Number 17	Meeting Date **07/07/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Previous Meeting Minutes	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

Call to Order

Amani Babekir: I will now call this meeting to order. Michelle, could you please take the roll call?

Roll Call

Michelle Hill: Yes, Madame chair. [takes the roll call]. We have a quorum; we can proceed with the day's business.

CFP Antitrust Statement

Babekir, Amani: I would like to remind you that the Conference for Food Protection antitrust is statement is active in this call. So just want us to keep that in mind.

Previous Meeting Minutes

Babekir, Amani: And we could proceed to our first item in the agenda. We want to approve the previous meeting Minutes – the most recent is still being processed, so we will vote on the Minutes from June 9th. I sent it out just a couple of minutes before this meeting. If you could please open it and I will give like 2 minutes to review. And then we're going to proceed with the discussion and voting. OK, so I will entertain a motion regarding the minutes of our last the meeting from the June 9th.

Hill, Michelle: And just for clarity's sake, they run from page 57 to 71 of the Word document that was emailed by Amani.

Ben.Wagner: This is Ben. I move to approve the meeting minutes.

Babekir, Amani: Thank you.

Garvin, Amanda: I will second.

Babekir, Amani: Thank you. So, is there any discussion on the Minutes, before we proceed to vote? [long pause] Anyone opposed to the motion, please say no, or raise your hand. [long pause] Do we have anyone abstaining? [long pause] The motion passes to approve the Minutes as is. Thank you.

Framework Points

Babekir, Amani: And we could proceed to our first item in the agenda. We want to approve the previous meeting Minutes – the most recent is still being processed, so we will vote on the Minutes from June 9th. I sent it out just a couple of minutes before this meeting. If you could please open it and I will give like 2 minutes to review. And then we're going to proceed with the discussion and voting. OK, so I will entertain a motion regarding the minutes of our last the meeting from the June 9th.

Hill, Michelle: And just for clarity's sake, they run from page 57 to 71 of the Word document that was emailed by Amani.

Ben.Wagner: This is Ben. I move to approve the meeting minutes.

Babekir, Amani: Thank you.

Garvin, Amanda: I will second.

Babekir, Amani: Thank you. So, is there any discussion on the Minutes, before we proceed to vote? [long pause] Anyone opposed to the motion, please say no, or raise your hand. [long pause] Do we have anyone abstaining? [long pause] The motion passes to approve the Minutes as is. Thank you.

Babekir, Amani: So now we could go to the second item in the agenda, which is to continue reviewing and working on the framework. I sent out the latest version of the framework, and now let me share it with you. You could follow me on the screen if you want, or you could open your version. Can you see my screen?

Hill, Michelle: Yes, Madam Chair.

Babekir, Amani: OK. Thank you. So, I'm just going to go over some of the comments that we got from the previous meeting and add the notes to it. One of the things I noticed is that after we finalize the draft, we need to go back and change the table of contents because we deleted some of the sections and all of that. So, if the template, A team, is going to take care of this.

Hill, Michelle: I know how to do that, Amani. I'd be happy to assist in having that be completed.

Babekir, Amani: OK. Michelle, would you like to do it by yourself or ... Ben?

Hill, Michelle: I can work with Ben, if that's OK?

Ben.Wagner: This is Ben. That's fine.

Babekir, Amani: OK, that's good. Then the second one - we got a suggestion to make the document shorter than it is, and to highlight the definitions in the footnote of the document. So, per each page, if we see any word listed in the Definitions, we add it to the footnote of the page. What are your comments on this suggestion? Do you think it's better than the way it is right now, or we keep it as it is?

Ben.Wagner: So would that be replacing the basic dictionary at the end, or would it be just adding footnotes to every page and still having the dictionary at the end?

Babekir, Amani: I think from what I understood from the suggestion - and Devin, I'm not sure if he's with us today - is to replace the definition section, yes.

Dutilly, Devin: I'm here in the call, yes. I think the comment that I was passing along related to having it in the footnotes, in addition to having it in the in the definition section, just so that folks wouldn't have to flip to that section, or if they chose - on previous calls, someone had mentioned that somebody might just choose to print off 1 section and they may have it, or they might choose to, you know, print off only a small portion of it and not the entire document. They would still have some reference to what the definition meant, so both locations.

Ben.Wagner: I would just like to point out that it's not going to make the documents smaller, which, either way is fine, but I know that that's what the group seemed to try to be doing.

Hill, Michelle: I think that is an important point that's being made here. However, because I often print off one page of something and it's super nice to have that information contained at the bottom, it could be as small as six-point type.

Moritz, Erin: I kind of like the idea of having it in both places. I'm wondering if there's a way to, you know like Michelle is getting at, have it in smaller and maybe a lighter font, so it's less visually obtrusive. But I think we definitely need to keep the section at the back because they're all listed alphabetically - a quick reference there.

Babekir, Amani: Thank you. Any other point? OK. Thank you. So, I hear that the agreement is to have the some of the definitions in the footnote. Myself, I don't have experience doing that, who is going to take care of this one?

Hill, Michelle: I can work with Ben again. I've done a lot with this type of thing in Word.

Babekir, Amani: OK.

Hill, Michelle: Or anybody else is welcome. I'm just saying I'm happy to help.

Babekir, Amani: So, Ben, is that OK with you - that's to be taken care of under your subgroup, with Michelle.

Ben.Wagner: Yes, I think the subgroup can take it on.

Babekir, Amani: OK. That's good. Thank you.

Ben.Wagner: As long as you'll put a comment in here somewhere that that's what we're doing, so we don't forget.

Babekir, Amani: OK. We probably need to even give an idea here, or add the words that need to be added, under the footnote. They could be ...

Ben.Wagner: I think what the framework team can do is take the dictionary that we already have, do a search on the terms wherever the terms show up. We can mark that we need a footnote and then go from there.

Babekir, Amani: OK.

Moritz, Erin: Yeah, maybe with the exception of like food worker or something, I don't necessarily know if that has to be on every page.

Babekir, Amani: OK. Thank you. In the other point – here – we have couple of suggestions here - under this section, and Erin, I'm glad you are with us on this call. One of the suggestions is to - in this section additional consideration for the establishment is to make it simpler by just converting it to a checklist so it will be easy to read and the way it is right now. And also, we requested references when we were in the first draft round, but we probably wouldn't need it here. Just for the sake to make the contents here more simple. So, what do you think Erin and your group? You think that's something you will take care of? And if you have any other different opinion, please let us know.

Moritz, Erin: Yes, I think a checklist we can certainly try. I guess my hesitation is that I'm not sure all of these will apply in all situations and establishments. Would bullets be better? Any better than like A and 1?

Hill, Michelle: Perhaps it needs to be more of like a flow chart if then.

Hill, Michelle: That's a whole can of worms, isn't it?

Babekir, Amani: Yes.

Moritz, Erin: Again, I think a lot of these will overlap. Not all of them will be applicable in all situations. I saw one or two hands up.

Babekir, Amani: Yes - could you please speak up? I can’t see the hands.

Vinson, Scott: This is Scott. I have a question. It might be on the next topic we're getting to, I'm guessing, but the references.

I noticed Amani you highlighted some of the references in here. I think that's a reference to the Southern Nevada Health District. I'm wondering if we need the references in the body of this document, maybe they would be better placed at the end. I think we have two different audiences with this document. The first is really the folks at CFP who gave us our committee charge to come up with this document – I think they want to see our references - where we came up with this. Our other audience is the reader of the document, the ultimate reader, which will be the retail food workers. They're probably not really going to be that interested in seeing references in the body of the document. Maybe it's OK to leave it at the end if they're really interested, but they probably really don’t care about references, so maybe we should just put them all at the end.

Moritz, Erin: Yes, I think that's what we ended up doing for the other references. I think we probably just missed this section.

I agree. I think you know we have one Section - one short section at the end - with the References used to create this document.

Babekir, Amani: Yes, and we have …

Ben.Wagner: This is Ben. We did actually take any sections that were labeled as Reference sections from the individual groups and put them all as one at the end. Anything that was an inline reference we didn't touch.

Babekir, Amani: We do have a section where you have all the references combined, and even the breakdown by different sections, so it would be easy to refer to.

Moritz, Erin: Yes, I think that's fine. Just stay consistent with just keeping them all at the end.

Babekir, Amani: OK, that is good. So now we're going to come back to the point of making this section more concise because we have several points here. On our previous call, the agreement was let's work on trying to make this document more concise so the readers are comfortable going through it, I would say. We wanted to think about how we could put this section in a different way.

Moritz, Erin: So, to me this is at least when we were creating this, to me this is basically like a laundry list of things that establishments can think about when they're developing their plans and so I think anytime I see something that's a laundry list, I kind of expect it to be long because this is where we're getting very detailed and this is where somebody who is really thinking about the nitty gritty of their plan. They are the ones who are going to be reading this, so that was our thinking behind it because there are so many considerations, and those scenarios are going to be different based on the kind of establishment and where it is. We're certainly open to suggestions, but that was the point of this particular section, if somebody's really sitting down and thinking about what their plan is going to look like, these are things that that could help them.

Babekir, Amani: OK. And I agree that building an emergency plan is at the core of our charges. Any other suggestions about presenting this section in a different way? [silence] Could it be in a different or are we OK with it?

Garvin, Amanda: This is Amanda Garvin. Somebody had mentioned a checklist, an option for the checklist might be kind of something we do for a facility, and we have, like these are the SOP's that pertain to all facilities and then we have a list of, this is what pertains to some facilities so only included if applicable. So that might be an option.

Moritz, Erin: OK. So, kind of group it based on.

I don't know if these are specific enough to try to narrow down and say, this is good for a full-service restaurant, This is good for a Taco truck. Although that's one possible thing that we could consider doing. Thanks.

Hill, Michelle: Oh wait, we could know it for this section, like as a prelude to it, that it's meant to be used in that way, that you might not have answers to all of these questions. There. You do. You do say that might have additional questions to consider.

Moritz, Erin: We could certainly try to shorten the paragraph - I think that's doable. And then similar to - Michelle, what you were just saying? I wonder if there's some words we could add or change in the section title that just make it more like, If you're just reading this for general interest, don't bother with this section.

Hill, Michelle: Perhaps we could say something as easy as if you were intending to form an allergen plan - isn't this really targeting an allergen response plan? - so if you're looking to have that for your organization, that this would be what you need.

Moritz, Erin: Yes.

Babekir, Amani: And this is …

Hill, Michelle: Something similar. Right, yes.

Moritz, Erin: Writing a detailed plan, because this is very detailed stuff.

Babekir, Amani: And this is one of the elements of the charges, to show the customer how to walk through, or the restaurants staff how to walk through building these emergency plans.

Dutilly, Devin: Just commenting, I think that about shortening the document and some of the discussion right now, is there a need to do a small section - like a summary, an executive summary type document and then have the rest of the document exists … or something like that. I don't know if that's going to be helpful or not. Is it because the intent is to have it in a detailed emergency? Because you all had just said this is not an action plan or an emergency plan, detailed one, right. So, it's just the detailed one. And then is there some way we can go through each section and just scratch certain things and then make it a summary of what's in there that is also useful but not detailed. So, then we have like two documents, one is like an executive summary document and then one is like this. Based on what we already - not to creating more information - just using the existing language and wording and just scrapping certain text. It's just a thought.

Babekir, Amani: Amber has suggested to create like a short document from this version.

Moritz, Erin: And I think for this particular section, the poster that we developed kind of serves it as that executive summary.

Dutilly, Devin: OK. That makes sense.

Moritz, Erin: That's kind of where we were going with that poster.

Hill, Michelle: Quick. But.

Dutilly, Devin: Yes. OK, great, good.

Hill, Michelle: We might talk about how this is a detailed inventory of what you would need you know in order to do the plan or to comply with the chart - the poster, which I think is very effective, by the way.

Moritz, Erin: Yes, I like the idea of scratching that paragraph and maybe doing one sentence saying that this particular section is designed for – has detailed considerations for …

Hill, Michelle: Sorry. The final line might be enough. These questions and scenarios may be used as a practice drill for your food establishments staff or don't have to - maybe not even practice drill, but …

Moritz, Erin: We could just keep that sentence and say these questions, that scenarios may be used to develop a detailed emergency - allergen reaction and response plan, and can be used as a prep. And then delete the rest of that paragraph

Hill, Michelle: Yes.

Hill, Michelle: And may also be used as a practice drill.

Babekir, Amani: But now? Could you say the sentence one more time?

Moritz, Erin: OK. These questions and scenarios may be used to develop a detailed Emergency … Allergy reaction? What did we officially call it? An emergency response plan. And that gets to the other things I wanted to discuss about the section that you guys deleted. But let's finish up with this first.

Babekir, Amani: We could do that.

Moritz, Erin: And – can be used as a practice drill ...

Babekir, Amani: For your food establishment staff.

Moritz, Erin: Yes, I think the rest of the sentence is OK.

Hill, Michelle: As I said, you could strike, you could just say period after drill. I mean, it's obvious we're talking about your staff, but the …

Moritz, Erin: Yes, that's true.

Babekir, Amani: Do you want to make any change on the title?

Moritz, Erin: How about, could we use the word detailed in the title again?

Hill, Michelle: Forming a detailed response …

Moritz, Erin: Detailed considerations for the establishments.

Babekir, Amani: Or, for developing emergency response plan.

Hill, Michelle: Yes. Is that our charge? Let's call it what our charge is.

Babekir, Amani: Are you OK? So detailed. Consideration. It's not additional, is that right? Have we? Umm.

Moritz, Erin: We can remove additional, I think. I think really what we were going for was detailed instead of additional. I think that's good.

Babekir, Amani: Any point or any suggestion before we proceed on this section, are we good with it?

Hill, Michelle: If we're intending this to be a form, let's say that somebody could take and fill in. I don't know if that is the intention, but this could be set up with little boxes that could be checked as I move through and have spots to write. I don't know if that's our intention though, but if we wanted them to be able to just copy it and use it, that's something we might want to consider.

Moritz, Erin: Yeah, I'm not necessarily opposed to that. My only hesitation is some of these will be applicable to some establishments while others might not. But you know, it's certainly up to the establishment to decide if they're applicable or not. We could try a text box or a checkbox - otherwise you know even if bullet points might be a little bit less intimidating than the letters and the numbers. And you know, open to feedback from the group.

Hill, Michelle: But I've been looking to work on this with the template team. If or maybe Erin directly.

Moritz, Erin: Yes. OK.

Babekir, Amani: OK. That's good. So, we could proceed to the next point. Erin, you said you have a comment about one of the sections we deleted here from.

Moritz, Erin: Yes.

Babekir, Amani: From your part.

Moritz, Erin: All right. Can you guys all see this? For the most part, I was fine with, you know, all the suggestions here. I do want to take a moment to explain the rationale of why we kind of broke this down into different scenarios. Allergic responses look very different, and so lots of people when they think of an allergic reaction, they think of somebody sitting at the table clutching their neck because they can't breathe, but there's a really wide continuum of consciousness - ability to communicate. There're people like me, I have a peanut allergy, but it's very mild. So, I would actually be pretty mad if an establishment called an ambulance for me and be especially angry if I got stuck with a bill for it. And so, I'm definitely OK with deleting this kind of detailed suggestions. Basically, a flow chart but with words - but I do think we really need to work in somewhere else that a person could be alone, they could be with a group. And what do you do with them? They could be unconscious, which obviously you call an ambulance. But if somebody says, I ate a peanut from your dish, I'm just going to take a Benadryl. I think you know we want to basically draw attention to the fact that there's really wide continuum of severity and so I'm thinking it would make the section we were just trying to shorten a little bit longer, but I'm wondering if we could add this first.

Add somewhere in here, something like think about what role your establishment would play if the person is alone versus with a group. If they're in distress versus in distress but can still communicate. So, it would not be necessarily this kind of prescriptive steps

to take, but I do really want to get establishments thinking about beyond that sort of classic sitting at the table gasping for air, if that makes sense.

Hill, Michelle: I think it's really important, the point you're making, Erin, because they do present very differently, especially when you consider children versus older groups.

Moritz, Erin: Right. And so, if we do - like I said, I'm fine with deleting, you know, these step-by-step things, but we need to put it in here somewhere that it's not always going to be the diner sitting at the table turning red, clutching their throat.

Babekir, Amani: I'm wondering if this section or the message on this section being addressed is in the training section. Is Amber with us?

Amber Potts: I'm here.

Babekir, Amani: Have your team addressed you know the different level of reactions in your section and just to bring awareness about this.

Amber Potts: No, no we didn't.

Moritz, Erin: If we wanted to add a little blurb about that in the training section, that would be good. But like I said, I'd be happy if we mention it in the section that we were just working on too. I don't know if any other members of the emergency subcommittee are on – if they have thoughts.

Hill, Michelle: I don't know that they would be much point in graphics of people actually experiencing allergic responses. To show that there's a huge variation. Or is that just too difficult or too much?

Moritz, Erin: It's not a bad idea. I think it would be included in a very specific, day long allergy training.

Hill, Michelle: Yes.

Moritz, Erin: I think what we're putting together is a lot more broad than that, but I do like the idea, of course, I always like the idea of graphics.

Hill, Michelle: Picture says 1000 words.

Moritz, Erin: Yes.

Babekir, Amani: So, Erin, do you think you could … Yes, Amber, go ahead.

Amber Potts: I like the idea of keeping it broad as this is not the training. We're not developing a training per se, just a, you know, a document to help them write their own allergy plan. And so we, I think we should at least mention it, but I don't want to - and we have to remember they have no medical training. So, I don't want to put that kind of responsibility on a restaurant owner or server. And then I don't want them to interpret that as such either, so I think it's just a general statement. Basically, it's like if you've ever done lifeguarding - the drowning isn't as you see in the movies where it's splashing and yelling, there's no - it's silent. So, just an acknowledgement that you may not see what you think you're going to see - something like that - and then leave the training - when they take that training - for it to be a more in-depth kind of training.

Moritz, Erin: Yes, and what I do really want these restaurants to think about is there's going to be these wishy-washy scenarios where their staff are not going to be sure if they should call the ambulance. Like if somebody reports a reaction but they don't want an ambulance but they're turning red - you know these are these are actually the much more likely scenarios that they're going to come across. And so, they just need to be thinking about it. And even just be aware, like you said, Amber that you know … you're not gonna be splashing around in the pool yelling for help, metaphorically.

Babekir, Amani: Yes, Scott.

Vinson, Scott: Maybe this is already in the document, I can't see it at the moment, but maybe put something in there about, ask either the customer, or someone with the customer, if they would like the facility to call an ambulance. Because, like someone said a moment ago, you have some customers that might be annoyed if the establishment calls an ambulance, and they didn't want them to. Maybe they get stuck with a giant bill. So, is that in there? Oh yeah, there it is.

Moritz, Erin: And that's what we had here, but maybe that is too specific - it's I feel like that's an important enough question.

That if we for example, put an additional, you know bullet point down here, we could just call that out as like a sub bullet.

Vinson, Scott: But that's really all the establishment can do if the customer says no, or the person they're with says no. Then the restaurant can't do anything else - they can't constantly monitor the customer for possible other signs that aren't necessarily obvious signs that someone having an allergic reaction. I think we need to keep this.

Moritz, Erin: Some establishments might be willing to do that though.

Vinson, Scott: They might, but I don't think we need to spend a lot of time or take up a lot of space in this document writing about it. The main point we want to get across to the establishment is somebody might be having allergic reaction. Beyond the classic signs, there might be other signs. Ask the person or whoever is with him if you if they want you to call an ambulance, and then move on. They have a business to run.

Babekir, Amani: And we have it on #5. If you scroll to number 5. Here we have it. If someone reports an allergic reaction, I think that's where it is. Start is when the customer says I have an allergic reaction and then they will proceed with their steps. Do we need to add any clarification about the level of allergic reactions. and then ask them to first, ask the customer if he wants us to call the 911 or not?

Vinson, Scott: It really has to depend on what the customer wants. And this part in here. When in doubt always call 911 I from what I heard a moment ago from whoever said it, they don't want that necessarily. So maybe we should take that part out.

Moritz, Erin: Well, this is when in doubt.

Vinson, Scott: Well, yeah, and there's.

Moritz, Erin: Like if I was a business and somebody told me not to call 911, but then they stopped breathing.

Vinson, Scott: Well, that's just common sense.

Hill, Michelle: It is, and it isn't, though. I mean, what we're really asking here is what's the liability?

Vinson, Scott: If you put both messages in there, it's going to get confusing for these workers. If you put when in doubt, always call 911. But then you also say ask the person whether they want you to call 911. Which is it?

Hill, Michelle: I think that maybe it's personal discretion. The way we talk about this. What is the liability if somebody in your restaurant - they eat something and they drop dead. Are you responsible for that?

Vinson, Scott: No.

Babekir, Amani: What if …

Moritz, Erin: They told you that they had an allergy though.

Babekir, Amani: Yes, I think there ...

Moritz, Erin: I think I would assume the liability would depend on whether the customer mentions a food allergy.

Babekir, Amani: Yes.

Moritz, Erin: Like if they don't mention it then, well, that's a whole. I don't know. I'm not a lawyer, so will stop talking.

Babekir, Amani: Yes.

Hill, Michelle: So, it's a sticky wicket, I think really.

Moritz, Erin: It's very sticky wicket, yes.

Babekir, Amani: Yes, but there could be liabilities, especially if they label it in their menu, like for example, these dishes, gluten free. And then when I eat it, it turns out it is not, and I have reaction. Yes, that will bring them some liability.

Hill, Michelle: That's like misbranding …

Babekir, Amani: And we have it here on this section, on the first, on the second sentence, saying that procedures may differ depending on the severity of the reaction, so maybe just we need to add more clarification here. To address all of these doubts between calling 911 or asking the customer.

Moritz, Erin: So maybe I can draft - what? I would suggest - I hate to, you know, keep everybody talking about this for hours and hours - send it around to the emergency response group and then we can, you know, tweak it as needed and send it back to you, Amani. Does that sound OK?

Babekir, Amani: Yes, that sounds good.

Moritz, Erin: OK.

Babekir, Amani: And are you OK about the other deletions? Do you have any extra comments, Erin? Because there are additional things we might need also to delete in the section.

Moritz, Erin: Let me - I think there is only one other thing I wanted to kind of get your take on and I can just share it - share my screen again since I have it right up here - we have this particular poster …

Babekir, Amani: Yes, that was my question - about this poster.

Moritz, Erin: I think we like it because it did have some like facts underneath it and it's certainly one that a restaurant might want to print out and post somewhere if they like it. So basically, we could leave it in there as a potential resource for them. But I guess I'm OK with removing it if the rest of the subgroup is as well. It's just another resource that the establishment can use.

Babekir, Amani: Are there any comments about this one? Are we OK with keeping it?

Hill, Michelle: I think it's necessary.

Moritz, Erin: OK.

Babekir, Amani: Thank you, Michelle.

Moritz, Erin: OK.

Vinson, Scott: Wait a minute. Can you go back to that poster? Step four says go to the hospital. So, is that for? This isn't for retail food workers. They're not going to go to the hospital with them.

Moritz, Erin: No, this is a general yeah. This is a general.

Vinson, Scott: So, this a sign that we envision the establishment maybe posting, a customer facing sign, somewhere in the restaurant or facility?

Hill, Michelle: Yes.

Moritz, Erin: If they yes, they want to. It does make some good points. But yeah, it's not specific to retail food establishments.

Hill, Michelle: I really like it because it covers the full bases. If it's a true, you know if it ends up being a true anaphylactic response that you have to treat with an EPI pen. It covers all the bases.

Moritz, Erin: But I can kind of see where it might - it would be confusing. Now you know, we don't expect anybody from the food establishment to go to the hospital with the customer.

Vinson, Scott: So, this is really for people who have food allergies.

Moritz, Erin: It yeah, it's definitely possible, since it's from an ID.

Vinson, Scott: I'm not sure it belongs in this document. Then we're supposed to be developing guidance for the establishment.

Garvin, Amanda: I suggest a better place for it.

Babekir, Amani: Sorry, Amanda. What did you say? Couldn't hear you.

Garvin, Amanda: Sorry about that. I'd have to agree with that. I think that this is not quite the correct place for it, and I have. Like it's sounding like some of the stuff we've already said in different areas, so. I'm not sure if this is something we could just get rid of, and I do hear that you know it is important. As a response to definitely have the right responses, but I think this is another one kind of confusing it up again of don't call 911, call 911, wait, send up to the hospital. Oh, what should I go with them? I think we just need to kind of tone it down a little on this and, what can we do to get them to think about - when should you do the things?

Babekir, Amani: Thank you, Amber. Any other point?

Moritz, Erin: Does anyone very strongly oppose removing it?

Abel, Greg A: I have one point to consider.

Moritz, Erin: Sure.

Abel, Greg A: You looking at some surveys? I read someone where 65%. Of the surveyed say they wouldn't know how to cope if faced with the customer suffering an allergic reaction. So that's over half a staff and this was - the study was dropped at food service workers, so with that. With the 65% not knowing how to cope, you know, are we taking anything away from that guidance that would not benefit someone who is having an allergic reaction.

Hill, Michelle: To that point. That's why I like this document. Because there tends to be a lot of mystery - when I teach, I ask them how many people have actually seen a response.

Abel, Greg A: Mm-hmm.

Hill, Michelle: And especially the variance of response. I like that this addresses that. What's their experience? Maybe it needs to be called something else. Referenced in a different way.

Babekir, Amani: Ask. But.

Vinson, Scott: This poster is directed toward people who have food allergies. So, it's not really for the establishment or the people who work in the establishment. I'm going to actually call for a vote on this page.

Moritz, Erin: Sorry, could you say that again? I didn't quite catch it.

Babekir, Amani: You want to call for a vote.

Moritz, Erin: Oh OK. I do think you know, we throughout this entire document, you know, we do kind of have to balance. Of course, we'd like to include boatloads of information and make it 8000 pages long. That would be ideal if people would read it. But we also want to limit confusion as well and people don't like to read anymore. So yes, I certainly see both points of view.

Babekir, Amani: OK.

Hill, Michelle: You know, perhaps this would be better as a hot link at the end, saying these are some resources that we like, or we could recommend and maybe it lives there as a hot link or something they can follow if they choose.

Moritz, Erin: To me that's a happy compromise.

Babekir, Amani: Yes, or as a supplement to the document, because beside this draft, we're going to have the short version.

Moritz, Erin: Right.

Babekir, Amani: Of the work of the framework and we could have extra documents like this. As an attachment.

Hill, Michelle: I keep forgetting about that - the short version.

Babekir, Amani: Yes. So, are we fine with that? To delete it but still keep it as either attachment or add a link to it if we have a reference.

Hill, Michelle: Scott has his hand up, Madam Chair.

Babekir, Amani: Yes, Scott.

Vinson, Scott: I forgot it was still up. I think I still would like to call for a vote on this document. I don't think we need to include it as an attachment because it's not directed to our audience. It's directed to people who have food allergies, and I'm one of them.

Babekir, Amani: OK.

Vinson, Scott: So, I'm calling for a vote.

Babekir, Amani: OK. That is, that is good. So, let's do that before the end of the call.

Dutilly, Devin: What is the vote for? What is the question that you're asking to vote on?

Babekir, Amani: I will entertain a motion regarding this poster. Scott, you could proceed with your motion.

Vinson, Scott: I move that we vote on whether to include this, Food allergy aware - six that save lives page in our document.

Moritz, Erin: Or link can we specify cause now we have two potential solutions which would be – one, include as a supplement or a link, and then one solution would be deleted completely and move on with our lives.

Vinson, Scott: This is going to be a paper document in these facilities, so I don't think links will be very helpful.

Dutilly, Devin: I think that that was why some people were thinking of including the poster.

Hill, Michelle: Exactly. I was thinking about the suggestion we had about turning this into a smaller Canva-type app that there could be some dynamic linking there as well. If we were to include it in that space versus printed.

Babekir, Amani: So. I'm not clear very clear …

Vinson, Scott: I'll repeat it. I move that we vote on whether to include this document in whatever form. Bully printed page or link or whatever. I don't think this document is addressed to our audience.

Babekir, Amani: OK. Thank you, Scott. So, the motion is Do we need to include it in whatever version or not. Anyone 2nd?

Garvin, Amanda: 2nd.

Babekir, Amani: Thank you. So. You already heard the discussion about this, so I'm going to proceed to the vote. Is there anyone who opposed to the motion? Please say no or is raise your hand. Probably it will be easier to raise your hand so we could count it.

Ben.Wagner: I am confused as to what we're voting, if we vote yay.

Vinson, Scott: Just to clarify the motion is not whether to - the motion is to exclude this document from our guidelines.

Ben.Wagner: So, yay vote is to exclude, and nay vote is to include. Got it?

Vinson, Scott: Correct.

Babekir, Amani: So, the motion is to exclude, as he's said. So, if there anyone opposed to the motion. Which is to exclude this document. You can raise your hand so we could count.

davidread2861: So, this is to exclude it if you vote. If you raise your hand, you're voting to exclude it.

Babekir, Amani: You are voting. To not exclude it because I'm asking about, is there anyone opposed to this motion?

Moritz, Erin: So, the question is keep or exclude?

Babekir, Amani: That is right, and the motion is to kill it. So, if you are not with killing it, please raise your hand. Michelle, can you see the all the hands?

Hill, Michelle: Yes, Madam Chair. I see 4 to keep it and the rest to exclude.

Dutilly, Devin: I think there wasn't a vote for other side, right, there needs to be a vote for the other side.

Babekir, Amani: OK.

Vinson, Scott: Amani, you kind of, you kind of did it backwards, Amani, by asking for the no votes. You probably should just ask for yes votes. People who support the motion. The motion is to exclude. So ask for of the voting members. Who votes yes for the motion to exclude.

Babekir, Amani: OK so - Yes for excluding this poster from the document. Please. Raise your hands.

Hill, Michelle: Madam Chair, I see three hands that are in the yay for exclusion.

Babekir, Amani: So who abstains - any abstains?

Hill, Michelle: I do not see any hands raised.

Babekir, Amani: OK. So the motion is passed.

davidread2861: I thought there were four votes to keep it as well. You said there are only three votes to exclude it.

Hill, Michelle: I was under the impression that we were voting from the start all over again, and when she asked the question, I counted three hands raised in the affirmative to exclude.

davidread2861: Right. But I thought when you first did it - those that didn't want it excluded - there were four hands.

Babekir, Amani: The three is to exclude - the three are with the exclusion.

davidread2861: And four were to keep it.

Babekir, Amani: Yes, the motion failed.

Vinson, Scott: So the motion failed. Amani. You really need to vote Amani. You need you need as the chair to conduct a vote you need to ask for yay votes and nay votes. You need to ask for the yay votes first. There were three yay votes for the motion. The motion was to exclude and then the next step is to ask for the Nay votes. And I think there were four Nay votes. But you might wanna do it again, because I think there was some confusion.

Babekir, Amani: OK, let's do it again, because the way we usually doing it, we first ask about the person who is no say no to the motion, and then we count those people.

Vinson, Scott: Well, that's backwards.

Hill, Michelle: OK.

Moritz, Erin: Can I make an additional suggestion?

Babekir, Amani: Yes.

Moritz, Erin: Can we? I don't know if we can do this, but I'm wondering if it would be less confusing to say, the motion is to keep it. And that way if you vote yes, that means you like it. And if you vote no, that means you don't. But that might confuse things even more at this point.

Hill, Michelle: No, I think it's clarity. I think that would be clear. So if you're voting, if you raise your hand, you're to keep it, if you're lowering it, you're to get rid of it.

Babekir, Amani: OK. So I want to entertain another motion. I would like to entertain a motion.

Vinson, Scott: Did you?

Babekir, Amani: Regarding this poster.

Vinson, Scott: Did you dispense with my motion?

Hill, Michelle: No, we just changed it from a double negative to a positive. That's all we've done.

Babekir, Amani: Yeah, we because it seems like, you know, the Members here are confused about what we are doing because we kept jumping from yes, no, no, yes. So, we wanted to redo it again. So, it will be more clear.

Vinson, Scott: OK, I withdraw. I withdraw my original motion.

Babekir, Amani: OK. Thank you, Scott. So. I will entertain a motion regarding this poster. So, I want to hear the motion that say we want to keep this poster so we can vote on it. Erin would like to move?

Hill, Michelle: No.

Moritz, Erin: Am I allowed? I'm. I'm not. I'm a non-voting member.

Hill, Michelle: How about Scott?

Ben.Wagner: This is Ben. I move that we vote to include this poster in some form in our documentation - our document.

Babekir, Amani: Thank you. Wait a second.

davidread2861: I'll second it.

Babekir, Amani: Thank you. So, let's proceed to the vote on the motion. Is there anyone opposed to the motion? Please say no. I don't want to keep. Or raise your hand.

Vinson, Scott: I think everyone is confused by the way you pose the question you asked for. People who are opposed to the motion.

Babekir, Amani: Yeah.

Vinson, Scott: This is not parliamentary procedure - I think that's part of the confusion. The way you were conducting votes seems to be backwards.

Hill, Michelle: Madam Chair, if I may, perhaps we could ask for those that are in favor of the motion to exclude, to raise their hands.

Babekir, Amani: OK, people.

Ben.Wagner: The motion is not to exclude the motion is currently to include.

Babekir, Amani: The motion is to include – and watching this thing so the people who are in favor for this motion, please raise your hand.

Moritz, Erin: And the motion is to include.

Babekir, Amani: That's right.

Vinson, Scott: And this is only voting members, right?

Babekir, Amani: That's right.

Abel, Greg A: On the chat, Amber Potts had to leave but she voted to remove the poster whenever you get there, that's what that was counted or not.

Hill, Michelle: It was not. Thank you, Greg.

Hill, Michelle: I see five hands, Madam Chair.

Babekir, Amani: OK. So. I would see that the motion is passed, to include the poster.

Hill, Michelle: I think we have to ask for those to raise their hand that are not in favor of the motion. Am I incorrect about that?

Babekir, Amani: It's already passed, but I think we need to ask about abstaining. Is anyone abstaining?

Hill, Michelle: OK. I don't see any hands, Madam Chair.

Babekir, Amani: Yeah. Thank you. So, the motion passed to keep this poster and we keep, we can keep discussing how we want to include it. Do we want it to include in the actual document or move it somewhere else

Adjournment - Babekir, Amani: Anything else before we conclude our meeting today. OK. Thank you everyone.

Meeting Number	Meeting Date		Meeting Time
18	**08/04/2022**		2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Previous Meeting Minutes	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

Meeting Call to Order

Babekir, Amani: I call this meeting to order.

Roll Call

Babekir, Amani: Michelle, would you like to start with the roll call?

Michelle Hill: [Takes roll call of Voting Members] Madam Chair, we have a quorum. Our new quorum is 8. We do have 8.

Babekir, Amani: OK, that is great. Thank you, Michelle.

CFP Antitrust Statement

Babekir, Amani: I would like to remind you that the Conference for Food Protection Antitrust statement is active in this call. So just keep it that in mind during our discussions.

Previous Meeting Minutes

Approval of previous Meeting Minutes was tabled by the group as the processing for these documents is not yet complete.

Framework Points

Babekir, Amani: And let me first start by bringing up our agenda for today. I will share my screen. Can you see my screen?

Michelle Hill: I can.

Babekir, Amani: What we're going to do today is we will review the timeline of our work and introduce the FDA and the USDA comments that we received on the framework and decide on how we want to proceed with working on those comments and refining the framework. First, just looking back at our timeline, which we built together when we started our meetings. We are done writing the framework and now we need to refine it because we have other things to do - which is deciding on what changes we need to recommend for the food code. I remember from our previous calls we decided on working on indicating this framework in the Annex section of the Food Code, but we still need to refine our discussions on this part, so we need to dedicate time to do that. The suggested timeline - we need to keep in mind that we need to finalize working on the comments and finalize the framework by the middle of September. Because as I said, we need to work on the second charge and also our final reports need to be submitted. And Michelle, could you remind us about when the final report is due?

Michelle Hill: Certainly. There is an interim report due shortly here, that Amani and I are working on. It is the report to the Executive Board about how we've moved through the work pertaining to our committee's charges. The report will be published on the CFP

website at foodprotect.org. You are welcome to view our previous filing, which was the Spring report, to see the type of information and how will be reporting that.

As far as when our actual work is due, the master calendar has us slated to have everything completed and sent to our Council Chairs by the end of December 2022. The Council chairs prepare and suggest improvements to the report that are needed in order for the report to be submitted to the Executive Board to be included in the next biannual meeting in April.

Babekir, Amani: That's good. Thank you, Michelle.

Michelle Hill: Certainly.

Babekir, Amani: Any questions about the timeline, any points you want to bring up?

Vinson, Scott: Amani, this is Scott – I have a question. It looks like we're going to be missing the July 30th deadline to have the written framework completed, because we still have this review of the FDA feedback to complete, which you're saying is due by September 15th.

Babekir, Amani: Yes, that is the reason we must agree on a revised timeline - trying to complete it by September 15.

Vinson, Scott: Is there a way we can do all - track these things - or do they have to be done sequentially?

Babekir, Amani: This is what we'll discuss as the second topic - how we want to proceed. I emailed you each the documents with the comments we received from the FDA and the USDA. Would someone open voting – make a motion – like, do we want to do this in our general meeting or in our subgroups and it will be faster if we are able to do it in the subgroups because we could work all of us on it at the same time on the on the document.

We're will decide on that a little bit later in our meeting - just keep it in mind. If we are working within subgroups, that is the fastest way to meet our deadline.

Vinson, Scott: If we do the work in the subgroups, and by that we mean have each subgroup review this new FDA feedback. People who aren't on a particular subgroup won't necessarily get to see what the feedback was and have a voice on it. Is that right?

Babekir, Amani: Yes, so the general Group, if it's kind of format or stuff minor like that, could work on it together. If it's something essential the subgroup could suggest the change that they would like to make and bring it into the general meeting. That's what we are planning to do. Are we OK with that? And we could proceed that way.

Vinson, Scott: Well, speaking for myself, I think I would prefer and maybe we can do it on this call. I would prefer that if maybe the people from FDA who proposed or gave the feedback documents to you - I don't know if they're on this call or not, but maybe they could just sort of speak up as to each individual comment. Maybe if we could go through the 24-page document, just sort of page by page before the entire group, so that everyone has benefit of seeing what these proposed changes from FDA were. These documents sort of came as a surprise to me because I thought we had already done all of this reviewing and then for these documents to sort of come in after we already had two previous full committee calls to review all the pages – I wasn't anticipating that.

Michelle Hill: Well, wait now – we did announce that.

Babekir, Amani: We announced that, and we were expecting it because we kept checking in with Devin, our FDA consultant, about their timeline to give us their feedback. We were waiting for it while we were working on refining the draft on our side. We meant to make it a parallel effort, so we could save time and consideration of the comments wouldn't hurt our progress with the framework.

Michelle Hill: We have been waiting on the feedback. We've talked about it in several previous meetings. The meeting minutes are forthcoming for prior meetings - they are being worked on and will be out shortly.

We did discuss this, and I think this is part of the greater issue that we're talking about. You know that we're going to address is how do we move forward with this? Do we do it as a full committee? And I respect what you're saying, Scott, I think it's very important that everybody has a voice in how this ends up, at least looking in the end. But we've also sent these documents out with comments for quite a period of time now. You've had them in, everybody's had them in their possession, I think at least three weeks. Am I wrong on that Amani?

Babekir, Amani: That is correct. Once we received it, we send it out.

Michelle Hill: I was hoping that people would have been able to take time between then and now to have a good idea of what was being said so we could have a productive conversation. I like the idea of reviewing each one with the consultants here, but perhaps that's something we do in two weeks when we give them time to actually prepare to do that - just a suggestion. Thank you, Madam Chair.

Babekir, Amani: Thank you.

Vinson, Scott: Well, this is Scott again responding to Michelle. Yeah, I appreciate the fact that Amani did send these documents out a couple weeks ago at least, but some of these changes may be controversial. I don't know. This is something that really should be discussed and considered by the group as a whole, rather than forcing Amani to sort of take every - you know, there are a lot of people on this committee and to have everyone go through each of these three documents and give the thumbs up or thumbs down to each individual change that might be proposed - I'm not quite finished - change that might be proposed would be a lot of work for Amani. It just seems to make sense to me to just do it on one of these calls. Perhaps this one - we have a full hour. And whoever proposed them from FDA can just say here's what we're proposing here. If they're just minor things like, you know, formatting or syntax or whatever, I don't think anybody is probably going to object. But if there's substantive changes, that should be discussed for the before the entire committee.

Babekir, Amani: Yes.

Michelle Hill: If I may, Amani and I work on this together and it's not just her doing the function. She communicates because she has the ability to do that. So, I just wanted you to know that we are together, Amani and me. We co-chair this committee. The other part I wanted to say is that we are able to talk about this within the meeting. I think that's a very good idea. I don't know how - I guess this would be the point where we would ask Devin, and the other people that contributed to the review, to speak as to whether they're prepared for this today, we didn't let them know that this was what was going happen.

Babekir, Amani: Yes. I would like to add a note here, before we open the floor to Devin, really this is the communication I received from Devin and the group who added comments on the framework - that is all these comments are suggestions and just things we need to consider when we are refining our framework. So, it is not binding statements from any organization. These are the things that are highlighted, and I'm really appreciative of Devin, and also for Lauren from USDA, for walking me through their comments; How to understand it on the documents with the different colors and their suggestions on each point. We need to open the floor for Devin, and any other Federal Partner, to go over these comments 1 by 1 - that is something we could do also here.

But I want to also hear from the other committee members because all our idea is we need to work right away on those comments. Do we want to work on this as one group, including our FDA and USDA representatives? Going through these comments one by one and working on it in the general meeting, or we want it to do it in the subgroups?

That is something we could do - I'm going to need a motion on it, but before that, I open the floor to Devin and Jennifer, if you want to add anything or any points about your comments.

Devin Dutilly: Thank you, Amani and everybody else. This is Devin. Erin is raising her hand as well.

Maybe I'll make it just a brief comment and let Erin and Jennifer comment. Just as a point of clarification, the comments that I submitted, me being with FDA, they weren't just FDA comments, there are comments from other federal partners. So, these are federal partner comments, so USDA, FNS, FDA, FSIS, Erin included, and some other partners from CDC.

They all commented on the Framework, and I compiled the comments from the agencies and pass them forward. So, the comments weren't just from FDA, they were compiled comments from all three agencies.

It is exactly right to say they're just comments to consider and suggestions myself, Erin, Jennifer and Greg, and others from FDA, USDA and CDC have been working throughout this process to kind of express some of our thoughts as we move forward. And we do really appreciate the collaboration and partnership to help raise the awareness and to provide resources for our stakeholders when it comes to Allergens.

So, Erin had her hand raised, and she's been a great partner in this as well. And Greg as well is here, and Jennifer - so thank you.

Moritz, Erin: I was just going to ask if it's worth kind of doing a hybrid. You know, separate it out into the subgroups to, I guess deal with sort of the low hanging fruit that maybe doesn't need the entire committee to discuss, and then leaving it up to the groups to turn over any larger, sort of thorny issues that can be discussed with the larger committee. That was just kind of kind of my thought as to how to proceed. Over.

Babekir, Amani: Thank you. Jennifer, I think I heard something.

Green, Jennifer: I do appreciate the opportunity to contribute, and I look forward to seeing how everything's going to progress.

Babekir, Amani: Thank you, Jennifer. Now we're getting to the point to decide. And thank you, Erin, for your suggestion to decide how we're going to proceed. I sent an email poll, but unfortunately the quorum is 14 and I got just seven responses - 6 within the group working on the subgroup and one is working on the general meeting, so we need to vote on it now.

I would like to entertain a motion about how we're going to proceed with addressing the FDA and the USDA comments.

Vinson, Scott: Madam Chair, I have a motion.

Babekir, Amani: Yes, please.

Vinson, Scott: I move that the full committee now on this call just consider the comments.

On the three documents that you circulated and if Devin or someone else from FDA wants to speak to the suggestions that's fine. We can probably dispose of this fairly quickly, I'm guessing.

Babekir, Amani: OK.

Devin Dutilly: Yes, and just to clarify, I think that we tried to make the comments as clear as possible. So, you know we can - there's a number of us on the call, so we can try to clarify anything that might be needed. But we tried to make the comments as clear as possible and make any suggestions in there. I'm happy to walk through the documents on this call as an FDA consultant, I'm happy to offer any clarification on the comments that were compiled by the three federal agencies. Amani had asked the question, would somebody be prepared to help us walk through the comments today? And the answer would be yes. Thank you.

Babekir, Amani: Thank you. I just would like also to keep in mind, if we're going to work on it in the general meeting, we need to move the meetings to weekly instead of biweekly to be able to meet our deadline, so I have a motion on the floor to work on it in the general meeting. Can I hear a second?

Moritz, Erin: Can I quickly clarify something about the motion - Scott would the motion be to work on all the comments in the general meeting starting today, but potentially, move into weekly meetings at the same time as that, correct?

Babekir, Amani: That is correct. So instead of having biweekly, it's going to be at the same time weekly meeting.

Moritz, Erin: OK.

Vinson, Scott: Actually, that was not part of my motion.

Moritz, Erin: OK.

Babekir, Amani: I know it's not part of your motion, but just something to keep in mind if we're going to do it in the general meeting, we need to move the meetings to weekly because we wouldn't be able to meet our deadline.

Michelle Hill: Perhaps what we should do is vote on whether we want to do it in the larger meeting and then we'll vote on how we proceed with that motion. Is it weekly? Is it biweekly?

Babekir, Amani: We'll work on the motion working on the comments in the general meeting. Any second?

Amber Potts: [Seconds the motion]

Babekir, Amani: Thank you. Any discussion, any points on the motion? OK, so let's proceed to the vote on the motion. If you agree with the motion to work on the comments in the general meeting, please say yes. All raise your hand. And Michelle, could you monitor?

Michelle Hill: I have six people that have voted in favor - Voting members that voted in favor.

Babekir, Amani: OK. We'll give it extra one minute.

Michelle Hill: Amani, please remind me, do you and I vote on this? I can't remember. I don't think we do, do we? We do. OK. Alright.

Babekir, Amani: Is there anyone abstaining?

Babekir, Amani: Do you see any hands, Michelle?

Michelle Hill: I do not.

Babekir, Amani: OK, so the motion did not pass. We need 8.

Michelle Hill: That is correct, yes.

Babekir, Amani: Yeah. OK.

Any further comments or suggestions from the committee members? I know Erin you raised suggestion before. Any reactions or other suggestions to be presented - this question for the all the committee members.

Michelle Hill: So, we voted not to do it today, as a larger group, but we didn't necessarily agree on how to proceed moving forward. We should we perhaps entertain a motion regarding that.

Babekir, Amani: Do we want Erin’s suggestion to be a motion or there is any other suggestion or motions you want to present here?

Moritz, Erin: I can't raise.

Babekir, Amani: Correct.

Moritz, Erin: I can't raise a motion and I'm a non-voting member but, do you want me to repeat what I was suggesting and then somebody could motion on that?

Babekir, Amani: Yes, please.

Moritz, Erin: OK. My suggestion was to first start with subgroups reviewing the comments from the federal partners within their own subgroups and address any comments that they're able to address there. Any outstanding issues that they'd like the feedback from the larger group would be taken to the larger committee.

David Read: OK. I'm just curious if we do this in subgroups, if somebody from FDA would be willing to participate in some of those. Otherwise, it seems like it's easier almost to do it in a group, but if you do it by subgroups - rather than flounder around, if there's questions, it might be nice if we could have FDA on those subgroup calls.

Michelle Hill: Since they some of the subgroups are headed by our federal partners, so they're present in, and if they're not, we could certainly invite them.

Babekir, Amani: We have federal partners on our subgroups - the emergency plan we have Devin, and the training we have Greg, in the notification we have Devin, in the practices we have Greg, and on the template, we have Erin.

Babekir, Amani: We have a good representation for them on the subgroups and if we want to add more members, volunteers, that also could be done. I'm open also the opportunity now for that to be done. Do you think that is sufficient, David?

David Read: Yes, that'd be fine. I just know that they're busy and maybe haven't been able to make all of the subgroup calls, so.

Devin Dutilly: I think we, if needed, can figure out how to provide coverage. If one of us can make a meeting or something like that, we work together to provide comments on the documents. We, from FDA and I think I can speak for USDA and CDC as well, appreciate the partnership and we're here to support CFP and this progress. We'll definitely support, wherever we can and whenever we can - we'll provide coverage for sure. Thank you.

Babekir, Amani: Thank you. OK. We could define the members of each subgroup later in the meeting, but we still have to decide on maybe on how we want to proceed. I would like to entertain a motion. [Long silence]

Michelle Hill: Which means somebody has to make a motion for us to move forward - A voting member?

David Read: I'm sorry, could you repeat?

Eisner, Crystal: Yes, what was that? Can you repeat it?

Babekir, Amani: We need to have the motion to decide how we want to proceed. Erin suggested that we work on the comments in the subgroups, and then if there are any outstanding issues, we could bring it to the general meeting to discuss it. That is a suggestion that has been brought up, and the previous motion did not pass, which is working on the comments in the general meeting, so I would like to hear motion. What if you want to further discuss it – I would also like to hear it - about how we want to proceed, how we want to work on the comments.

Libby Thoma: To clarify, we have two options. One, we work in our subgroup with our regulatory partner, or we do it together in a in the total group, but that didn't pass, correct?

Babekir, Amani: That's correct.

Libby Thoma: I motion that we work through these comments in our subgroups, Madam Chair.

Babekir, Amani: Thank you.

Eisner, Crystal: And I second the motion.

Babekir, Amani: OK. Thank you. Is there any discussion, or any additional point on this motion?

Moritz, Erin: I do want to clarify that my suggestion was not just working on the comments with the subgroups, but it also includes if there are any comments that the subgroups do not feel confident making decisions with, we could still bring it to the larger group.

Babekir, Amani: Thank you. Libby, would you like to amend your motion to incorporate this or ...

Libby Thoma: Yes, I amend my motion to include that if there are any outstanding issues, we bring those to the large group.

Babekir, Amani: Thank you. OK. Any second?

Eisner, Crystal: This is Crystal, I second it again.

Babekir, Amani: Thank you, Crystal. OK. Let's proceed to vote on the motion. If there is no further discussion. If you agree with on working on the comments in the subgroup and bring any outstanding issue to the general meeting, please raise your hand or say, yes.

Michelle Hill: [Voting members vote] Thank you. I have 7 yeses.

Babekir, Amani: Thank you. Anyone abstain?

Vinson, Scott: Madam Chairman, point of clarification.

Babekir, Amani: Yes, Scott.

Vinson, Scott: How many voting, how many voting members do we have in the call?

Babekir, Amani: We have 8.

Vinson, Scott: And for a motion to pass, does it require a majority of voting members or a majority of people in the call?

Babekir, Amani: Eight, we need 8. Eight of the voting members.

Vinson, Scott: So, we need every voting Member on this call to vote in favor of something for it to pass.

Babekir, Amani: That's correct, yeah.

Vinson, Scott: Oh dear.

Babekir, Amani: Do we have any abstaining? Michelle, do you have any counts?

Michelle Hill: I have seven in favor. No abstentions. So, the assumption is that we should collect the No votes.

Babekir, Amani: Yes. This did not pass, we need 8. So, it seems like we need to find a way to be in the middle to bring both groups together.

Michelle Hill: Perhaps we begin the review – bring up the documents so we can all of us get a good look at them together and maybe entertain a motion to do at least that part today, with everybody still on this call. And then we can decide after we look at it, what kind of work is in front of us and form a plan … someone has to make a motion.

Vinson, Scott: Trying to move it, I move what Michelle just said.

Babekir, Amani: Yes, I think I think we need to do it that way. OK. So, Michelle, could you access the documents because we hosted all the documents, we received with the comments in the Teams side.

Michelle Hill: I got it fine with the call, but I have no access to any CFP files on Teams.

Vinson, Scott: Madam Chair, I have that e-mail open. I can share my screen if you'd like.

Babekir, Amani: But we were hoping to work on the same documents. If there is a way anyone of you could access the Teams side the CFP …

Babekir, Amani: The idea was if we are going to work on it in the subgroup, at least one member could be able to access the documents and help the team members to work on it. But it seems like we are not able to access it while we are in the call.

Vinson, Scott: Madam Chairwoman, this is Scott. I just shared my screen. Is this one of the documents you are referring to? This was in that e-mail you sent around.

Babekir, Amani: No, that is just the summary for the comments from the USDA. It's the other one which has the actual comments.

Vinson, Scott: OK, here it is. I think I've found it. Is this correct?

Michelle Hill: You've got it! Turn on comments or scroll down to see if comments are turned on. Oh, there they are.

Babekir, Amani: I don't think that is - what is that? Could you open the other one? You could start with that one.

Vinson, Scott: OK. Can you see this one?

Babekir, Amani: That is the one.

Michelle Hill: Thank you so much. If we can start making - reviewing at least the first beginning part of this right now, you could just send me your document. I'll make sure it gets left loaded where it needs to live. Is that OK with you Amani?

Babekir, Amani: Yes, that is OK. Let's start with the first comments. Could you maybe click on it so you could show the whole comment?

Vinson, Scott: Oh yeah, there.

Babekir, Amani: We could give it like a minute just to go over the comments and then we can discuss it.

Michelle Hill: Yes.

Babekir, Amani: OK. Let me now open the floor for the discussion on this comment.

Eisner, Crystal: The comment says consider changing it to major food allergen framework, but then it says, can you also include non-major food allergens?

Moritz, Erin: So, regarding the suggestion to change it to major food allergens, I think one of the key questions is if somebody comes in and says, I have an allergy to Jell-O, which is not one of the major food allergens. Do provide guidance here that can be used for non-major food allergens.

Michelle Hill: Am I wrong in assuming that the point of calling it a major food allergen framework is, that is the verbiage that appears in the food code - Is that right?

Abel, Greg A: Correct.

Libby Thoma: Correct.

Abel, Greg A: That's correct. And the document only applies to the major food allergens, the eight soon to be 9, correct.

Michelle Hill: Correct. Thank you.

Babekir, Amani: Also, would like to remind that our charge is addressing the major food allergens.

Eisner, Crystal: We should probably name it the same.

Michelle Hill: Do we need to entertain a motion to make this change?

Babekir, Amani: I think that will take long time.

Vinson, Scott: Maybe it'd probably be faster just to ask if anyone has any objections to any of these suggestions.

Michelle Hill: That's good advice.

Babekir, Amani: Are we good with the change? Are we good with changing the document title to major food allergen?

Vinson, Scott: Yes.

Babekir, Amani: OK. Any other point? OK. So, Scott, could you type that please?

Seymour, Jenna: I do hope that this other point within that comment is not missed about just having something somewhere that points people, like in this case with Celiac disease that came up a lot in discussions. Just pointing people to the gluten intolerance group. It's not like this document would have to say anything about it except to say if this is also a concern,

go here [insert GiG website address]. Just do not ignore what is obviously something that a lot of restaurants are hearing about and wanting to address.

Michelle Hill: We perhaps also could refer to the FDA advice on what is gluten free. That might be a good part of it too.

Devin Dutilly: I think that in addition, the broader question would be what Erin had said about these procedures these techniques, these points may also apply to other allergens as well, so you know it's not a major change to the document, but that's what the comment essentially is capturing - is that you don't need to make major changes, or perhaps you might need to make major changes, but small tweaks.

Babekir, Amani: To what?

Moritz, Erin: I think a long time ago, we did have some kind of verbiage in here about how this, even though this is the charge, is specifically for major food allergens, a lot of the materials are relevant to you know gluten sensitivities or any other food sensitivities.

And so maybe just a sentence or two in the introduction and then pointing, since gluten is such a such a prominent sensitivity, pointing to some gluten sensitivity resources.

Babekir, Amani: Do you think we could point to this in the introduction of the document.?

Moritz, Erin: To me, that's kind of where it fits most, because it's before we are even getting into the main purpose of the document. Or maybe if we end up doing a references page at the end possibly? Certainly open to other suggestions.

Michelle Hill: I did notice that the comment below the one we're working on also dealt with a similar or same issue. I'm wondering if it would inform our process.

Babekir, Amani: OK. And Scott, could you please change the title on the document to Major? Thank you.

I'm going to give it 30 seconds to go over the second comment.

Michelle Hill: And this might be how we achieve what we're trying to achieve, which is they're saying to add possibly a disclaimer on the scope of this document. We could say, yes, it deals with the nine major food allergens. However, it's also applicable to, fill in the blank, really.

Babekir, Amani: It seems like it's the opposite. It's like you disclaim that it is just the nine major food allergens.

Moritz, Erin: We'll have to state somewhere whether everything in here is just for the nine food allergens. And if we're saying that some of the parts can be used for others, then maybe it's not necessary to consider it a disclaimer. We just have to write something somewhere.

The key question is what we want to do about the fact that some of the stuff is going to be applicable to other food allergens and other sensitivities.

Babekir, Amani: But is it enough and sufficient for the other Allergens? If we want to generalize the document and say this is for major food allergens, but it could be applicable for other type of allergens, do you think that's a fair statement?

Moritz, Erin: I think we use wishy washy words like, it could be applicable to other food allergens and other sources of food sensitivities, etc.

Michelle Hill: Including celiac disease, perhaps.

Seymour, Jenna: I get a little uncomfortable with that one just because …

Moritz, Erin: OK.

Seymour, Jenna: That's why it was me that put that gluten intolerance group into the into the comment because they do training for restaurants on specifically how to deal with Gluten intolerance and celiac disease.

Michelle Hill: Yes, they are awesome - I was really glad to see that.

Vinson, Scott: I was going to try to add an asterisk here and then put down at the bottom what we just talked about a disclaimer, but I can't seem to figure how to do it, so maybe it would be better done on page 4 in the verbiage of the introduction.

Babekir, Amani: So do we want to say it's just for the 9 Major food allergens or it's also applicable to the others?

Moritz, Erin: I don't know how often this would happen, but I would hate for somebody to.

Say, I learned all this stuff and I have all this stuff, but somebody came in with a Jell-O allergy; now what do I do? And Jell-O allergy being an example of something that not many people have.

Michelle Hill: No, it's that allergy to gelatin, and I happen to have it – it is obscure.

Moritz, Erin: Oh, you do. OK. I'm sorry. I was trying to think of something very obscure.

Michelle Hill: The question I keep thinking of is would we change our behavior if we knew other information other than, Is it an allergy? and we would take hopefully the same precautions that we do for allergy that we would for Celiac.

Moritz, Erin: In anaphylactic shock to gelatin and your emergency response, I think should not be any different than if it were for one of the nine.

Michelle Hill: No.

Vinson, Scott: If we had that type of language, are we going beyond the scope of our charge?

Moritz, Erin: I think we would be dipping our toe beyond the scope. In in my mind, as long as we don't go in depth and discuss other scenarios. I guess it's just common sense to me that we could say something like that and be OK.

Vinson, Scott: How about something like this?

Moritz, Erin: Certainly, certainly open to other, you know, other opinions.

Babekir, Amani: I need to end the meeting at 3:00 pm because I have another meeting and I wouldn't be able to stay on the call. We need to stop it here and we could proceed on the other comments the next meeting.

Babekir, Amani: Do we want us to make this weekly meeting? I think we need ….

Michelle Hill: We didn't reach a consensus, did we?

Babekir, Amani: I hate to delay working on it for two weeks.

Moritz, Erin: For what it's worth, I think we're going to have to meet more often, especially if this is kind of the direction that we're going in, in terms of how we're going to address these.

Babekir, Amani: Please send me your suggestion if you think it's better, we move to the weekly meeting instead of bi-weekly so I can set-up a meeting for the next week at this time. We need to convene now.

Abel, Greg A: One quick comment – the document that was reviewed by the federal partners here was an older version, and I know you guys met two more times to revise the document. So, what you might have in the current version of the document may have changed since the comments on this revision, from what I understand.

Babekir, Amani: There are some changes here and we could look at it and compile it into one document.

Abel, Greg A: OK.

Babekir, Amani: Yes - before we proceed with the comments.

Michelle Hill: Thank you for making us aware of that. I'll work with you on that, Amani. I'll be happy to.

Babekir, Amani: Yes. Thank you, everyone. Scott, please send to us this version and see you either next week or the following week.

Michelle Hill: Stay tuned. We'll be asking your opinion on how we should move forward via e-mail.

Adjournment

Babekir, Amani: This meeting is now adjourned. Thank you.

Meeting Number 19	Meeting Date **08/18/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Previous Meeting Minutes	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

Babekir, Amani: Michelle, would you like to do the roll call?

Michelle Hill: Yes, Madam Chair. I can do that. [takes roll call of Voting Members] We have a list of seven and I do believe that's our current quorum so we can proceed with the business of the day.

Babekir, Amani: OK. Thank you, Michelle.

Babekir, Amani: I would like to remind you that the Conference for Food Protection Antitrust statement is active in this call. So just keep that in mind.

Babekir, Amani: Let me share our agenda for today. I'm going to give you an update about our voting members.

So we could you could see how we ended up with the seven as our quorum.

Babekir, Amani: OK. So we're going to postpone approving the minutes of the previous meetings to the next meeting, so we're going to have almost like, 3 or 4 Minutes to approve, so hopefully we could do that in our next meeting.

Babekir, Amani: I want to also give you an update about our voting members. So two of our voting Members are not with us anymore. Vy has moved to a new job and is not able to serve in our committee and Cassandra, she retired. So they are very active members in our committee and it's a big loss for us. We should all the best to them. Both of them are representing the local regulatory, and we want to keep the balance of the floating members. So we moved one of our alternate members from local regulatory - Christine - to the voting members. So I'm really glad Christine has agreed to be a voting member in our committee. Hopefully this will make our voting process easier, and we will meet our quorum in our meeting. Any questions before I move to the next item in the agenda? [no questions are asked]

About the timeline.

I received a couple of questions about “what is our timelines” and we are looking into the extra work we need to do with the framework, we really got a little bit worried about our timeline. So, the updated timeline - that is per November 18 - we need to submit the final reports, the final documents and also the Issues we want to submit to the Council for the next Biennium.

All of these need to be ready for a round of review from the Council members, and then we're going to have a chance to make a second round of edits before the final solid submission. But this is the deadline - November 18th, so we need to be ready with all of our documents by then.

What we propose to do in order to finalize our work in the framework, because we're going to need also some time to spend on our Issues, we going to dedicate kind of four weeks to review the comments we received from our federal partners. In these four weeks we are hoping, and I sent an e-mail about this, we are hoping that we do some work or even just go over these suggestions and see which one we want to address.

Which one we think we could refer to maybe a future committee's charges. Or we could disagree with it and have a different opinion than doing any change on the framework. For the sake of time, we thinking what will be the way to do it? And because we couldn't come to an agreement in our last meeting, as to having a portion of the comments to be worked on the subgroups, and some portion we review it in our large meeting.

And thank you to Michelle. She put all of the comments in one document. And this way we could review it in our meeting, just look into the comments, see which one needs to be discussed here in our large meeting, which one we could, you know assign to the subgroups just by doing it so quickly.

And we did do this initial kind of work, me and Michelle, we worked through all of the comments, and we thought, OK, this one is one of the basic things that we need all of us to discuss in our large meeting. Some of it is format or just extra information needs to be added, which could be handled with the subgroups. Thinking about what we sent in the e-mail and what we suggested right now, I'm opening the floor for any suggestions, any comments and any points you want to raise before we move forward with reviewing the comments.

And I can't see any hands. Michelle, if you see hands.

Amber Potts: Scott has his hand up.

Vinson, Scott: Can I share my screen?

Babekir, Amani: Yes, please.

Vinson, Scott: OK, so I'm the leader of the group E, which focuses on Practices, and I will share my screen. So these people are in Group E practices, Ben Wagner, James Baldwin, Aubrey Noller, Greg Abel, Amani and James O'Neill Amani, you're on, I'm on, I didn't hear during the roll call many of the other folks in my Group E on the call - did I miss anyone who's maybe on?

Babekir, Amani: Yes, I know. Ben Wagner is traveling, so He is not able to join us on the call.

Vinson, Scott: James, are you on?

James O'Neal Yeah, I'm here, Scott.

Vinson, Scott: OK. Amani and Michelle, how many people does it take? How many people do you need to have a quorum on a Group to have a call?

Michelle Hill: I think it's just simple majority.

Vinson, Scott: Supermajority. OK. Well, I don't think we have it cause it's just me, James, Amani. I was going to ask my Group E if we could meet following this call at 3 pm or whenever this call ends, so we can perhaps dispose of some of the comments from our federal partners. Let me share my other screen to show my Group what they are. So I have reviewed the comments from Devin Dutilly: , one of our federal partners. Let me share my screen so you can see what they are. Here it is. So group E, we are actually "section B Food handling practices" in the framework document, and our section comprises two pages, pages six and seven of the framework.

Devin has submitted 20 - I counted them up across 2 pages - comments, most of them are picayune, and merely like suggestions or observations and don't require a great deal of any consideration? Some do, but I was wondering if my Group could maybe quickly dispose of them, act on them on a call after this call.

Does it sound like we have enough people to do that? I'm going to be out for the next two weeks. This is August, which is vacation time for people involved in the public policy making apparatus in Washington. It's and surrounding areas. So this is the time when we're out because Congress is out. So this. I can't work on it the next two weeks. I know you would want the subgroups to take it from here.

I guess we'll have to come back in early September to do it, if that's OK with you, Michelle and Amani.

Michelle Hill: One thing I wanted to point out, Scott is, and I don't know that this is the case, but there's more than just Devin's comments that are part of the considerations. So there were comments from FSIS.

Devin Dutilly: Yes.

Babekir, Amani: Yes.

Michelle Hill: Devin had condensed a bunch from other federal partners under his own name, so some of that data, of course, came from other agencies like USDA. Is that right, Devin?

Babekir, Amani: Yes.

Vinson, Scott: Well.

Devin Dutilly: Yes. Thank you for. Thank you for clarifying it, Michelle, that's correct. So the comments that were submitted, I submitted the comments and as we discussed previously, those comments were comments from USDA, FSIS, USDA, FNS and CDC as well as FDA.

So the comments that are underneath my name are compiled comments from the federal partners. So they're federal partners comments, even though my name appears. And we don't have ability yet to change who submits them, so they're all submitted underneath mine. So I compiled all the comments that were submitted, and we discussed the comments as federal partners. So those are federal partner comments. Thank you. Thanks, Michelle.

Vinson, Scott: OK.

Babekir, Amani: Also, Scott on the e-mail which I sent, I sent the version of the framework with merged comment because also we have comments from the USDA.

Vinson, Scott: That's what this document says at the top of the screen, doesn't it, merge comments?

Babekir, Amani: Ah, yes. That is the one, OK.

Michelle Hill: Ah, that's not the most recent one we sent, though. We sent one that was laid out in a landscape fashion with all the comments for everybody at the bottom. I did a clipping of each part where the comments pertained to and then they're all in a grid below the picture of what you're commenting on, or what the comments were on. Does that make sense?

Vinson, Scott: This is the document that Amani sent out last night.

Babekir, Amani: That's correct. Yes. So this is the actual framework with the comments, the document Michelle referring to is that second document on the e-mail which includes the list of all the comments. But Scott, you are good. That is the document you need to work on with your subgroup.

Michelle Hill: Even though no other partner comments are on that one?

Babekir, Amani: That should have all of the - that should have the merged comments.

Vinson, Scott: OK, so there are three documents in the e-mail you sent out last night. I'm sharing it on my screen here. I don't care if everyone sees.

Michelle Hill: What you should be looking at is federal partner comments.

Vinson, Scott: OK. Well then that was confusing, so I should be looking at this one.

Michelle Hill: In your attachments, there's one titled federal partner comments 8/12/22.

Babekir, Amani: Yeah, but that, that one, Michelle, that's contained just the comments, but if they are going to start working on the actual framework document, they need that one with both comments because we merged it together.

Vinson, Scott: OK, now I'm confused. So I think the document that I was originally sharing on my screen that said merged comments with all the comments in the right margin, I think that's the one we're that the subgroups are supposed to consider, correct?

Babekir, Amani: That's correct.

Vinson, Scott: OK, so I was right.

Babekir, Amani: Yes.

Michelle Hill: OK. And the one that I'm talking about it? Can you bring that up, please, Scott? Because there is some important information on that that I want people to be aware of.

Vinson, Scott: Which one is it called?

Michelle Hill: Federal partner comments 8/12/22.

Vinson, Scott: OK, let me pull up that e-mail again. So this one.

Michelle Hill: Yes.

Vinson, Scott: Federal comments.

Michelle Hill: Correct.

Babekir, Amani: When we were planning to review it, to go over that document just after Scott's point, yeah, we want to go over the list of these comments and then show you which one we think we need to discuss it here in our meeting and which one we could assign to the subgroups.

Michelle Hill: This seems like it's crazy because it's 57 pages, but, what was done was the information that the comments pertained to was clipped and pasted above as a static picture, so you can't actually change the data and then the first column there “D” that means it came from, you know, the Devin Dutilly: labeled stuff, and then you know what they said. And then in the far-right column, it's what Amani went through, and we decided, OK, or we thought about. You can of course suggest any changes, but we just did a quick look and thought, OK, who should work on this? Is it a whole group issue? Is it a template group issue? And Amani color-coded based on is it a? Is it a formatting particular or is it - what was the green again, Amani? I don't remember what the bluish green was.

Babekir, Amani: Yes, so these one that's we need to consider, we need to think about and the yellow is formatting changes or the blue also might refer to like text addition.

Michelle Hill: That third column would be used to actually make the language changes or suggestions. And then we can meet as a group and merge it all together. That was the thinking. You don't have to use this, but we've already done some of the vetting and we're just trying to improve the flow in the process. And so at some sections get repeated because they had multiple sets of comments. So if you see repeating same data, it's because there's still comments that have to be addressed.

Vinson, Scott: I am now totally confused.

Babekir, Amani: What we're trying to do with this one, which including all the comments, is to look at it here in our larger group and think about it. But as a subgroup, you need to work on that document, Scott, to look and see the comments. We want to ensure that you are using the right comments which have both the FDA and also the USDA comments together in the same document.

Michelle Hill: And FNS was separate ...

Babekir, Amani: Yes - so all the partners.

Michelle Hill: The original one you were showing.

Vinson, Scott: This one.

Babekir, Amani: Yes, do you see other comments beside the Devin comments? Do you see other comments with other names?

Vinson, Scott: No, they all have Devin's name. Click on each one. But he said that is just because he merged all of the agencies - Federal partners - into one under his name.

Babekir, Amani: Yes, you should see all the comments and labels.

Vinson, Scott: Well, there's one, yeah. There's one.

Babekir, Amani: OK, so that means you're good. Yes – FNS - that is another comment. So we merged both of them into this one document.

Michelle Hill: OK, I'm really glad you made that clarification, Amani, because all I was hearing was that it contained only Devin comments. So I'm glad to see FNS would be part of that too. So good - thank you, Scott.

Vinson, Scott: So the subgroups are to use this document that I have open now - that you all see on your screen - and each group should go to their section of the framework and consider so for example , you know the training group should consider each one of the comments.

Michelle Hill: Yes.

Vinson, Scott: OK.

Babekir, Amani: That's correct.

Vinson, Scott: So I don't have, it looks like enough people in the practices Group E to do this today. So my question for you, Amani and Michelle, is, is it OK if our group waits until early September?

Babekir, Amani: September? So you're going to have like early September, that's mean you're going to have like 2 weeks to complete it. Do you think this could be done within two weeks?

Vinson, Scott: Well, my group, we only have 2 pages. And it's 20 comments. Many of them are fairly innocuous - don't seem to require - I mean this is more a comment than anything that requires action. This section could be applied to all food allergens, but our regs are specific only to major food allergens. OK, and your point is, I don't know, but I imagine our Group is going to just say, OK, whatever. But there are some that are substantive, but I don't think it'll take two weeks or probably take one call.

Babekir, Amani: OK, that sounds good.

Michelle Hill: So Amani should we put a deadline on that like we would like to have data back by September 15th perhaps or?

Babekir, Amani: Yes, we agreed that this is going to be done within four weeks. So that means by September 18, we need to be complete, yeah.

Vinson, Scott: And so just so we all know all the group leaders know how many people do we need on our group calls to have a quorum.

Michelle Hill: I think they're subgroups, do they? Isn't it just a simple majority?

Babekir, Amani: Yeah, you don't need quorum because you're not going to be voting. But if you have enough people that you feel comfortable to proceed with, you know the change.

Vinson, Scott: Well, we may well be voting.

Babekir, Amani: You may, I don't ... Wendy? I think Wendy is with us. Hi, Wendy, can you hear me? Are you with us?

Bell, Wendy: Yes, I can hear you. And it's so I believe Michelle is correct as far as the subgroups, I would assume that you would bring your decisions to the main group if there's something that needs additional attention and just the nature of how many Members we have. And on this committee, it's I think we just need to proceed forward. And then if there's an issue we can bring it to Michelle and Amani and we can move forward from there.

Vinson, Scott: So we are not to vote in the subgroups we are to reach consensus on whatever we can where we can't reach consensus, we need to bring it to the full group.

Michelle Hill: That's awesome, yes.

Babekir, Amani: Yes, that's correct. That will make your job easier, without stress. Because we're going to have a chance to review the subgroup work in our large meeting. We're going to have two or three meetings to do that. So it's any critical things, any additional points, because now we're going to go to the document Michelle just discussed. Any additional points about the subgroup work?

Michelle Hill: I think it was Amber who said in the Chat that she would like to follow the same thing for her group. Is that right, Amber?

Amber Potts: Yeah, I agree. And ours is even smaller or like a page and a half. So it'll probably just take one meeting to go through the comments and that would be it. So I'll send a "when it's good for my group?".

Babekir, Amani: If that is good and for the notification group, I have a meeting this Friday and I moved it to, I think 3:30, so I could give Devin a chance to join us. Scott, would you be able to join if we move it a little bit later? I know you did not accept it or you're going to be on vacation. You are going to be out.

Vinson, Scott: What date are you talking about?

Babekir, Amani: Tomorrow at three.

Vinson, Scott: I'm on vacation. I'm traveling.

Babekir, Amani: OK, so it will be fine. So for the notification subgroup, we're going to meet tomorrow , and that should be the other one. Michelle is going to take care of the equal considerations' subgroup. So, Michelle, are you good with that one?

Michelle Hill: Yep. Thank you for reminding.

Babekir, Amani: Thank you. And I'm gonna send an e-mail to Ben for his subgroup and Erin, are you good with the starting your emergency plan group?

Moritz, Erin: Yeah, I'm gonna send out a "when is good" poll and just put some meetings on the calendar based on that.

Michelle Hill: Erin, I think you already do invite me, but could you for sure invite me for those?

Moritz, Erin: Yes, absolutely.

Michelle Hill: OK. Thank you.

Babekir, Amani: Thank you. It's great. And let me share that document which including all the comments together just to give it a look. So here are all the comments and I'm glad that we resolved the first two comments good with that one.

All these comments are related to formatting and having a footer section, so that will be taken care of by the template team. And this one - the one which you see I put committee on - we need to discuss it here.

These comments are about the title of the document, which is the retail food establishment.

Do we need retail on it? Amber, we discussed this one before here. Do we need it to keep it retail food establishment or … ? Consider all other all retail food establishment are not specifically called out in terms of special consideration for this type of food establishment. Do we need to think about other names or add any additional comments to the document? Just give yourself some time to go through these comments, which I'm just highlighting.

Eisner, Crystal: What's the current title?

Babekir, Amani: Now the title of our framework is "At retail food establishment" here, and also, we have it here, retail food establishment.

Moritz, Erin: Do we have the definition of that anywhere? We put that in our definitions?

Amber Potts: The food code calls it food establishment.

Babekir, Amani: We have it as food establishment, not retail. Even in the definition section.

Amber Potts: I think we should just put it as food establishment.

Moritz, Erin: I'm good with just food establishment.

Babekir, Amani: Thank you. Now we could move to the second one. So talking about food intolerance and sensitivity. Just take a moment to go through it.

Amber Potts: I think the only comment I would think is I don't like gluten intolerance. I would prefer like with I'm, I'm assuming it's referencing Celiac. Which is more severe? You know, I have a lactose intolerance, but if I eat it, I'm not gonna get severely ill. I think

don't we already have something that mentions it? I feel like we should mention it, but Celiac is it called a gluten intolerance? Is that what it's called?

Vinson, Scott: I have Celiac disease and it's referred to interchangeably as Celiac disease or gluten intolerance.

Moritz, Erin: Are there degrees of severity where you can be intolerant, but it doesn't rise to the point of Celiac disease?

Michelle Hill: Yes, and that's referred to as gluten sensitivity, not intolerance.

Moritz, Erin: I see, Celiac disease and gluten intolerance are synonymous. So, I think if anything, to be correct, we would refer to it as gluten sensitivity or Celiac/gluten intolerance, I guess, if people aren't familiar with the term Celiac disease.

I don't think that's really getting at what this comment is addressing. I don't know if we want to say it's not intended for gluten sensitivities.

Michelle Hill: You know, because really logic would dictate you don't treat them any differently. The answer is complete exclusion of the protein from the meal. So, is the behavior different?

Amber Potts: No.

Moritz, Erin: Yeah, that's a tough one.

Amber Potts: I don't know this much about food science. Can you have a product with wheat but not with gluten? And can you have a product with gluten and not with wheat?

Vinson, Scott: Yes.

Michelle Hill: Wheat is the greater allergy. Yes. And gluten. There are some wheat grains that are gluten, low gluten or no gluten. And that is the difference. So it's Gliadin across the board and then you can also have the Gluten as part of it, or separately.

Seymour, Jennifer: So I just, I just wanted to correct something because I was feeling like what was just said before, was not right. So I just checked, to back me up, that gluten intolerance is not the same thing as Celiac disease when they're talking about gluten intolerance, which is talking about people with issues of bloating, etcetera, that is not Celiac.

Vinson, Scott: I mean, look, the advocacy groups, there are several advocacy groups for people with Celiac disease, some of them call themselves the Gluten Intolerance Group.

Seymour, Jennifer: Right. Although I'd take GiG does work on addressing issues for people with gluten intolerance as well as Celiac, which might be why GiG is called that.

Vinson, Scott: Look, I think I'm probably the only person on the call who actually has Celiac disease, so maybe.

Seymour, Jennifer: No, I do also, sorry I do.

Babekir, Amani: I do, I also have it, Scott.

Vinson, Scott: OK, well, when we were diagnosed, we were diagnosed with Celiac disease, right?

Seymour, Jennifer: Yes.

Vinson, Scott: And our doctors also referred to it as gluten intolerance. Gluten is a protein that is found in wheat, rye, barley and sometimes oats, due to cross contamination.

Babekir, Amani: To address the intolerance and sensitivity, and also to consider mentioning gluten specifically so, do we want to do that?

Amber Potts: I think it's worth a mention.

Moritz, Erin: Yeah, I think so. There's what we call it, which ultimately, we'll have to come up with something we agree on, but the larger comment is whether we feel comfortable saying that what we've put together can be used to prevent exposure.

Amber Potts: Right.

Moritz, Erin: People from being exposed to gluten? So there's kind of two questions that were discussing.

Michelle Hill: The point I was trying to make earlier is if the behavior is different then we need to talk about it differently. But if it's the same behavior you're gonna employ to control the problem we could say, the concepts contained here, or the advice is guidance. It effectively, when implemented well, will effectively control for Celiac, gluten intolerance, whatever you're going to say, … I don't know if that's agreeable, but ...

Moritz, Erin: I think that's the goal of what we set out for at the beginning … was to have it be helpful in both situations.

Michelle Hill: Yes

Michelle Hill: And from a person that teaches this stuff it just seems like the confusion is around boots on the ground. Confusion is, "Is my behavior different? And if the behavior keeps the allergenic protein controlled, you still need the same skill set. Reading the label, knowing the how it is prepared, what's its flow …

Vinson, Scott: Right.

Babekir, Amani: But is it? Is it sufficient? So is it sufficient to control gluten – the information we include here? Or could it be used as part of the gluten control?

Michelle Hill: Well, really any allergy.

Vinson, Scott: It's probably not. I mean our charge was to control for the eight allergens. Rye and barley aren't among the eight Major or nine major allergens. So we probably should just include a sentence in here, something like ….

Michelle Hill: They don't exclude Rye, Barley, because those are types of wheat grains. They're in the grass family. So those are descriptions or examples of how we talk about that allergen in the food flow and labeling.

Vinson, Scott: Say that again, Rye and Barley are types of wheat.

Michelle Hill: They're in the wheat family. And so when, for instance, when you look at a fish allergy, it also says like cod. I can't remember what else I see if I asked, flounder, cod? Or when they talk about shellfish, they say lobster, shrimp, crab, am I wrong about that? People on the food code? That's meant to give you examples of what that allergen is.

Babekir, Amani: Probably I think wheat is just the wheat.

Devin Dutilly: What you had said is correct. The food code, the allergen definition, major food allergen definition, contains those examples behind it. Yes, that's correct.

Michelle Hill: What? Which means they're included as part of that allergy they're describing the allergy. What's under this umbrella of allergy?

Vinson, Scott: So you're saying because the nine major food allergens include wheat, that barley and rye should also be understood to be one of the nine major food allergens?

Michelle Hill: Absolutely. In fact, the way it is taught by most companies that train people for the CFPM is to learn what are the derivatives - what is this allergy? We can say dairy, but really you need to read the label for casein. So if you go back through and read the food code, it's gonna give you parts to include examples of what is included under that major allergen category, or within that category there's actually ...

Seymour, Jennifer: But that that really surprises me. I agreed that barley is a grass, but that not ... so it might be included in the category that are grasses, but to say that it's automatically excluded when wheat is excluded, that seems very suspicious to me.

Michelle Hill: I'm not wrong on this. So can you guys please speak to this, the people that know about this from the FDA, Devin perhaps?

Devin Dutilly: Yes. So, just to clarify the way that the major food allergens are defined in the food code aligns with the same way that they're aligned within the FD&C Act. I'll just go to it just so that I'm not misquoting anything here. So the major food allergens read, "Milk, egg, fish quantities such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster or shrimp, tree nuts such as almonds, pecans or walnuts, wheat, peanuts, and soybeans.

So it provides such as behind fish and it provides a such as behind crustacean shellfish it currently, as it's written, it does not provide such as behind wheat. That's the question.

Babekir, Amani: Yeah. So.

Michelle Hill: The framework we teach from includes descriptions like for the egg it would be yolk and then white because they're different protein structures. You can be allergic to one and not the other. Umm so interesting.

Vinson, Scott: Rye and barley are not wheat. But and I don't think it's their commonly understood to be wheat, it's probably an academic question for our purposes. So we should definitely mention in this comment that people who have been diagnosed with Celiac disease are intolerant to gluten and gluten is found in wheat, rye, barley and frequently also oats.

Babekir, Amani: So the main the main question here I think, and we have an agreement on it, is that we should mention gluten in our introduction of the document, as an example.

Moritz, Erin: Yes, I think at the very least, we need to say something about it. Because people are going to say well to this apply to gluten and personally, my opinion is that much of what, if not all, of what we've developed can be used for gluten. I'm not super familiar with all the processes that can happen in food establishments, so am definitely interested in hearing what other people think.

Vinson, Scott: I think we should list them, so that people in the restaurant, the food service workers, know they need to be aware that people who have Celiac or gluten intolerance or even gluten sensitivity need to watch out, not just for wheat but also barley and rye, oats, which may be present in the facility.

Michelle Hill: Have you ever seen it labeled that way? Scott, I'm just curious on a consumer label, have you ever seen it? Where they do, they just say wheat and wheat probably is present. Do they say wheat and parentheses?

Babekir, Amani: Yes.

Vinson, Scott: On boxes, on the consumer on the ingredient labels, yeah. You will frequently also see them in a restaurant or food service setting. It's gonna be less common - the consumer's not gonna see it, but the people working in the back of the house may see those ingredients listed on ingredient panels, in product packaging.

Michelle Hill: And it'll be listed as gluten or as wheat.

Vinson, Scott: They'll be listed as wheat, rye or barley. It won't be listed as gluten. That's very, very, very rare to actually see gluten in a product panel. Unless the product is actually gluten, I mean you will see gluten. You can buy gluten at the grocery store.

Seymour, Jennifer: Right, sometimes you'll see vital wheat gluten listed or something like that.

Michelle Hill: I was wondering how does the world treat Rye, barley that aren't wheat, do they list it as a wheat allergy? I mean, is the allergy the list for wheat or do they not list for barley? Is barley not considered? Do they ever call out barley?

Seymour, Jennifer: I would think yes.

Vinson, Scott: Barley's a separate grain. Barley is not considered wheat. It's a separate grain. So is rye.

Seymour, Jennifer: I think I have definitely seen a barley mushroom soup. And you know, that would not be labeled as a problem for a wheat allergy?

Vinson, Scott: That's correct.

Seymour, Jennifer: Something come like that? Yeah.

Babekir, Amani: OK, so I think, yeah, I think so. The introduction group needs to consider gluten on when they are working on their introduction, do we need to mention any cautious statement that is this document might not be sufficient to control gluten.

Seymour, Jennifer: I think so. Yeah. I think so. And that's where I think we were talking last time about including the link to the Gluten Intolerance Group, because just right away, I think of things like, you know, malt that's made from barley but people may not associate because it doesn't say barley or all those kinds of things, where if you really want to understand and make something gluten free you have to know a lot more about all these different, like what we're talking about, Emmer or and triticale and spelt and all these things that people would have to understand to make things gluten free that aren't necessarily. I mean it. Those last ones would be related for the wheat allergy, but I think both are good examples, or the fact that oats are often contaminated.

Seymour, Jennifer: All those things are worth having a link to somewhere else for understanding the issue of gluten.

Vinson, Scott: Yeah, but we shouldn't put links in this document, because I mean, they're probably gonna be printed out. So we should just list them out. It just put in the def in parentheses behind gluten and put all of the things that fall that contain gluten. All the grains that contain gluten, wheat, rye, barley, oats. Barley malt.

Moritz, Erin: And we direct them to the home page of good websites - I think the Gluten Intolerance Group - list out the name of the organization.

Seymour, Jennifer: I think the Gluten intolerance Group is the place to direct them, even if it's not a link, just direct them because they work so heavily in restaurants and helping restaurants to be appropriate for people.

Moritz, Erin: So even if it's printed out, we can say. Please go to gluten intolerance group at … and then list the website of their homepage.

Seymour, Jennifer: Yes.

Moritz, Erin: If they want to follow up on that, they'll at least have the home site web page, which hopefully will stay at least stay the same for a while.

Devin Dutilly: I think the intent of the comment was to provide some sort of disclaimer and including, if it says something, this is not intended to address this, but, “here you can get more resources” and so and there's a resource section at the bottom that we have so even if the links are printed off, you could put the actual live link so someone could type in the resource section at the bottom, so we could potentially put it in two areas, but that's just a thought, but the intent of that comment as Erin had mentioned, and Jennifer too, is to capture what is or is not and if it is, don't just say nothing's available. You know adding something like, the GiG might be a resource for someone who is looking for this - so there is something available.

Babekir, Amani:

Babekir, Amani: And that's good. Thank you. And I think we could move to the next one. This one is questioning the document, should it be framework or a toolkit?

And as per our charge is called framework. So do you have any other opinion on this comment?

Amber Potts: No, I keep it as framework.

Moritz, Erin: Yes, to me, a toolkit is a document where we would put a bunch of links to other sources. We do have a couple posters, but I think what we put together maybe is not like in the strictest definition of either one of those, but to me it's more, it has stayed more of a framework.

Babekir, Amani: OK. Thank you. The second one is about adding sections a limitations section to the document, so the user could understand where, how this document was developed; to frame any topic that might be forthcoming or emerging?

Amber Potts: Yeah, I like this. I think we should add at least where who developed this, why we developed it that way. People can learn about CFP and all kinds of things.

Babekir, Amani: OK.

Moritz, Erin: I don't understand why it's a limitation section.

Amber Potts: Yeah, I don't know if that's the right word. This is not regulated; you know enforceable code.

Michelle Hill: We wouldn't necessarily call it guidance either then, huh?

Amber Potts: Disclaimer, I don't know.

Babekir, Amani: No.

Moritz, Erin: Yeah, I think something towards the end may be detailing how it was developed. And then, if there's any disclaimers, like especially important disclaimers, we might want to have them at the beginning and in the section at the end.

Babekir, Amani: OK.

Moritz, Erin: That's what they were going for with limitations.

Babekir, Amani: OK. It's good. So let me see - what is - so this one. This one is talking again about a disclaimer and the language and disclaimer to let the readers know some of the documents could be generalized, so I think we addressed this one already. What do you think?

Amber Potts: Yes.

Babekir, Amani: This one is talking about temporary food events. Do you think we need to address that one, or is it out of the scope?

Amber Potts: But this is considered - what does that charge have about? What does ... they use alternate? What was the wording it used?

Babekir, Amani: Equal consideration.

Amber Potts: For alternate. What's it say?

Babekir, Amani: Yeah, alternate food sources such as food pantries, food bank, probably this is the one.

James O'Neal: Well, and I think if we're going to use the definition of food establishment from the FDA, I feel like … let me pull it back up. The definition of food establishment includes an operation that is conducted in a mobile, stationary, temporary or permanent facility or location. So I think that would fall under that.

Babekir, Amani: OK.

James O'Neal If we're going to utilize that definition, I think we would probably have to address it.

Babekir, Amani: So do you think we should address it under the equal consideration section or?

Amber Potts: Yeah, I think so. Although they need a lot more training because they don't, some people do this at temporary events. They don't do it for a living. You know what I mean? They just want to sell their whatever. I know, as someone with an allergy, I don't eat at Temporary events, so it's just not safe.

Babekir, Amani: OK. So this one talking about Major food allergy versus food allergies. We recommend changing this term, presumably food allergy. What do you think?

Amber Potts: What section is this coming from?

Babekir, Amani: This section is on the person in charge on probably a food allergy definition, food allergy.

Amber Potts: OK. Is this for the training section?

Babekir, Amani: For the training, yes, under …

Amber Potts: Yeah, we'll discuss that in our group and get back to everyone.

Babekir, Amani: The comment is to use through the whole document cross contact. That is one of the comments and also this about sanitizing, and equipment used for preparation, for preparing the customers allergy free meal. So. I'm not sure what it behind these comments, other than just to bring awareness.

Moritz, Erin: So are they saying that just washing and rinsing should be enough? I'm assuming like the soap would destabilize the proteins, maybe.

Devin Dutilly: I think the comment for sanitizing is not relevant because of the wash, rinse and sanitizing procedures in the in the food code that relates to microorganisms, so …

Moritz, Erin: Oh, yes, the definition of sanitizing is reducing microorganisms. OK, I get it.

Michelle Hill: Yes.

Devin Dutilly: So using the term for microorganisms, so sanitizing doesn't - you have the term is not defined towards removing or denaturing proteins, so.

Michelle Hill: Yes, and that would be an extraordinary chemical too, wouldn't it?

Babekir, Amani: Yes, but you still need for the proper cleaning. You still need to sanitize food contact.

Moritz, Erin: Yes, that's what I think. We should maybe leave it like that just because we don't want them thinking like they're still gonna have to properly sanitize it for microorganisms I would think, maybe they won't.

Babekir, Amani: That that is the proper procedure, yeah. To wash, rinse, sanitize.

Moritz, Erin: I get what the comment is getting at, but I don't necessarily know if removing sanitizer is the best approach.

Amber Potts: Is there science?

Vinson, Scott: But you don't sanitize between every customers meal preparation, you do it maybe once or twice a day, but it's not. It's not routinely done between each meal.

Babekir, Amani: Do you just wash and rinse and that's it? If you're gonna wash and rinse it, you're not …

Babekir, Amani: Yes, you probably need to do the third.

Moritz, Erin: Yes, it has to be with soap for sure.

Michelle Hill: The steps we teach as you guys have been saying are wash, rinse, sanitize, air dry.

Babekir, Amani: OK. So we're good keeping it.

Amber Potts: Yeah, I just have a question.

Vinson, Scott: This is one of those. So this is my group, our section in the Practices section. So we didn't know we would be addressing issues that so, so are we supposed to just remember our subgroup. Just remember that we've already addressed this at the full group level. So we don't need to discuss it when we have our subgroup call. Oh, OK. Got it.

Babekir, Amani: That's correct, yes. So I'm going to send out this document after we get done. And this one, we have just one. I think this does not use the allergen free terminology. We use it here, allergen free meal.

Devin Dutilly: I have to I have to jump off the call. Thank you very much. If you have any questions I would. This is just a just a personal recommendation, but if you are holding meetings and you think you would benefit from previous conversations of a federal partner being present, I would think that if you would like that please feel free to include all the federal partners on the on the meeting invite so that everybody is aware that they're occurring.

So if you need some input or something like that, feel free to include all the federal partners in the meeting. So at least somebody may be present on the meeting. So just to keep that in mind. So thank you very much. Again, thank you.

Babekir, Amani: That's great. Thank you, Devin.

Devin Dutilly: Thank you. Bye.

Babekir, Amani: Yeah, I think, yeah, I think we are over time and so that was the last one. We could keep it for you, Scott. So to discuss it to discuss it in your subgroup. <meeting adjourned>

Meeting Number 20	Meeting Date **09/01/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Previous Meeting Minutes	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

Review changes by training, emergency and notification group

Template group with work on it

Two volunteers joint equal consideration group (get names from Michelle)

Issues will be worked on in the next meeting

Devin suggested issues to reform committee, update previous year notification and promote the current documents.

Amani suggested an issue for posting the framework in the CFP

Meeting Number 21	Meeting Date **09/29/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

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i.	Meeting Call to Order	Amani Babekir
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v.	Framework Points	Amani Babekir
vi.	Adjournment	Amani Babekir

MEETING MINUTES

Babekir, Amani: Michelle, would you like to take the roll call?

Michelle Hill: Certainly. [takes roll call of voting Committee Members]

Alrighty, we have eight, so I think that meets our quorum.

Babekir, Amani: Yes, thank you, Michelle.

Babekir, Amani: And just would like to remind you that the Conference for Food Protection, antitrust, this statement is active with this call. Just keep that in mind and we could get it started with our agenda items.

Babekir, Amani: First thing I want to share is the progress we made on the framework. I'll just give you an overview from the version which I have. Michelle and Ben, they are working on the format, and I will give them a chance to just give us a summary about what they are doing. I will share with you what we have done before we hand it to the format team. Can you see my screen?

Michelle Hill: Yes.

Babekir, Amani: What I've done here, I just combined together all the updated sections which I received from you. And we already reviewed it in our large meeting, so I just accepted all the changes and I kept some of the comments which need to be addressed by the template team.

We still have the introduction section we need to work on, and the template team will take care of that one. The training section. We have it here. All good. We have the handling section, food handling policy and practices, and it is all good here.

And we have also the notify customers check section, which is clean.

There are just notes for Michelle, and then to address some of the points, and adding the footnotes. The emergency response? We added here the updated version.

And, Wendy, since you are with us today, can I ask you a question before I jump to the next point in our agenda?

Bell, Wendy: Sure. I'll try my very best to answer.

Babekir, Amani: We were wondering about using existing pictures and the copyright around the pictures, … I sent out, I think, an e-mail about it, but we are still waiting for the response. I'm wondering if you could give us some insight about using the pictures in our documents and what is the copyright concerns that we need to address or any concerns about the copyright?

Bell, Wendy: I will figure this out with Vicki as she is who we present these questions to. So let me get a working e-mail and that way maybe we can get an answer before the meeting's over or we can definitely get one as soon as possible.

Babekir, Amani: That is great. Thank you very much, Wendy.

Bell, Wendy: OK. Thank you.

Babekir, Amani: So there's just one of the points that we need to clarify about the pictures. Other than that the section is ready. All good. And then I have we have the equal considerations section that Michelle is leading ...

Michelle Hill: Yes, and I'll have an update for you … its yet to come.

Babekir, Amani: OK, that's good. And then we have the definition section - and there is a couple of comments here and I think at one point we started discussing it … I wanted all of us to take an action while we are in the call and make the change on this section.

Ben Wagner: Amani?

Babekir, Amani: Any question before we address the comments on this section and get the update? Yes, Ben?

Ben Wagner: Michelle and I had worked on all the comments on the copy that you sent us for the framework, and we took those comments in the definition section and so we did make some changes based on those comments, that we thought would work for the group and we planned to have the group review and agree.

Babekir, Amani: That is fantastic. That is great, Ben. Do you think you covered all the comments here on the definition section, so I wouldn't need to worry about it?

Michelle Hill: Yes.

Ben Wagner: Correct.

Babekir, Amani: OK, that is great. And what about the definitions section? Also you will take care of that one, OK? I think that's all the updates; any questions before I turn it over to Ben and Michelle, if they want to add any extra information about the updated document.

Michelle Hill: Amani I'd like to share my screen if that would be OK with Ben. Is that OK with you? I think I have the most recent.

Ben Wagner: You do have the most recent copy.

Michelle Hill: OK.

Babekir, Amani: Yes, please go ahead.

Michelle Hill: OK. Thank you. Good. Alright, so the this is a dynamic table. It will update when we tell it to, so we won't have to worry about page numbers being right or wrong as the formatting changes. We did universal cleanup when it came to punctuation. Spacing of information on the page - we employed styles so that it's a predictable change when it does occur. So if you see something you don't like visually, let me know and it could be changed. We can now make one change through the style guide and have it update globally.

I've also removed any hyperlinking to the external world. Any linking that does occur or would occur as this gets published would be within the document itself.

Ben, thank you for doing this, dropped in all the definitions as per the definitions at the end of this document, they've been dropped in as footnotes, as agreed by committee.

We did things such as reorder the listing here because we looked at how it was actually listed officially within the Food Code, and so we've carried this convention throughout on how this gets listed so that it's always the same information appearing the same way.

We also made adjusted the title of the document to “Major Food Allergen Framework,” as that is the title, and we've carried that through to the Header for every page.

We've given a uniform look to the statement of purpose throughout - any time this appears, it'll look like this, where it's all cap and underlined.

Again, the flow here, the allergens are listed just as they appear in the same order here.

We did make sure we did correct leveling throughout so that all information appears at the correct level as part of an outline format. There's good continuity here visually on how things are appearing - visually clean things up.

Ben Wagner: Michelle, do you wanna take away the carriage return marking and all that?

Michelle Hill: Yep, I'm happy to do that. Thank you. I'm so used to seeing it that way. I don't even realize it. So thank you.

Pagination will change as I increase the font size as well. I went up to a 12-point font. We were at 11-point, and I printed it and it's really hard to read. It's a lot of information on the page. It put us up one more page, but I think we can play with spacing and keep it capped at 24 pages.

Umm, we did have a recommendation to make this a full sheet size sheet. So I wanna show you how it will look like when it goes to print for the person using this guidance.

This is our example. A lot of the icons did not carry through and so I went to just using regular keystrokes and we can talk about this if you guys don't agree. If this doesn't make sense, but if it's an X we've defined that as having the allergen present. If it's a lower-case M, it means it may contain the allergen depending on how it's been prepared. We also cleaned up the labeling on this table. It's called table one example, food allergen matrix used to say, food allergen table. All the stuff we've looked up all of it referred to as a matrix when it's laid out such as this.

I put a new graphic in here - the blueberry smoothie contained other ingredients and we just trimmed it down to what it might actually contain. This is the blank matrix, so this is Table 2, the template food allergen matrix. We've added this other four columns here called other components, and we've dropped in a footnote at the bottom that says a table such as this could be customized for gluten free and other food intolerances and sensitivities by utilizing the other components column, which is what these four are on the far right. So the idea here is that they could print this, have a clean copy and pencil it in. I did print it and it is easily used in this state, so I don't know about giving more space for that. I was able to legibly use it as a person would in the field.

Cleaning up some of this stuff, waiting for feedback on whether we're gonna keep these pictures of the auto injectors, and then we did drop in this table down here. We eliminated the little icon with the verbiage around they're being posters available because it was already listed here, so we just made it into a table and then we'll call the page number once the pagination has been set and all it really does is just tell you what the poster title is and it talks about how these are examples of posters that can be placed this section, the food allergy reaction, emergency Response Guide section is the only one that employed the use of that icon. So instead of having it at the beginning of the document calling out saying this would be used.

We figured that this would be a more efficient way to address that issue, and perhaps a clearer way. And so then we took direct language from the way these posters are named and made sure that's what we call them in the table. And then this is the equal considerations for other community food sources - FARE has a very nice guide available which we will be parsing information from for the correct language here, and then we'll call it out as a reference. There's quite a bit, so there's some nice guidance there, so I'll drop that in. We did clean up how this appears.

This is the definitions section - we decided to go with bold with the definition starting on the next line. The table was pushing out to too many pages, and we felt like this was more visually pleasing and kind of more of a traditional way of doing it.

So if you have feedback on that, that can be changed and, that's it. So hopefully I made sense.

Babekir, Amani: Do you have the reference section?

Michelle Hill: Yes. Oh, I wonder why that's not showing up. Ohh yeah, here it is. I'm sorry. I just had to go one more time. Yeah, I was just trying to figure that out right now. And I'm glad you brought that up because what we were wondering about is we've got the footnotes. Do we drop in another series of maybe superscript? That says, “here's our references”, or how do we wanna call it out?

Moritz, Erin: I thought that we took out all in-text references.

Babekir, Amani: So I'm wondering if we have the footnotes, do we need the references section at the end of the document?

Michelle Hill: All that's included in the footnotes at this point in time other than that table reference description - the footnotes are carrying the definitions of the words at their first appearance.

Babekir, Amani: So question to the committee, what do you think? Do we need to keep the reference section by the end of the document?

Moritz, Erin: Sorry, could you clarify?

Moritz, Erin: Are they? Are there references in the footnotes, or is it just the definitions in the footnotes?

Ben Wagner: So currently the footnotes only came from the original definitions table. The first time you see that word, that word or phrase, the definition is given in a footnote, none of the references are currently footnoted.

Babekir, Amani: Ah, I see. OK.

Michelle Hill: And maybe it's just because I was looking at it as a place that we were defining words, but obviously footnotes can be anything. So it would just be another footnote, if that's what you guys want to do. And that would eliminate the references section, potentially.

Although we do have the definition section still, even though they're referenced throughout.

Moritz, Erin: My personal preference would be to leave the reference section in. I feel like putting them in footnotes would just make it even messier with something that not everybody is going to be using.

Michelle Hill: The other thing to that point, Erin, after I printed this because I don't, I don't know how many people actually have printed this, but when you go to functionally print it, it is really nice to have that sheet, with just the references as part of a printout.

Babekir, Amani: That is good. I think we're gonna keep it as it is. Any comments from the team? Any suggestions? OK, so I think that's very good work, very nice work. Thanks to all the subgroup teams – you have done fantastic jobs just addressing all of the comments and updating your sections. So thank you very much and thank you Ben and Michelle for making it look very pretty, as it is right now, very good job.

Michelle Hill: Thank. Thank you, Madam Chair. I have run a spell check and it's a good thing I did because we had some misspelled words. And I also ran for whatever it's worth. I went through the process of reviewing it within word for readability and all of that 100% across the board for editing for whatever. It was really good scoring, easily read.

So yeah.

Babekir, Amani: That's good. What about, do we have any kind of template or format that we need to follow for the Conference of Food Protection when it comes to the guidelines?

Michelle Hill: That's a good question.

Bell, Wendy: This is gonna be posted on CFP website, correct.

Babekir, Amani: That's correct.

Bell, Wendy: So that is another Vicki question, because I know that the Food Defense Committee gone through some of those same issues, and I can try and look up what she said. But there are some stipulations to that, and I can definitely provide those to you.

Babekir, Amani: Thank you. Anything else before we go to our Issues? Thank you, Michelle.

Michelle Hill: Certainly. Thank you.

Babekir, Amani: That's good. So since we are good with our framework and we are within our timeline which will need to submit the framework by November 18, along with our Issues. We plan to work on the language until the end of October. So then we will have some time to put it in the right format and all of that.

So here just some of the points I wrote down just from our discussions from the comments, while we are working on the framework. Just wanting to refresh our discussion on this point. What do you think? What is the best way we could point to this framework in the food code? And I'm opening for discussion. If you raise your hand.

Michelle Hill: I was wondering if anybody from FDA could speak to that. I don't know who's on the call and looking here.

Michelle Hill: I don't see Devin on the call today.

Babekir, Amani: I think, yeah, I think Greg's maybe with us.

Abel, Greg A: We could put it in the as an annex right into the food code has a big annex section of resource materials. It could be proposed to be put in as a tool for those establishments wishing to create a food-allergen friendly environment, and here's the guidance to do so.

Babekir, Amani: OK.

Abel, Greg A: I think that's the most appropriate, it can be another direction. It could go is as is CFP supporting document to food allergens as well.

Babekir, Amani: And does it need to go in the food code?

Abel, Greg A: In the annex section, there's seven annexes for in some of the annexes, there's examples of the inspection form. There are examples of employee health policies that establishments could use to develop their own written policies. So and then there's chapters that talk about how to do a risk-based inspection, the public health reasons behind the provisions in the food code. And then there's an annex on references … there's one possibility to entertain - could it be another annex on food allergen management in retail establishments, and then if that doesn't go, it can be supported and recognized by the CFP on their website. I think there's an outdoor cooking guideline that committees have worked on over the years, and that's on the CFP website that people reference oftentimes. So we could go either direction and, in my knowledge, the big one would be to get the document into the Food Code as an Annex and then every time the Food Code is published it will be there.

Babekir, Amani: OK. Thank you.

Abel, Greg A: So two routes.

Moritz, Erin: I was also wondering if - Greg, you can certainly steer me in the correct direction here - but if there's anything in here, like any piece of it that might be worth requesting to put in the codified language, you know that would be strong enough to be held up.

Maybe it's, I know this might be the previous CFP, but something like requiring a list of ingredients used, or requiring maybe an emergency response plan, just like a small a small piece of what we put together that might be, you know, strong enough to put into the codified language. Does that ever happen in these kinds of situations, Greg?

Abel, Greg A: When these food allergen committees started forming, that was back in 2007. The first hurdle we got was to recognize that food allergens are real, and we made the person in charge to be knowledgeable on them, right? That was the first piece we got. I don't know the direction of where FDA is going with the last committee and some of the recommendations what was accepted? What's gonna be used? One thing, with putting food allergen management systems in the code as codified language, it would be difficult to enforce because a lot of inspectors aren't trained to recognize, like your example and learn about a list of ingredients. Provided you know, I think that could be a future endeavor, but to make sure that list is accurate, how do we enforce that right? And how do … who keeps track of that? But perhaps the idea of having the emergency response to an allergen event could be something that could be required, kind of like how we have written notification of a diarrheal and vomiting plan. You know, that's a requirement in the food code that all establishments have a way to rectify diarrhea and vomiting in the restaurant. Having an allergen response plan could be certainly something that could be taken from this document and suggested that that also be in a food establishment.

Moritz, Erin: And I think would be easier to enforce than something like an ingredient list.

Abel, Greg A: I've done this for The City of Minneapolis School District system, I think they have 80 schools - to develop an allergen free menu and my gosh, just on something that's simple as a school system that receives commodities. How difficult and time consuming it is to make sure that's accurate? So it's almost a whole new division of food safety, right?

Some manufacturers are some establishments and some states, like Minnesota for example, they keep, in the deli - if they have one - they keep a list of the ingredients that they use to make their Deli products. So if a consumer did ask, they can go to a binder or some kind of reference system and say, OK, we use this particular product, and this product contains these ingredients. So they could tease down any hidden Allergens, right? It's not a requirement, but some establishments do keep a list of ingredients voluntarily.

Moritz, Erin: So it does sound like, if we really wanted to take a small piece of this - something like requiring an emergency allergy plan - that would be one direction. My other question I have is, if this goes in, for example, as an Annex, could we still advertise it, you know, publish it through CFP?

Abel, Greg A: That's, you know, that's a good question. I don't know the answer for that - I can find out.

Babekir, Amani: OK.

Moritz, Erin: So I'm just wondering if it's like an either-or type situation or if we can do multiple steps.

Garvin, Amanda: Multiple.

Michelle Hill: Yes, I believe it's multiple as well.

Abel, Greg A: OK, I think you could advertise it and say, hey, this is where it's at. This is where it's published. It's published in the food Code Annex. It's published also at the CFP website.

I think it's a great tool, what's been created here. If those of you that have been around for a while, when FALCPA was passed in 2004 and became effective in 2006 , that public law said that FDA would work with CFP and develop a Food allergen guidance type manual, right. That was back in 2006. I was actually one of the authors of that manual, and we worked on it for two years, and it was kind of kind of doing the same thing that this committee is doing except this committee's work is a little more - we've learned a lot more about food allergens, a little more detail, there's more resources. I think it's easier to use. But FDA's document that was created in 2007, 2009, it never did pass our executive leadership, so I never did come out. We never did follow up with that public health law, so now the committee's kind of doing this work.

Babekir, Amani: Yes.

Abel, Greg A: I think it's great work.

Michelle Hill: So glad to hear that. Thank you, Greg.

Babekir, Amani: That's good. And to your point, Erin, about the previous committee works and any change to the food code they did - when we reviewed the previous work, we found in a couple of events that they did manage to add extra wording in the provision of the food code pertaining to allergens, so that's something. Also we could, besides creating the framework, change the food code. So you have the option now for the Annex, the CFP website and - do we want to add some of the nuggets inside the provisions of the Food Code? Amber, you suggested the emergency plan … anything else you think might be beneficial to addressing the whole profession there? What about the notification of the customer or …

Moritz, Erin: Yeah, that's kind of where my mind went next would be some sort of Notification requirements. Although I think that could get very messy if we really wanted to go down a rabbit hole with it.

Abel, Greg A: The notification one is very hard to do right. Remember, the city of Saint Paul, MN, one of the council members tried to pass a city law that he wanted all restaurants to declare and notify all food allergens that are possible in the menu. And at that time, food allergen people and groups came out to testify against it, because of the inaccuracy of it.

Who's gonna create the list when ingredients change? Especially right now you look at our food supply chain from a food manufacturing side - ingredients are changing left and right, left and right. Big companies can't get their main suppliers and they have to change micro ingredients a lot. So with that in mind, if something comes in, that's an allergen - who keeps track of all those menu details? And when you get into a retail environment, a restaurant, not a chain, that's everything's processed in a certain way, but more independently owned. We have different chefs making different creations. Here I mean, gosh, you know, having a notification is good, but on the other side, the case that notification was not accurate, and someone made their decision on that written notification and then had a reaction, right? So it's very difficult to enforce and to make sure it's accurate, if it becomes a food code provision in my opinion.

Babekir, Amani: Thank you.

Michelle Hill: Greg, I love what you just said and I'm thinking that maybe our opportunity to be part of the Food code language would be just around understanding how important a label is and accurately labeling things for allergen derivatives. I don't know if that's something that we can be very specific about, but as a consumer that's my biggest problem … is it correctly labeled … cause it's not.

Abel, Greg A: Yes, right. And people that live with this condition - if they have children and themselves, I mean, the first piece, the written notification, gives them a clue of what to eat, and start to ask questions. The next piece is to talk to the chef and find out how things are actually made in the kitchen or talk to the manager to get the assurance that your food definitely is going to be safe to eat.

Michelle Hill: Yes, I've lived it. I agree with you completely. Soy oil hides everywhere and my kid was so allergic to it, he would just projectile vomit. I'd be like, “you didn't tell me about the soy oil you used”.

Abel, Greg A: I have three celiac kids and I've been living with it for I don't know, 20 some years before FALCPA. In my spare time, I run a nonprofit and we have a booth at the State Fair of Minnesota, a gluten intolerance awareness booth and celiac disease, and we play the “Jeopardy” game to engage people, to come in, and it's surprising to me where we're at today. How much ignorance there is out there about even food allergens and gluten, cross contamination and such. Any education or awareness is great.

Vinson, Scott: A lot of times I've observed that people confuse gluten with glucose. So if you tell them that you're gluten intolerant, they think you can't have anything with sugar.

Babekir, Amani: So what about the training piece? Since we are talking here about awareness, I know in the food code there is some pieces about the training when it comes to allergens. If there is anything we want to add there …

Michelle Hill: To be more prescriptive in that regard, yes, I would love to know how to do that. Let's talk about that. I teach this stuff too and I would love to be able to say, look, you have to know this.

Abel, Greg A: Yeah, I think you know, in the certified food Manager courses that are accredited, there's an allergen chapter in those courses, right?

Michelle Hill: In the same place as physical contamination.

Babekir, Amani: So you think that probably will satisfy the detailed information about allergen training … we don't need to add anything extra?

Michelle Hill: How do you talk about knowing and understanding derivatives or how it appears in the food you're serving, because that's where I see people fall down anytime auditing for allergy. It's like going into the Bloomington School district here, which I'm working with right now for allergen control across their 17 schools. I'd love to talk to you, Greg, because this is the problem. It's a hairy beast. And so you have to assess your risk. You know, how many people are at risk and how are they at risk and then carrying that also to - because the schools have to keep not just the food safe, but the classrooms too. So my son is so allergic to soy that washable paint is soy based and he will break out in a rash any time he is exposed to it. So even understanding that allergens can be tactile, aero-inhaled and consumed, all of that's important! I don't know if that fits here, but ...

Babekir, Amani: I see. So I guess we need. To figure out if we want to stick this in the Annex and make changes or comments around addressing the framework in the Annex section or trying to figure out which pieces, we want to add to the actual Food Code.

Michelle Hill: Can we do both?

Babekir, Amani: So if you want to do both.

Let's figure out what nuggets we want to add there beside the emergency plan. We touch on the training - bring up the section of the food code that is addressing this training and look at it. Where do you think the emergency plan will go within the Food Code?

Michelle Hill: I like Greg's idea of having it be part of its own Annex or …

Babekir, Amani: Yes, but I mean, if we want to address it in the provision section of the Food Code - you want to add something?

Abel, Greg A: You would probably want to put it in Chapter 2. And I'm looking at it. OK, in Chapter 2 called 2-5 “Responding to contamination events”, and that's where the cleanup of vomiting and diarrhea events is located. So to me it seems like it would fit under Chapter 2-5 along with this “responding to food allergen events.”

Babekir, Amani: OK.

Abel, Greg A: Seems the most logical.

Moritz, Erin: And would we get any kind of push back? For considering an allergen, a contamination, do you think?

Abel, Greg A: Umm gosh, you know ...

Michelle Hill: We could call it a contaminant.

Abel, Greg A: Yeah, you know, it depends on who's looking at it, right? I mean, for 95% of the population, it's not right or whatever the statistic is. We could call it something else. “Responding to adverse … “ we could make a new chapter, “responding to ...”.

Moritz, Erin: How about we could call it something like, maybe based on the symptoms. For the medical result. Like for example, anaphylaxis.

Michelle Hill: We could say also that it was Food allergy - we could say it's a contamination event due to cross contact.

Moritz, Erin: Yes, I mean, I guess so for example, if somebody says, “don't make my meal with nuts” and nuts are in it, then it technically would be a contamination event ...

Michelle Hill: … due to allergen cross contact. I don't know why they have to be mutually exclusive. It's only because we think of that way ...

Moritz, Erin: This is me, putting on my little, tiny little regulator hat of what I might think if something like that came across … I think if that's worth pursuing, then yeah, let's do it.

Abel, Greg A: And then you would have to, if you pursue it through as CFP issue to add to a food code, then you'd have to be prepared to say, “well what should this Response plan include” - and it's in the document. And then what happens then is states will have to adopt it. And then that would mean all retail establishments would have to have an allergen response plan. So that means a booth at a State Fair would have to have one. That would mean a temporary food event for a car rally would have to have one, a restaurant, a grocery store Deli - which is fine. I mean, that is the scope of the food code.

Michelle Hill: I say yes.

Abel, Greg A: Yeah, it's kind of like the vomiting and diarrhea clean-up plan, right? We just want people to have some kind of a notion that you just don't go out with a mop and clean it up because if it is norovirus, I mean the person who's cleaning it up could spread it to the rest of the staff or other customers. So you want to take some types of precautions, even though it's something that's not going to, you know, take down a restaurant from operating, I mean, at least having that plan out there, and if we can get compliance of a certain percentage each year and increase that, then boom. You know, slowly get there with an educational piece, even though it's requirement.

Babekir, Amani: James … I see James’ hand.

James O’Neal: Yes - we're looking for somewhere to fit it ... could it fit … Chapter 2, section 103.11, which is a person in charge duties. I think it could possibly there as far as that the person in charge is knowledgeable about allergens and however, we wordsmith that, that could be a possibility.

Abel, Greg A: Yes, another good spot under subparagraph - that talks about employs properly trained, and food allergy awareness. So it could fit there too, and also say, “include an emergency response plan to an anaphylactic reaction.

Moritz, Erin: We just tack on ... trained in food allergen awareness and actions to take in response to a severe allergic reaction, or something like that ...

Abel, Greg A: Yeah, that would be easiest path. Thanks for that recommendation. Whoever gave that, I don't see you on my Teams list. Yeah.

Babekir, Amani: Thank you, James. Yes, Scott.

Vinson, Scott: I just want to clarify that this framework we've developed is just voluntary and not mandatory, is that right?

Babekir, Amani: That's correct.

Abel, Greg A: Yes.

Vinson, Scott: OK, the reason I ask is because some of this some of the discussion … go ahead ...

Moritz, Erin: But then whatever we decide to put in - any little bit into the food code - that little bit would become a requirement, but not the entire framework. That's my understanding, Greg. Is that correct?

Abel, Greg A: That's correct.

Moritz, Erin: OK.

Vinson, Scott: If it makes its way into the Food Code, which is a model code - then the States and local jurisdictions have to adopt it. The reason I ask is because we want to be careful that we don't Inject provisions into the food code that are controversial or could be construed by some state legislatures or agencies as too onerous, because that will discourage adoption of the food code. My organization has supported universal adoption of the most recent version of the food code across all jurisdictions, and we encourage all jurisdictions to update their food codes. But there is this movement afoot. We had a speaker from NEHA yesterday – they talked to my food safety task force members yesterday about this. This food freedom movement, which is causing some legislators in some states to reject the Food Code, and to not adopt it … and we don't want that to happen. So I want us to avoid a situation where we – especially with smaller establishments, which I don't represent, but they're not represented in these conversations – so somebody has to sort of bring up their interests. Do we keep this as a voluntary framework in that we don't try to shoehorn into the food code - subsets of this framework - to try to get it to be made mandatory. I have a feeling, I'm just getting an inkling from some of the earliest discussions, that some people on this call are trying to do that … that could backfire on us in the long term because some jurisdictions could then be less likely to adopt the food code. We don't want that to happen.

Babekir, Amani: Thank you. It's good.

Michelle Hill: But it's part of our charge, though. Correct, Amani - that's part of our charges, yeah?

Babekir, Amani: Yes. So what is happening here beside the framework - we wanna bring awareness about the framework, so it doesn't have to do anything about making it like a law to follow. And one of the things is to address it in the Annex of the Food Code, which is not kind of regulations there. The Annex is just kind of differences and more clarification to the provisions section of the food code. The other piece is to add, maybe three words on the provisions section of the food code. For example, the word of "emergency plan." We are gonna discuss that further, but just let's conclude what we are discussing here.

Chapter two. We say we're talking about the knowledge of the person in charge and maybe one of the pieces we say there, besides knowing the food allergy, also know the response plan if there is any event. So just maybe one sentence or two or three words. That's what we are discussing here and that's still under discussion and this is a good point to be aware of Scott. Amanda?

Vinson, Scott: So the response plan is one part of this framework document, and so what we're talking about is just including those provisions in this framework document, what to do when an allergen gets into a customer's meal, in that kind of a situation, putting that into the food code only.

Babekir, Amani: Yes. Erin?

Moritz, Erin: If we decide to go this route and essentially make something required, it's gonna have to be very basic for the exact reasons Scott just talked about, and it has to be doable too.

Babekir, Amani: Correct. Amanda, I wanna give you a chance before we end our call as I see, your hand.

Garvin, Amanda: You already said it Amani, but I wanted to highlight it again - is putting this in the Annex 2 "References", which I really think we should try for, is a really great idea and that is a way for us to put it in the food code. Look under Annex 2 - anything they have used to help with the food code is in here and some of the documents we've done through CFP are in here too. So not only putting it on our website, but definitely putting it in Annex 2 for sure. And I also do very much like the idea of having … I'm saying that the person in charge does have to be knowledgeable on allergens but not too in-depth, of course, but they should be knowledgeable. I think that's a great point, though, if we're gonna say they need to be knowledgeable, we might want to say how far do they actually be knowledgeable? Because I know that's something that an inspector could do very easily.

Abel, Greg A: Well, that part's in there - this demonstration knowledge on allergens.

Garvin, Amanda: It was in there.

Michelle Hill: Yes.

Abel, Greg A: It talks about the person in charge describing foods identified as major food allergens and the symptoms that major food allergens could cause to sensitive individuals.

Garvin, Amanda: To when we were saying that knowledge, but we were saying duties, Mm-hmm.

Abel, Greg A: Well, there's two parts - one is demonstration of knowledge and then the other piece talks about the duties, and the duties' part talks about that employees are. trained or have food allergy awareness, as duties require.

Garvin, Amanda: Yes, and I thought it was in there, but then, which one did we mention earlier? Somebody mentioned something earlier that I thought was excellent beyond there, OK.

Abel, Greg A: Duties, and I think Scott brings up a very good point when you start qualifying things, especially on food allergens like this. I'd be very careful if states are going to adopt this because I would give you example, North Dakota adopted the food code by reference and the legislators tagged on that they didn't want required - they didn't want the person in charge to have certified manager certification because they looked at the state of North Dakota and that was an added expense. So everything got passed except for that. So you know, putting something in on this nature and especially without health departments having the staff to enforce something like that.

Babekir, Amani: That's good.

Abel, Greg A: You know, might not get passed, so it it's. It's a delicate balance. There's one provision that's in the food code that hardly anybody knows about. It's an allergen control piece. And that piece is, and if you read the food code carefully, it says when you go from raw fish to another raw animal food protein, you have to stop, wash, clean and sanitize because of a fish allergen. So many people read right past that, and so many jurisdictions that do catch it say we're not enforcing it right now. They're not going to enforce allergen control as a mechanism in the code. This piece here I think is so robust with information sits in Annex 2 I think has its best shot of being part of the food safety culture of including food allergens.

Babekir, Amani: Yes. Thank you.

Moritz, Erin: But you said it's not either or.

Abel, Greg A: Say that again?

Moritz, Erin: So we could put this in the Annex and then take a little piece.

Abel, Greg A: You still can, yeah.

Moritz, Erin: And make codified ...

Babekir, Amani: Amber?

Abel, Greg A: If you decide to like maybe having a … Go ahead …

Amber Potts: I just wanna re-read our Charge for this specific topic. Just "recommend changes to the food code that support retail food establishments to operationalize Framework to prevent and control food allergic reactions." So maybe we can start next time with just seeing if we can vote on whether we want to actually put that in the code defined section or if we want to add that to the Annex or neither and just add it to the CFP website, but whatever we do should be supporting retail food establishments.

Babekir, Amani: And thank you, Amber, and thank you for the suggestion. Yes, I think in our next call that's gonna be our main objective – to vote on which option we wanna go for and focus on it, so I will just put down all the summary of the discussion we've done today and go from there. We don't have a lot of time you know to decide on this, just maybe two other calls to finalize this so we need to agree on our path moving forward. So thank you very much. It's great discussion. Thank you everyone and see you next in our next meeting.

Meeting Number	Meeting Date		Meeting Time
22	**10/13/2022**		2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Framework Points	Amani Babekir
vi.	Adjournment	Amani Babekir

MEETING MINUTES

Babekir, Amani: Hi everyone, and thank you for joining us today. I don't see Michelle, so probably she will join us later. This meeting will now come to order, and I remind you that the conference for food protection antitrust statement is active during this call.

Babekir, Amani: I'm going to just go over the attendance. We have six voting members, so unless we have more people joining us, we wouldn't be able to vote. We can discuss things without voting. Then we could vote during a future meeting.

Babekir, Amani: First item on the agenda. I want to share with you the updated framework and really, its very good job being done here - from the subgroups and also from the template team – just making it a pretty, and very concise, document. I hope you get the chance to go over the Framework, so if you have any comments or any notes, feel free to share it in our meeting today because we don't have a lot of time remaining to keep working on this document. By the middle of next month we need to submit it for its first round of review by the Council. So we have just a couple of meetings to go over it. Feel free in between, if you have any comments, to send them our way.

There are couple of components here we need to discuss together as a group. I know I will start first here with the introduction section. We did add this section, which highlighted it in yellow to address the point about not restricting this Framework to just controlling for the Major Food Allergens, but all food allergens. But also there is a recommendation here to add a “limitation” section. As you can see on this comment - to address that this document is not covering all types of allergies. And maybe something needs to be also addressed in further work. What do you think? Do you think this part - which we added in the yellow – sufficient that this document is only focusing on the nine major allergens and there are other types of allergens, or you think we need more added language to the document? I will give you a couple of minutes to just go over the text we added and also hear the comments being addressed, by Devin here. If you could please admit people, if that is possible to do, and speak up because I can't see hands raised.

Vinson, Scott: So I see the parts you highlighted in yellow there. So you're asking us whether we approve of that sentence. That you highlighted in yellow, and whether we want that to be included in the document?

Babekir, Amani: Yeah. So.

Babekir, Amani: That section we all agreed on and we added it here in our meeting. What I'm trying to say is, “do you think that section is sufficient to address the comments here?” Or do we need to add anything further to the document?

Vinson, Scott: Oh, I see. Well, I like that sentence.

Ben Wagner: I feel like it's sufficient.

Babekir, Amani: Right. Thank you. Any other point or any other opinion? We good?

Dave Read: I think it looks good.

Babekir, Amani: OK. Thank you. There is this one about the limitation ...

Michelle Hill: Madam. Madam Chair, if I may, I jumped on. I'm here now. I apologize for my lateness.

Babekir, Amani: No problem. Thank you, Michelle. So we have this comment here. So, just going to give you a couple of minutes to go over it - it's about adding a section that is addressing the limitation of the document. Do we need to add this section?

Michelle Hill: Madam Chair, if I may, we did address this - we added language around this earlier in the document. OK. Oh, I see.

Babekir, Amani: Yeah, that is the one highlighted in yellow. So you think that is sufficient, are we good that is sufficient, or we need a separate section to address limitations?

Vinson, Scott: I think it's sufficient.

Babekir, Amani: So there is another one here also, and Ben wanted us to address it as a group. So before we go to the next comment, just I want to give you also an update about the image. I know we have questions about it, about the copyright. So the response we got from the Council is to keep the image in the document. We could blur the brand names here on the image, but also there is another option. We might need to delete the whole image, so this is still under discussion, but there are two options. We could blur the brand names, or we could do away with the whole images.

Michelle Hill: I'd be happy to blur the brand if that's how people wanna go. It's an easy fix for me.

Babekir, Amani: Thank you, Michelle.

Babekir, Amani: So this is about the equal consideration section. And Michelle, you might be able to respond to this one.

Michelle Hill: Yes. Thank you, Amani. This was put together with resources used from FARE and also USDA. I do have to drop in the references. I have notes around that to show where this information came from, but it was lifted directly from FDA and FARE and then just listed in a way that matched the document. I am totally open to input on whether it has to change or if it's acceptable. We just had to get something plugged in there that was from a reliable source.

Babekir, Amani: Thank you, Michelle. And do you think this comment from Devin, that it seems like this section is just hanging and we need to increase attention to the inclusion within the document.

Michelle Hill: Yeah, that's a good point, Madam Chair. I did notice that in the very beginning we addressed it in the first paragraph of our framework that we will have equal considerations for other Community food sources, and that wouldn't necessitate this section be here if you want to strike that language, that would be one way to go about it. We do talk about having a section that directly deals with this.

Babekir, Amani: Yes.

Ben Wagner: It was part of our charges, wasn't it?

Michelle Hill: It is indeed, yes.

Babekir, Amani: That is correct. So have we mentioned it in the introduction.

Vinson, Scott: Amani, are you asking whether we want to delete that entire section E?

Babekir, Amani: No, the comment we have resolved it, we don't need to do any action.

Vinson, Scott: Yes, I don't want to delete section E.

Babekir, Amani: No. OK. Then we have this comment here - the comment adding a footnote about food label formation being made available … have we addressed these one, Michelle in this section?

Michelle Hill: Yes, that is correct, we did adjust language for this.

Babekir, Amani: Is it under this section or where … ? Here are the comments ….

Michelle Hill: Oh yes, we recommended doing food label information made available in … And I think that's your bullet. “Allow consumers the opportunity to review original food packaging so they can read the labels, know the importance of reading every label every time, etc.” so maybe we don't need that.

Babekir, Amani: We don't need a note?

Michelle Hill: Well, we might though cause this section’s referring to specifically when you're feeding a large group of people. We might want to even have information posted. I know it doesn't say that, but that was the discussion around that item.

Babekir, Amani: So do we need to add any additional language to address this comment, or we are good to go? Going to give you some time …

Vinson, Scott: So we're specifically looking at bullet #2 under that sentence when offering foods to large groups.

Babekir, Amani: That's correct.

Vinson, Scott: Is that right? Bullet #2 is while most sections of this document aren't applicable to both food service venues etcetera. We're basically just telling the reader that they should have the staff of these facilities be mindful of allergens and how they're disclosed on food labels - that seems sufficient to me.

Babekir, Amani: OK, so we could resolve that one. And last one here. So there is recommendation, we have the definition of food intolerance/sensitivity, we have this definition, and the recommendation is to add more language. I don't know if you already added this. This is a way more detailed definition so are we good to add this definition instead of that one? Give you a minute to go over it.

Vinson, Scott: Just reading through the definition as a person who has celiac disease, I'm a little bit concerned that this proposed definition from FNS might seem to minimize the importance or severity of food intolerances. They say they're generally not life threatening. Over time, if a person who has celiac disease, for example, continues to consume gluten they may eventually get intestinal cancer, and so can be life threatening over time.

Michelle Hill: Absolutely. And I was considered with this definition. We talked through this quite a lot and it really is the case, I prefer the one that's listed there. But that's just me and it's for the same reason that Scott is bringing up.

Seymour, Jennifer: I guess the thing that I'm trying to understand here is celiac disease is an autoimmune disease. It's not a food intolerance.

Vinson, Scott: That's true. So.

Seymour, Jennifer: Right. So I guess you know maybe there is a need to possibly make that clear … I don't know if there's a way to but … You know, and that's where the difference between gluten intolerance and celiac disease, or important distinctions.

Vinson, Scott: Maybe we just sidestep the whole issue by not getting into the particulars because they may not be relevant for purposes of this document. To a reader, we just want to make sure that readers of this document, food workers, primarily food retail settings, are aware that they need to be careful about ingredients. Some people have allergies which could become immediately life threatening. Some people have food intolerances or perhaps other conditions which make ingestion of certain substances dangerous for them. I don't know that we need to get into the precise definitions and nuances involved because you're correct, Jennifer. The way that sentence reads now “Food intolerance/sensitivity and adverse reaction to a substance and food that does not involve the immune system” is not entirely correct, at least with regard to celiac disease, which is an autoimmune condition.

Babekir, Amani: And I agree with that point. I agree with you, Scott. Any additional thoughts? Or points?

Vinson, Scott: If we were to just omit the whole section, would that present problems?

Michelle Hill: We decided that it needed to be defined and it's a footnote.

Abel, Greg A: Why not just add celiac disease as an autoimmune - as another category? Food intolerances/sensitivities are celiac disease and/or autoimmune disorder.

Babekir, Amani: So do we add here to the language of the definition or here in the title?

Abel, Greg A: Wherever it makes sense, maybe I was thinking the title.

Michelle Hill: We need to look up where this is footnoted, where it first appears. Maybe that would help inform us of how we should change that.

Babekir, Amani: I think it was on the first page.

Michelle Hill: It's pretty early, yeah.

Babekir, Amani: Here you see food intolerance.

Michelle Hill: Yeah. So how is it used in the document? I wonder where it appears. Right here there … it says that I think it's probably earlier. Higher up, yeah.

Babekir, Amani: Yeah, it was on the 1st section.

Vinson, Scott: Yes, scroll up a little bit to footnote 11. Let's see how it's used in context.

Michelle Hill: There it is. It's at first bullet. No. Sorry. Amani, go down to the next page again, please, under ‘training’.

Vinson, Scott: There it is 1A.

Michelle Hill: Yes, 1A. So actually this is very important we get this right because we're telling them that these are the definitions that they need to know.

Babekir, Amani: Also here. Here we have intolerance and sensitivity.

Michelle Hill: So what's up higher too? That's probably where it should be footnoted, and it should look like the other one.

Babekir, Amani: Yeah. We could add - decide you know - the intolerance sensitivity and autoimmune disorders thing or specifically celiac disease, or any other disease.

Vinson, Scott: Because I'm not aware of any other autoimmune disorders that relate to food, maybe we just name celiac disease specifically. Does anyone else know if there are any others?

Michelle Hill: Yes, there's Crohn's disease, which can be ...

Vinson, Scott: Is that triggered by certain foods?

Michelle Hill: Absolutely. And so is colitis. Certain forms of colitis.

Thoma,Libby: Yeah, IBS.

Michelle Hill: Yep. or lymphocytic micro lymphocytic colitis, for sure - directly related. Because I have it, so I have that too. It sucks.

Vinson, Scott: Which I have it too, but I've never been told that it's triggered by any certain foods.

Michelle Hill: Ohh well.

Vinson, Scott: That's why I ask.

Michelle Hill: Interesting. We have different doctors.

Babekir, Amani: So on we talk a lot about autoimmune response I think or immune system response something like that on the definitions …

Michelle Hill: Wonder how FARE talks about it. Should I look that up real quick and see if we can find?

Babekir, Amani: Umm OK, try that.

Babekir, Amani: Here we cover it, because at the end of food allergic reaction, and how our immune system responds to the food? If it is part of disease or not, but it is an interaction between the immune system and the food. That should be sufficient. Because even Celiac disease that's how it's happens.

Michelle Hill: I have from the Cleveland Clinic a definition of “when you have a food intolerance, it means your digestive system has a hard time digesting and then in parentheses breaking down a food.”

Babekir, Amani: OK, so it does not involve the immune system. So we are good with that one. And the question is - the definition we put here for the food allergic right? “Food allergy,” he did say involves the immune system, wouldn't that cover also Celiac disease?

Michelle Hill: Yes.

Babekir, Amani: I think we are good here and we probably wouldn't need to add all of these details in this definition. Are we good with leaving the definition as it is for “food intolerance”?

Michelle Hill: Amani. Do you mind? I'd like to drop some stuff into the chat that I've just … you did too. OK, good, let's see ...

Vinson, Scott: I just put something in the chat that maybe we could consider putting in that first paragraph or I think it was near the top of the document. At the beginning, when we talk about the fact that this document technically only covers, you know, the nine major food allergens, but that readers should be aware that customers may have other issues involving ingestion of certain other foods.

Thoma,Libby: What if we said “to assist consumers with allergies food sensitivities? To autoimmune disorders? And intolerances? ...

Babekir, Amani: And do you think you can live with that? Could be added to the definition I just highlighted in yellow - like in addition to what we listed there, we added ‘audio immune disorders’.

Thoma,Libby: I think so.

Vinson, Scott: I would prefer that we name them specifically, the way I've done in my comment in the chat, because we need to remember our target audience, the reader. Most consumers are going to reference specifically the condition that they have. If they're talking to a food service worker preparing their meal, they're going to say, oh, I have Chron’s or I have IBS or something. They're not going to say, ‘I have an autoimmune disorder’. People don't talk that way in real life, so I would get specific with the name so that readers can be all on alert for those specific conditions.

Thoma,Libby: Yeah.

Michelle Hill: And of course, we'll cover all bases by saying and any other immune kind of thing, because there's a lot of stuff we don't know about as a collective group, yeah.

Thoma,Libby: I agree.

Michelle Hill: And everybody loves Wikipedia. I dropped theirs in, but it's kind of an interesting way to talk about it … “detrimental reaction, often delayed.”

Vinson, Scott: Yeah, looks good.

Babekir, Amani: OK. And shall you have added here the definition for the intolerance? Do you think that needs to be addressed here where we have the definition.

Babekir, Amani: We're good. On that one, keep it as it is.

Vinson, Scott: Frankly, I would get rid of it. Because of the issues discussed at the beginning of the document that we just went over. And this just muddies the waters. This formal definition, you know, at the end of the document kind of muddies the waters.

Babekir, Amani: I think we use it in different places here through the whole document so. Mm-hmm.

Michelle Hill: It was standardized to appear that way, yeah. I'm not against deleting the definition, but I think that's something our large group has to talk about and have.

Babekir, Amani: Yeah.

Michelle Hill: How does it … what are the consequences of not defining it? If there are any, I don't know.

Vinson, Scott: But we defined it at the at the front of the document.

Seymour, Jennifer: I think the section which we added here - we gave examples here, but we did not define what is the intolerance and sensitivity.

Michelle Hill: Yeah, think Scott got a really good point here. It's like, “if we don't treat it as being something really other than just that - by calling it out everywhere that it appears you know, maybe we don't treat it as a defined term. Is it cited on the next page … I forgot where …

Babekir, Amani: Yes. So besides here it's defined on the next page where we have “Training”, and it's being called out ... the definition of food allergy and also food intolerances.

Michelle Hill: Maybe we say “definitions of food allergy, cross contact and our understanding of food intolerance and sensitivity” ...

Babekir, Amani: And now my opinion, because that is going to take some work, to just remove the definition and make it just as a sentence. But “intolerance and sensitivity” is still gonna be a question. If I'm a reader, or so we are talking here about food allergy. What? What is the difference between food allergy and intolerance and sensitivity? Why is it being mentioned in three different ways?

Vinson, Scott: Yeah, this is tricky.

Michelle Hill: The way that FDA addresses it on their website is in the way that we have it.

Babekir, Amani: Yeah, they define it separately from food allergies, so I lean towards keeping the definition as it is. What? What do you think? Do you think this is good … and the other committee members?

Vinson, Scott: We can always punt and just let FDA decide what to do. They're going to be writing it ultimately anyway.

Babekir, Amani

Babekir, Amani: Yes. I'm going to delete this comment and leave it as it is. If you feel the opposite, let us know. We are gonna work on it through next week, so just tell us if you have an opposite opinion about it. We could proceed to the next discussion. Save it here. And this way we addressed everything on the document, and we will work on it to finalize it. I’ll work with Michelle to finalize it and it will be ready to be ... I will send it out to the Council, and we will send you a version.

Hopefully a week before we do that, so if you have any final revision or comments, you will get a chance to do so. I think that's it. Any other point before?

I switch into the second document. Any additional point before I move to the next topic. OK, let's move to the next one – it’s about our Issues, and hopefully you got the chance to see the document which I sent out before our meeting.

I listed the Issues which we thought about, we talked about, and I got the

Council II Chairs to help put it the best way to address the Issues, and how we could submit it to the Council. We're gonna all go over them one by one, making sure that's we are OK with each one of them. If we wanted to keep it as it is, or if we don't want to submit it.

The first one is to submit to the committee the final report and we're gonna need an Issue for that and just asking the Council to review and acknowledge the committee work, so this is the first. Are we good with the first issue?

Vinson, Scott: Yes.

Babekir, Amani: Any comments? OK. Thank you, Scott. Any other comments? We good? Second one, and this is one of the least options we could do for the sake of our framework is to get it posted and the CFP website. To do that, we need an Issue. So, we're gonna create an issue asking the Council to post this document to their website and we will specify the file type, such as a PDF file. Any comments about this Issue? Another point - we will ask them to remove the older version so to update the older version which has just the notification section from the previous committee, with this framework packet. Any comments or suggestion on this one?

Michelle Hill: Madam Chair, so the suggestion is that we would pull the current document from the website and then somehow merge it with what we currently have or check for commonality. And if we've missed something we add it in …. Or are we asking to replace that document specifically?

Babekir, Amani: The thing is because right now I think on the on the website there is one document which we use to generate our notification section.

Michelle Hill: Yes.

Babekir, Amani: That document is from the previous committee. So we worked on updating and enhancing all the content of that document in our Notification section. So the suggestion from the FDA is to ensure that the old version is being removed from the website. So it wouldn't be used by the food retail and instead they will use this updated version.

Michelle Hill: Thank you.

Babekir, Amani: Yes. Any other comments or suggestion? Are we good with this Issue?

Michelle Hill: I like it. I think it's good - necessary.

Babekir, Amani: OK. And then the third one, we talked about it in our previous meeting, is to ask the Council to re-form the allergic committee to address those Issues, which we could in address, or we listed as limitations to our document, in a new framework or a new guideline?

Michelle Hill: So we say we're going to continue or re-form the committee, and these are going to be the charges, so future work OK.

Babekir, Amani: Yes, it is not us, but we will ask. The Council is to re-form the committee, similar to what's done to our committee, because last year, last term, the allergen committee asked to re-form the committee and that's the reason we had this committee. We are hoping to do the same thing for the next term, ask for the allergen Committee to re-form because there are Issues on some points that need more clarification. Such as allergen cross contact and all of that in the food retail.

And this one is flexible. If you feel like there is an extra charge we need to add, we want, we need to remove the charges from here. We gonna have some time to review it probably in our next meeting to refine it and we will try to present it the Issue format set by the CFP. So we could work on it, but how do we feel about it? Do we feel we need to do that or not? We need to re-form the committee, or not?

Michelle Hill: I think we have to re-form the committee.

Babekir, Amani: Do you agree with that?

Vinson, Scott: I have a question.

Babekir, Amani: Yes?

Vinson, Scott: Are we using the word reform in this context? Reform like “RE dash form” or “reform”?

Babekir, Amani: Yes, it's re-form.

Michelle Hill: To reform to form again, maybe say yeah, yeah.

Vinson, Scott: To form again. OK, so re dash form OK.

Thoma,Libby: Would we have to go through the whole application process again as well?

Babekir, Amani: Umm, yeah. So if it's re-formed it could be stand-alone committee, and people have to apply and all of that. Similar to the way we've done it in our committee.

Thoma,Libby: OK. So we don't just get too re-up basically for this one.

Babekir, Amani: That's correct, yes.

Vinson, Scott: So we're being asked to reconstitute the committee.

Babekir, Amani: Ah, that's a neat term.

Michelle Hill: That or re-establish or form again, yeah.

Vinson, Scott: Reestablish. Yeah. OK.

Babekir, Amani: OK. So that's …

Michelle Hill: Amani, I think the confusion for this is that we should drop in a dash between the “re” and “form”, under Issue 3, just so it's clear what we're speaking about. Thank you.

Babekir, Amani: OK. But “reestablishes” means the same committee, or you referring to the same meaning we have here Scott?

Vinson, Scott: I think technically. Well, I'm not quite sure … Issue 3, was that part of our …

Charge from CFP? Technically, I think what they're asking us to do is to reconstitute the committee. Are we?

Michelle Hill: Or continue the work of continue the committee, yes

Babekir, Amani: I think they use some similar language in the previous term. You know the previous committee they use this kind of language, but we still could go back and see how it was done on the last term and I think there is a format. I'm not sure about the actual language. But Scott you asked about our charge.

Vinson, Scott: Right.

Babekir, Amani: Our charge is to create the framework and also suggest any changes to the Food Code. What I'm trying to say here is, do we want to ask … because there are things we have to ask the Council - like to approve and acknowledge our work.

And if we think there is a need for further work to be done to ask the Council to re-form a, you know, the committee. Or we could do nothing about it, and just ask to acknowledge and review our report.

Vinson, Scott: So, this committee that we're all serving on now, our job was to come up with a framework for the major food allergens. So with this Issue 3 here on the screen, we are then going to go back to CFP, ask them to reconstitute, recreate, reestablish the allergen committee again for next time and next time they're gonna be addressing these new issues, one of which is our Issue one. Figuring out what to do about the non-major food allergens because we've already addressed the major food allergens, am I getting this right?

Babekir, Amani: That's correct, yeah.

Vinson, Scott: OK. So in addition to #1, the non-major food allergen stuff, we're gonna ask this new allergen committee, which will be put together next time, to do these eight things. I'm not sure I understand. Why we are? Why this existing committee is being asked to address … where did this Issue 3 come from? What are these eight things? What was the genesis of the ….

Babekir, Amani: Sorry – can you hear we have a fire alarm in our building.

Vinson, Scott: Ohh.

Babekir, Amani: So I need to leave, and we could discuss this in our next meeting. But I have I have to leave the meeting.

Michelle Hill: So as Co chair, I guess we'll come back to it.

Vinson, Scott: Oh, I was gonna say, can she just leave it on? And maybe we'll …

Michelle Hill: Maybe she can. I think someone else actually started the meeting.

It's possible we might be able to continue it. David, did you start the meeting, Dave Read?

Dave Read: No, I did not

Michelle Hill: OK, I thought I saw that somewhere, but it hasn't died, I guess.

Vinson, Scott: Right. We're still going so ...

Dave Read: Ohh, well I might have, I might have been the first one to sign in …

Michelle Hill: I think that if you stick around.

Dave Read: It come it comes up on Microsoft Teams is where it comes in.

Michelle Hill: Sure. Yeah. I think that you're our host today.

Dave Read: Ohh wow, I had no idea.

Vinson, Scott: Well, we still have a Co-chair in Michelle, so we can continue, I think.

Michelle Hill: Wait, we could.

Dave Read: Yeah. In essence, I've been on a few CFP committees. So generally what happens is you decide if there are Issues that have come up that you wanna have a future allergen committee to consider. It doesn't mean the same group members are there. You reapply for membership in each conference. Generally they will keep most of the original members if they're interested again, and then they also add a few new members as well.

Vinson, Scott: Who came up with this list? This Issue #3 and the 8 items under it?

Michelle Hill: Through previous meetings. It's kind of like a laundry list or running list of what people have said over time and what we've discussed in previous meetings. It's completely flexible. That's why she had it displayed because it's up for debate, absolutely.

Vinson, Scott: Through previous meetings of what, this committee?

Michelle Hill: That's correct.

Vinson, Scott: Well, I think that's this is really the purview of the CFP. This isn't really our domain. They need to review the work product that we've come up with before they can decide what the next steps are.

Michelle Hill: This is just part of the flow. If we want to have an allergen committee to address anything that's existing moving forward, now is our chance to re-form it. So we need Issues to do that.

Michelle Hill: And so we can certainly strike stuff that doesn't make sense, or we don't think it's within reach. Yes.

Thoma,Libby: And see if we can add to that list as well.

Dave Read: Or delete.

Thoma,Libby: When would that work happen? When would we find out whether or not a 2023 Allergen committee has been formed and … whether or not we're going to be serving on it?

Michelle Hill: It happens during the biennial meeting. So in April, in Houston, when we all get together to do this work officially, that's when we'll submit our work for our first Issue saying we've completed the current work of this committee, so please accept our work. The second Issue is to update the documents on the CFP website and post this one. The third Issue concerns “do we need to continue this committee? If so, what Issues present themselves and this is what our entire committee is doing.

Courtney Halbrook: Yes.

Michelle Hill: Membership at that time, as it stands, would vote. Am I right on that Courtney, is that understanding correct?

Courtney Halbrook: Yeah, absolutely. It's just, excuse me, I was just about to try and … but you guys were doing such a great job of explaining it, but I think you nailed it. I think Dave nailed it. You've nailed it, Michelle. Typically, in the Council process at the meeting in April, your final report is submitted as you guys described, begging at the result of knowledge for separate Issues. They're requesting both. The document we posted and then the third Issue would be, to request that the committee be continued with these charges.

Sometimes the new charges stem from the previous charges that you didn't quite finish or complete, and you want to keep working on them, or over the course of working on those charges, you discovered other things. They're brought to the table for inspection, and other potential work, that the allergen committee could do. And so you're asking what to do with these charges? It's at the Council, so it's important that those charges are well written, and carefully prescribed, so it's very clear what the work will be and it's not too flexible.

You know, that's just the way – it is difficult for the body discuss if you don't have really good charges. And then the Council will review that. And we'll discuss and debate the need to continue the allergen committee and the Council will debate and vote whether or not the committee should continue.

That would be on the list of all the committees, including the conference, that people can sign up for. And if you want to continue your participation, you sign up. You don't, you don't. And there will hopefully be you Members that sign up to join. That's where we got, after all the signups are done. There is work to place all of those people. Everybody really gets their first choice, but it's how

many ... another 100 people sign up to be on the allergen committee, obviously we have limits people will serve. This is announced afterward. I don't know exactly when after. Fairly quickly you are notified what your committee you signed up for will work out.

Michelle Hill: Yeah. And this current biennium was really fast because we're working on a truncated schedule. So it'll be a little bit different, I think that by October … It's April … How does that work? When does the new biennium start then? Right away in April?

Courtney Halbrook: Yes.

Michelle Hill: After the biannual meeting, OK.

Courtney Halbrook: That starts pretty much right away, and then you'll have the full 2-year cycle to work on …

Michelle Hill: Well, that'll be nice.

Thoma,Libby: I was gonna say these last two years have flown by.

Courtney Halbrook: Yeah!

Michelle Hill: Yeah, it's only been, what, 18 months? Really? It was a year in September that we've been formed.

Courtney Halbrook: That's why it's really important to decide as a group. I said this already, but four should work. You guys have collectively agreed that you've done everything you were asked to do.

Vinson, Scott: Courtney, it's really hard to hear you. You're coming in and out and there's some background noise and so I have not caught what you've been saying during the last five minutes or so.

Courtney Halbrook: Technologized. Sorry, I think it's probably my microphone wasn't working great today.

Vinson, Scott: My impression of Issue 3 is that we're getting a little bit over our skis here. Whether or not to reconstitute the Allergen committee for the next CFP is really the purview of one of the councils.

Michelle Hill: It's council two.

Vinson, Scott: It seems like a breach of protocol for a committee, I mean we report to one of the Councils - Council II, in this case, we report to them - seems a little bit like we're trying to usurp their role and tell us what we want them to tell us to do next time. That feels like a breach of.

Michelle Hill: This is custom. It's customary.

Dave Read: Hey, that's often the way it's done. Yeah, it's often the way it's done is that a committee will come up with the Issues that weren't part of the charges that they think need to be addressed. And then you propose that the committee be reestablished. You list some thoughts on what those Issues are. And then the Executive Board will probably decide whether they're gonna do that or not, or if there's some other Issues that come up that they wanna add to the charges. And again just because it's reformed, you reapply if you want to participate in the next committee ... It's not an automatic that you continue on.

Courtney Halbrook: This is Courtney. Can you guys hear me better now?

Michelle Hill: Yes, ma'am.

Courtney Halbrook: It is customary for the Co-chair or the chair and vice chair of a committee to Identify future charges for that committee, if there are any. I don't feel like some of the specifics that you land on for the future charges you will need to be careful that you're not just creating a charge out of thin air to work on. There is a meaningful need for it to be part of the committee's work, and that would come from prior charges that you guys have worked on that have identified new and continuing work.

There could also be Issues that are submitted at Conference for Council to hear that pertain to allergens and the allergen related sections of the food code and that sort of thing. So Issues can come that way as well. Oftentimes, how committees are formed is because an issue was brought to council and it's deliberated and if there isn't quite a consensus on the issue or it needs a little more exploration, a committee is often formed and so it can go both ways. It’s definitely committee Chairs and vice chairs, along with the remainder of the committee, and voting and consensus, it is customary for you guys to identify future charges. Doesn't mean they're gonna go into effect. They will be reviewed by Council II and voted on by Council II and submitted to the State Delegates at the end of the Conference for voting. And that's how it all works. So, I wouldn't be too worried about that. Scott, you are following the protocol. It's just when you identify what you think the charges will be for the future that you have to be very specific and that they need to be meaningful.

Michelle Hill: Thank you so much for that, Courtney. I appreciate it.

Vinson, Scott: It's new to me. I've served on other committees, and we didn't operate this way. So this is new to me.

Courtney Halbrook: What I would do to help, and I can help you, Michelle, if you have trouble finding any … I would go back and look through some of the past Issues and you might have to go beyond just the last biennium. You might have to go to the one before

that to look for some Issues that were submitted to Council II that would give you an example of a committee seeking to extend their charges.

Michelle Hill: Yes, ma'am.

Courtney Halbrook: And you could see, you know, kind of how they wrote the Issue, how they worded it, what those charges looked like in comparison to previous charges, and, that might be helpful too. If you can identify a couple of those as examples to look at maybe, you guys can share that at your next meeting with the whole committee to talk through this a little further.

Michelle Hill: Yes, I like that idea quite a bit. Thank you. That's well advised. And we do have that information. It's not going to be a hard thing to put that together for everybody. That's something we did right in the beginning, when we first set our committee up, was to review the past so we could see the path forward where the hang ups might be. So absolutely, I think that's excellent. If there's anything further this … we're at-time now for this meeting, I guess. Does anybody else have anything they need to put forth or … ?

Courtney Halbrook: All good here.

Michelle Hill: OK. Well then, I will officially adjourn this meeting. Please be aware that we'll be sending out e-mail shortly here with requests of review from you all. So thank you so much for your time and have a good afternoon.

Meeting Number	Meeting Date		Meeting Time
23	**10/27/2022**		2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Issues points	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

Babekir, Amani: Hi everyone. And this meeting will now come to order. We need to take the roll call Michelle; would you like to proceed with that?

Michelle Hill: I certainly would thank you, Miss Amani. [call the roll]

We have six voting Members present, three non-voting members present. I don't think that meets our quorum for voting purposes.

Babekir, Amani: OK, thank you, Michelle. So we don't have a major thing that's we need voting on today. So we just going to continue discussing our Issues. Hopefully you got the chance to look into the draft, which I sent out yesterday. But first I want just to give you an idea about what happened in the last committee, what issues they submitted and how they submitted. So to just get an idea the way they've been doing it in this committee. Before I do that just I would like to remind you about the Conference for Food Protection, antitrust statement and it is active. And thank you to Michelle because she dug into the previous issues and converted them into words to be easy to look at and she put together our draft for the issues we are planning to submit, so let me first share with you. Can you see my screen?

Ben Wagner: Yes.

Babekir, Amani: OK. Thank you. So as you can see in this one, the previous committee. The first thing they asked for is to acknowledge, you know the committee and their final report. And they thank the committee members and note that their work is complete. They ask for the re-creation of the allergen committee and that is the one which we were, you know, discussing in our last meeting and just back and forth about what is the best way we could do this.

So this how it's been done, it's just to ask for the re-creation of the committee and then we suggest Issues for this new committee. As you can see, we listed out the Issues we've been working on. It's starting from one, to two, to three. And then they have also another Issue that's they are asking the documents they developed to be posted in the website. And here is how they did it - it's just asking for the acceptance of the document by the CFP and authorizing the conference to make any necessary edits, and to post it on their website.

Another issue also they submitted is to make the change in the food code. And they have couple of issues under amend the food code. And they are giving more details here. So if we are thinking about making any changes into the provision section of the food

code we have to learn the language and where we need to put it and all of these details. So all their suggested changes - where in the language in the provisions section of the food code - so they provided all the language here.

OK, so that is just an idea about what happened in the last committee. Any questions before we proceed to our version which we drafted?

Michelle Hill: Amani, did you want me to share my version or the version that was sent out? Or are you going to do that?

Babekir, Amani: Can you see it on the screen?

Michelle Hill: Yes.

Babekir, Amani: So here the first one. We are asking to acknowledge here the committee final report and thanking the committee members, so we already agreed on our last meeting that we are OK with this section. Then here we are asking for the re-creation of the allergen committee to complete the following seven charts we listed. I'm going to open it now for discussion. What are your questions, suggestions, comments ... do you agree with this? Do we charge anything, we need to add? Just feel free to take the floor and just let us hear your voice.

Michelle Hill: Madam Chair, if I may, as putting this together, I just took the language, as was written in the draft document from our prior meetings. I'm curious about if item number 7 is correct. If anybody on the call is who asked for this, could you please speak up and tell me if this is right or correct it or whatever, and if not, we'll figure it out. But.

Babekir, Amani: Yeah, Michelle, this one was actually came out of the notification subgroup, which I was in charge.

Michelle Hill: OK.

Babekir, Amani: And Devin suggested that this is one of the points which is not very clear in our notification section and maybe needs more details of how we could provide the chef with more tools to identify allergens.

Michelle Hill: Alright, thank you for that clarity. If I may ask, who just arrived on the call, please, Welcome …

David Read: Well, this is Dave Reed. I was not able to get in through Microsoft Teams, so I ended up having to call in. Not sure if there's a new announcement there, if I missed it.

Michelle Hill: No, but you're welcome and glad you found a way. Thank you for being here. I'll mark you present.

Babekir, Amani: So David, now we are discussing the re-creation of the Allergen committee which we were discussing in our last meeting and just listing here all of the charges that we think might be worth looking at and discussing in the future committee, and all of this is from one to seven came out of our framework discussion, or just putting together the materials for all of the sections.

Amber Thompson: How long does the next allergen committee have to complete these charges, if we choose seven of those? What's the time frame? Is it two years?

Babekir, Amani: It is. It is 2 years but it is out of our hands because it's will be a new charge. It will be a new committee and they need to put their timeline on it, but the ideal time is 2 years.

Amber Thompson: OK.

Babekir, Amani: Any committee to finish their charge? Do you think that is too much or?

Amber Thompson: So we had we didn't have two years, right we had like …

Michelle Hill: A year? Yeah.

Amber Thompson: One year, right - less than a year. OK. Two years. No, this is fine. I think for one year. No, this but two years. Yeah.

Michelle Hill: And I think some of these will end up being that we direct other things to be done. It seems that we would have to ask for some kind of major study to be done around non-major food allergens, although I think that there's something really good posted at FDA right now on that specifically. Is that right? Does anybody know about that document? I'll hunt it down.

Babekir, Amani: Are we good with this points and with this section? OK, I think we are good with that one. So this is the first issue that we're going to submit. We're going to have another week also to look at it. So from now up to the end of next week, if you have any comments or any suggestion feel free to send it to us before we finalize the draft.

Michelle Hill: I just put into the chat a direct link to the FDA document. It's draft guidance on evaluating the public health importance of food allergens other than major food allergens. And it was what I was referring to just a moment ago.

Babekir, Amani: Thank you, Michelle. So this is the second issue here and this one is to publish the document on the CFP website, and giving more details about the title and giving the authorization to the conference to make any edits and to post it as a PDF format on the website. Any comments or change on this one? OK. So we are good with that one. And the third one is … the one which where we ask for this document to be included in Annex 2 of the Food Code. And I remember from our previous discussion's the recommendation we got from the Council and so we are going to ask for the document to be acknowledged in the Annex.

Michelle Hill: The way that this is written is that it would be in its full printed form, not just as a reference – it is actually a document that is present in its entirety within its own Annex is how this was framed. I don't know if that's right, but that's what I read.

Babekir, Amani: Remember in our last meeting, Greg said we need to identify the section where even in annex where we want to insert this.

Michelle Hill: Yeah. So there needs to be clarity here. I mean obviously we need to talk about this.

Babekir, Amani: Yes. But where do you think is the best place we could add it? Which section in the Annexes?

Amber Thompson: How many pages?

Michelle Hill: It's 22 pages.

Michelle Hill: As it's formatted right now. We could certainly reduce that. We wouldn't need a cover page, you know, and a table of contents, so what like 20 pages, 10 back-to-back.

Babekir, Amani: If you want to share the screen.

Moritz, Erin: '6 Steps to safety' from an emergency response plan that I think we just took that from.

Michelle Hill: Perhaps we suggest that it's just the language we keep and anything that refers to an outside published graphic, there's a direct reference as to how that can be found otherwise.

Babekir, Amani: Yeah.

Michelle Hill: I don't know how do they do that within the food code normally?

James O'Neal: So are we looking to where this would fit within the Annex? So I guess under what chapter is that what we're looking for?

Babekir, Amani: That is correct, yeah.

James O'Neal: OK, one section, let me pull it back up, a - Demonstration of knowledge, 2-102.11, Section 9. It describes foods identified as major food allergens and symptoms.

Eisner, Crystal: I think that sounds like a good area. We have not adopted the food code yet here in Harris County. Demonstration of knowledge does sound like it would be the best place.

Michelle Hill: So are you suggesting that it be addressed within the Annex that deals with demonstration of knowledge of a CFPM, or is it in the actual code that you're suggesting we would insert this under what the required education would be?

Eisner, Crystal: I think it would have to be under an Annex.

Michelle Hill: OK.

Eisner, Crystal: In my opinion.

Michelle Hill: Yeah, I think it has to be as well. So would it be the case that we would say in the demonstration of knowledge section, the 2-102.11 Section 9 – we would have a "please see Annex page, blah blah blah"?

Amber Thompson: So are we asking them to just take what we've created and put it in the Annex? So they're not going to do that. I mean, it's FDA who writes the food code, so it's going to have to go through like major revisions and all sorts of reviews and edits and I think the limited time. Looking at the food code, in Annex 3 public health reasons under food allergens person in charge, it talks about food allergies or increasing food safety is a Public health issue, goes on to talk about the "Why?". This came about in 2008, CFP passed an issue, but some parts of the Annexes gives a link to an FDA, another FDA web page. And so maybe we could house it on the FDA website.

Michelle Hill: That's an excellent idea.

Amber Thompson: For example, there's a link that says "food defense". So you click it and it takes you to the FDA food defense, you've got food, defense tools, plan builder. I don't know who wrote all these. So maybe that is an option. The FDA's website could link to CFP, which houses the Framework. That way it doesn't have to go through all the FDA approvals and all the Paper reduction act and all that kind of crazy stuff. Yes?

Michelle Hill: So are you suggesting, Amber, that it would be language that would appear in Annex 3 under L "Food allergens person in charge duties?" That would be a link out to CFP, where our document lives? OK. Sure.

Amber Thompson: Yes, if that's allowed. If not, then it would have to link to FDA, which would then link to CFP. I'm going to look through here and see if there's any other place I see a link that's not FDA and see if that's even in there, so.

Michelle Hill: OK, I think this is the right track.

Babekir, Amani: Yeah. So do I. Any additional thoughts on this?

Michelle Hill: One more thing, Amani, if you don't mind. Amber, was there a point in time where we discussed something about making an interactive, like an application does … ? Am I remembering that right?

Amber Thompson: Yes, it was going to be a Quick guide, right? A visual tool that had the major pieces of that framework in it. For those that maybe have a hard time reading where it's easier to just grab a booklet that has pictures and words, of course. But uh, more kind of shows them what to do instead of telling them what to do. , I'm looking through here. I do see outside links. I see a couple to ANSI, FSIS, Food marketing institute, restaurant.org. Here's a guidance on responding to food emergencies. We could have some kind of guidance on responding to food allergens or something like that, and they could house it here.

Michelle Hill: What is that again? In section … ?

Amber Thompson: Well, the guidance looks like they're located in Annex 2, which is the reference section.

Michelle Hill: Alright, thanks.

Amber Thompson: We could create a Food Allergen reference section in Annex 2.

Moritz, Erin: Would it be helpful if someone shared their screen?

Amber Thompson: Ohh yeah here.

Michelle Hill: You don't have a good imagination there, Erin.

Amber Thompson: I'm on one screen today, no. OK, so I'm in the food code.

Moritz, Erin: I mean, I could make stuff up, but.

Amber Thompson: See here references and then on four it's food defense guidance from farm to table. We could possibly add a 5. Major Food Allergen guidance or something like that. And then that way for future allergen committees, that's where they could house all the other guidance tools, tips, all that kind of stuff could be here, because if you go to this, Section 4 …

Michelle Hill: I wonder, I wonder if people would read this. I know I have been through this with a fine tooth comb before, it's just hard to remember what's there.

Amber Thompson: Oh yeah. I mean, you could read it and then reread it and find completely new stuff.

Michelle Hill: Yes.

Amber Thompson: It's like watching a really long movie and you watch it again. Like I don't remember that scene. Where did that scene come from?

Michelle Hill: Yeah. Or who's that character?

Amber Thompson: Right. They like their references, don't they?

Michelle Hill: I think other people have good ideas like we do! Chapter 4?

Amber Thompson: There you go. So if you go to this section, guidance on responding to food emergencies. And then we talk about CFP here and then it … Well, there was a section right here, "FDA publications". OK, you can click these links. Then you have USDA publications - so we could link … so there's some things from the National Restaurant Association, Food Marketing Institute , CDC, so we could possibly do what they've done for food defense, but for food allergies.

Babekir, Amani: Sounds like a good suggestion. Any comments on this one? And we probably need to define the language we going to put there.

Amber Thompson: Yeah, right.

Babekir, Amani: Uh, along with the link, yeah.

Amber Thompson: Right.

Michelle Hill: So is that something we can do over e-mail between people or as a committee or?

Babekir, Amani: Yeah.

Amber Thompson: Maybe if one or two people want to tackle the wording and then we all decide if we like it or not. And you can just possibly mimic what's already here, that it will be accepted more readily.

Michelle Hill: Amber, do you want to work on that with me and Amani?

Amber Thompson: Sure.

Michelle Hill: Anybody else want to be involved?

Michelle Hill: Don't mean to draft you, Amber, but you have good ideas.

Amber Thompson: It's OK.

Babekir, Amani: Any more volunteers? So I think, yeah, we could, we could work with you, Amber and let's say maybe early next week, we could work on this one and we could communicate by email to see your availability, to make just a very quick meeting, to put together the language. Does that sounds good, Amber?

Babekir, Amani: So, I think that we'll finalize our Issues. So we're going to have three Issues. One and two, just about addressing all the charges and the third one, the last charge ... our committee is asking to make a change in the food code, so these are the changes we would suggest. Any additional comments, suggestions? Do you think there is any further work we need to do or we are feeling good about it?

Michelle Hill: I should know this, but what's our next steps overall?

Babekir, Amani: Yeah. So about our next step, just we're going to, you know, put together the draft for the issues and also our framework draft. Then we're going to submit it to the Council in the middle of next month.

They will give it a review. And then hopefully they wouldn't send it back to us with a major change or anything. But we're going to have second round of review before we finalize.

Michelle Hill: Thank you.

Babekir, Amani: Amber, about the summarized document you're going to put together. I remember you said by the end of the year, like December. That is the rough timeline you give to us.

Amber Thompson: Yes.

Babekir, Amani: Probably, yeah, probably we need to submit it to the Council for review. Not sure if we have to do this by the middle of November or not, but I will keep you updated if it needs to be submitted by the mid of November. Would you be able to make it?

Amber Thompson: Uh, if with help, I can show you what I started working on it. Then I stopped. I was doing it through NEHAs Canva account. It's very easy to use. You just pop in information. I just grabbed a template and decided that was OK, so we can work on this then when we meet in Mid-December. If I can have someone help me with it, that should be fine

Babekir, Amani: OK, so probably Monday, Amber, we could meet and decide if we want to proceed working on it. I think it's better if we prepare it by the middle of November

Amber Thompson: Right.

Babekir, Amani: Any volunteers to help Amber with this document?

Michelle Hill: Amber, I'm always available too. I don't want to be volunteering for everything under the sun, though. Other people need to be involved too, but I'm certainly happy to help anyway I can.

Babekir, Amani: OK, that's good. So we have a good plan to do that, and finalize the language that we need on our third Issue.

Michelle Hill: Yes.

Babekir, Amani: And in our next meeting, we have bunch of meeting minutes we need to approve. We were a little bit behind on putting together our meeting notes. So we're going to spend some time, Michelle, to put it together and probably we're going to dedicate a lot of time in our next meeting on it and then we will decide what we are going to do about our future meetings - if we wanted to keep them on our calendars or if we want to make some changes on it, so we're going to decide on that later. Anything else? Any additional point before we conclude our meeting today? Thank you. [meeting adjourned]

Meeting Number 24	Meeting Date **11/10/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Issues points	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

Babekir, Amani: So hi everyone. Thank you for attending the meeting today. And I'll just remind you about the Conference for Food Protection, Antitrust statement is active in this call. Now our meeting come to order and Michelle, would you like to take the attendance?

Michelle Hill: Sure. I'd be happy to. [calls the roll]

We have 6 voting Members present.

Babekir, Amani: OK, Thank you, Michelle. So we don't, we don't have critical things to vote on today, so hopefully we will be able to finalize the Issues we have in our agenda and in our whole committee work because probably this one might be our last meeting. But before we do that, let's first get an update about the summary, because in our last call, we thought about, getting Amber ready to proceed with creating that short document. But they discuss it together, with her team members, and they decided not to proceed with it. Michelle or Scott - do you want to give us update about this one? But I don't see Amber with us.

Michelle Hill: I'm happy to speak to it. The meeting consisted of myself, Scott and Amber. We had quite a discussion regarding how to proceed. The original discussion was seated around creating a small application that could be used to share allergen information that anybody with a smartphone which most people have these days, would be able to have it right there at their fingertips. We ran into conflict because who is sponsoring it? Is it a CFP application? Is it data from USDA, FSIS, who? Who owns it basically, and who condones it, who endorses it? It just got kind of hairy. So we decided that if that's a tool that people want later on, that they can certainly readdress doing that at maybe in the next committee.

Michelle Hill: Is that your take on it, too, Scott?

Vinson, Scott: Are we talking about the same meeting the one we had just the other day?

Michelle Hill: Yeah.

Vinson, Scott: When we talked about the development of a pocket guide?

Michelle Hill: Correct. Yeah, it originally started out with the discussion of it being electronic being built in Canva, and then we migrated over to the discussion regarding it being a pocket guide. Yes, that's correct.

Vinson, Scott: Yeah. So we identified …

Michelle Hill: Oh, that's right, we did, didn't we? We pulled out content.

Vinson, Scott: We - I think we had a pretty substantive discussion about the type of content that we thought would be most useful for the audiences who would be using the pocket guide, the Food service workers themselves. So we went through the entire 22-page framework document and identified the most relevant parts that we want the audience to look at and that would be sections B, 1 – 5 of the framework document, as well as C, 4. A, B and D, 1.

Michelle Hill: That's what I have in my notes too.

Vinson, Scott: And we discussed in particular figures by 5, on page 16, the importance of including those icons to talk about the symptoms that people demonstrate when they're having an allergy attack. Then also graphics of the types of reactions that children can have when they're having an allergic reaction. Then we talked about the format of a pocket guide. If it's in printed format, it could be on paper stock and be either in a sort of a trifold 6-sided document, or a front and back smaller card stock-size double-sided document.

But I think we all agree that the intended audience would be the Food service workers themselves.

Babekir, Amani: We don't have time to create the actual document or the digital version of other content.

Vinson, Scott: Yeah, we, simply were identifying the most relevant parts of the of the longer framework document that we thought the FDA should focus on for inclusion in a possible pocket guide or electronic version of a pocket guide, whichever direction they decided to go. But we wanted to at least identify the parts of our framework document that we thought should be included.

Babekir, Amani: OK.

Michelle Hill: Kind of like “mission critical: This stuff must be known”. That type of information. Didn’t we discuss having language put into the current framework? Maybe a paragraph that's just describes …. quickly, like if you wanted to have a shorter version, this is what it should absolutely have contained. Or was it that we were gonna just keep that in our notes to tell FDA? OK.

Vinson, Scott: I don't remember if a decision was made on that. Michelle, I think you said you were gonna talk to Amani about the best way to proceed on that.

Michelle Hill: Yeah, yeah, and I forgot. Oh we did OK. That's right.

Babekir, Amani: And yeah, and we discussed it. Yeah, we discussed it. Michelle. Yeah, we discussed it and we found out that we don't have enough time to include it in the actual framework because we have to be done with it next week by the next week. But they there is an option I think to have it as a supporting document.

Michelle Hill: So what she's talking about is that when we submit our Issues, we have the opportunity to submit anything we want in support of our argument for the Issue. And this could be a simple document that we write out that would be how to create - or most the most critical points - about allergen control or something like our framework. These aren't the right words, but to catch what I'm saying.

Babekir, Amani: Hmm, that's correct. So are we OK with that option? If there is any other suggestion or any objection of this option? So I think we could proceed with that one and just take what you concluded from your meeting, and just put it in a short document. That's it and include it as an attachment to the Issue.

Michelle Hill: OK.

Babekir, Amani: Then the second topic in our agenda are Issues which we're gonna submit to the Council and thank you to Michelle. She spent a lot of time trying to put it on the correct format and adding all the public health significance language. So I'm going to give her the floor to walk us through what she's done on our three Issues. So now we have three separate documents, each one consists of one Issue.

Michelle Hill: Correct. Thank you, Amani. This is a condensation of a lot of people's work. I just happened to be the one in-putting. So, if you have comments, questions, please. We're gonna have to make these choices today. We need to really figure this out.

What the language is and what we're doing. So this first Issue is the traditional first Issue, which is asking them to accept our final report which is like the quarterly reports that Amani and I have been required to file. And this one just shows the wrap up of the work.

Included with the final report will be the attachment of the meeting minutes, in addition to attendance records for each meeting. We will be circulating an e-mail shortly here that will have the Minutes attached and we will give you a couple few days to review and make comments, request changes, and then I think we're gonna have to probably do an e-mail vote or something like that to get them passed. We do need to have them passed and approved by next Friday as they're part of this. They're submitted along with the final report.

So this is Issue one in the allergen committee final report, and what we're asking them to consider for the next biennium is to is to accept our report, acknowledge it, and accept it, and thank the committee members for their completed work. And then re-creation

of the allergen committee to complete the following three charges. This terminology, “re-creation” is a part of the template, and it is necessary language that cannot be modified. That is the word they use. So there's a 20-page document published by CFP. It's available on their website. If anybody would like to look at it, it's well worth a read and it's called , “Issue Pre-Submission Guidance”. It is how to fill out the final report template. It walks you through step by step. It's an enormous amount of information. I was really surprised, but we did it right as far as I can tell. So these are, this is language we're gonna “use existing research and resources”. So item one of the next charges will be using existing research and resources to identify the non-major food allergens, and how to control for them and expand the major food allergen framework to include this information.

So we're basically asking the next committee to embellish on our framework, to cover when we can or how we are able to anything that's a non-major food allergen. Support guidance on how to control cross contact including receiving, storage preparation and service. Letter “B” is identifying, gather existing research and resources, to form an allergen control toolkit for all aspects of the flow of food. Things in a toolkit could be lists of derivatives on how an ingredient can be named on a label, an allergic component. It would be an example letter “C - identifying established tools to ensure implementation and compliance when notifying a consumer about food allergen”.

So this is how do we know that we've implemented, and we have compliance around notification, which was something that the 2018 and 2020 Biennium’s dealt with. And then #2 here “recommend changes to the food code that support retail food establishments to optimize operationalized framework to prevent and control food allergic reactions.” Again, this is standard language carried throughout the BIENNIUMS for this type of request. It's always the same language.

And then #3, “report back findings recommendations to the next biennial meeting of the CFP - again template language is required. I have no control over these things … What do you think about the charges, and should I proceed to public health significance or how do you wanna do that, Amani?

Babekir, Amani: Yeah, there any comments about this section? OK, sounds good.

Michelle Hill: I'm hoping people had a chance to read it before the meeting. This public health significance was data that we pulled together from different sources, and they're also cited here. So any of the references are where we pulled either quotation (and they’re footnoted). And again, this is a convention laid out by CFP on how you list this type of information when you're using a reference to support your public health significance statement. So this talks about it, focuses on the fact that cross-contact is a really big deal.

And that that's pretty much what we're looking for - cross-contact control in addition to more knowledge around non-major food allergens and how they impact things.

And hopefully you've been able to read the statements and have changes or input … it would be very welcome here. To be short, to the point, Amani and I worked the language together, but we are certainly open to changes ... just had to get something pulled together. Should I read out the public health significance statement?

Babekir, Amani: Let us give them time to read it.

Michelle Hill: I'll leave it up on the screen.

Babekir, Amani: Let us give it a couple of minutes for people. Comments? [waits two minutes] OK, I think that's enough time. Yeah, you can proceed.

Michelle Hill: OK. Umm at the recommended solution, I think we'll be getting good feedback from our

Council II co-chairs. What should be put here? I simply cut and pasted from the top portion, and then I read the whole big document about how to do things and it says you can't do that. So I'm hoping you'll give us some good feedback on how to review this language. But we're basically saying what our solution would be and it would be to re-form the committee and undertake the charges as we presented them. The attachments that go along with this document will have the final report that we will submit to the Executive Board for approval - again, that's next Friday.

And then attached to that, we'll have meeting minutes, meeting attendance, and then we'll also include these supporting attachments. These are meant to give background information to the Council when they're thinking about the current Issues that we're presenting here. So the two documents that we recommended as supporting attachments are “components of an effective allergen control plan.” It's a framework for food processors, which if you guys take a look at that, here's the link to FAARP out of U Nebraska. It's an excellent framework. It's well done, and it could be a good guideline for the future Committee, if they undertake and pursue these charges.

The second is the “draft guidance from FDA on the non-major food allergens. All they talk about - anybody can pull this document off the FDA website, and this will be very useful to the next committee as well if they need it so any impact or input on this would be welcome too always. Do you think there's other stuff that we could include that would support our argument for proceeding as we've recommended.

Babekir, Amani: I think also we could include the Summary document of the Framework.

Michelle Hill: OK. So regarding the summary document? Yes. Thank you. And we'll call it ... I don't know if this is what people want, I'm just typing ... we call it whatever you want. I'm just trying to work it on the fly.

Babekir, Amani: I think we could use our Framework title; we just will highlight that it is a summary.

Michelle Hill: Perfect. Thank you. Alright, so that's Issue one. I'm not hearing much about this. If you guys think of stuff after the meeting, please just e-mail us, if it strikes you later.

Here's Issue 2. This deals directly with the request to post the major allergen framework document to the CFP website. Again, specific language that's been dictated ,that we need to use around this issue, or as we propose this issue. So we've requested that this document entitled “Major Food Allergen framework”, and we're authorizing the CFP to make any necessary edits prior to posting the document. The edits would be things such as consistent format and non-technical content. Any changes cannot affect the actual meaning of the document.

The third was to prior to posting this document, we want it reviewed to remove any potential violations of the commercialism comity policy. We did remedy that a little bit ahead of time by blurring the brand names on the image of EAIs.

And Issue number 4 - we're going to remove the CFP-approved document “food allergy notification, a guidance for industry” for the simple fact that it's been incorporated into our framework document, and it's perhaps redundant at this point. So, that's the charge. Here's the public health significance. This is a long one … FARE - they have an awesome content.

Babekir, Amani: Michelle, I have Scott. Yes, Scott?

Vinson, Scott: I raised my hand prematurely. Go ahead, Michelle. I'll ask my question in a moment.

Michelle Hill: OK, all of this is footnoted. A lot of this data was taken from the FARE website itself. It just got reorganized a bit to be cobbled together in a way that makes more sense. We did draft some language, but I just would like people's input on this. All right. Thank you, Scott. That's all I'm gonna say about that.

Vinson, Scott: Yeah. So my question is, “Are we sure?” I see that most of this document’s Issue consists of our actual framework document. I just wanna make sure of that, because we had confusion on the call that the three of us had the other day about whether we were using the most updated version. Are we sure that this is the most updated version of the framework document? .

Michelle Hill: Yes, I have. Yes, we do have the most recent addition, absolutely.

Vinson, Scott: OK.

Michelle Hill: That's a good question. So if you - anybody wants me to make anything bigger so they can read it better, I can do that. I can try and get the “public health significance” on one screen, if people want to review that. Again, this is the committee’s words, so people need to have their input. You know, I'd really appreciate it actually. I've never submitted an Issue before ever to the conference, so this has been a big learning curve for me too. So, I'll stop messing with it so you can maybe read it.

Babekir, Amani: Going to give it a couple of minutes, so feel free to read it from the screen or you could pull up the document I just sent this morning.

Vinson, Scott: I looked at it earlier today and it looked fine to me. Are we voting to approve things today or do we not have a quorum or?

Babekir, Amani: Yes.

Michelle Hill: We don't have a quorum, but this technically – Amani and I – are responsible for filing these as the Co chairs, but we don't wanna just file stuff, we want everybody's opinion, so it doesn't necessarily have to get voted on, but we do need input and it's on a tight timeline at this point and that's why we're doing this, is that right Amani?

Babekir, Amani: Yeah. And I, Scott, we did vote on it in our previous calls.

Babekir, Amani: This is the bulk of the of the of the Issue, which is what we want the CFP to consider. We discussed it. We said that's what we're gonna ask - the whole document.

Vinson, Scott: Yeah. So you're just asking us if you filled out the paperwork properly and it looks fine to me.

Michelle Hill: Essentially that, and if there's any glaring omission or a statement that you don't agree with. Sometimes things get left out - more eyes are better than just mine and Amani’s. So we want you guys to know you're part of the team too. It's not just us generating this stuff - there should be consensus.

Michelle Hill: So this is Issue 2. Should I pull up Issue 3?

Babekir, Amani: Let's give it extra minute, just to go over it.

Michelle Hill: I'll try and center this so it's readable again.

Babekir, Amani: OK. [waits two minutes]

Babekir, Amani: Michelle, thank you. Can proceed to the third one?

Michelle Hill: So this third Issue, this was probably the hardest one. I think that we've worked on these charges for the next committee essentially. No, I'm wrong. Excuse me. Pardon me. This is not that. This is where we want to insert this into the food code. And actually what we're aiming for is the Annex … Annex 2, specifically. So the title of this document "major food allergen framework", we wanted to be included within Annex 2 of the Food code. So we're requesting that CFP send a letter asking FDA to add the document to Annex 2. And then we say the reference could be added in the following places within an Annex 2. And we give them 3 possibilities.

These are not in any order. They caution us, as we draft Issues, that we don't have multiple decisions within an Issue. It would be that these are suggestions and where it could go, but they're free to do what they'd like with where it gets inserted. So letter "A" deals with what we've listed here and is the actual page in the printed Food Code. The current one listed on FDA 2017 supplemental edition and then the PDF page that this content falls on, because they're different numbering conventions. So for clarity, we did include that we were thinking about going in as #5 in a list of things within references Section 2, and we would title it, "Food Allergens", maybe "Food Allergen Control", whatever …. And then we could house our major food allergen framework document there. And so then it's part of the of the Annex 2 section. And then because we have made a heading for "food allergen" information, we can keep adding content in that same spot. So it's kind of like building a little bit of a house for us in that way for the future. Letter "B", it's gonna be what we could do it within a list that's already there, and it would become item number 8 of that list. Or letter "C" - it would fall as letter "W" of another list. These are lists about how to train people and what's expected of them.

Babekir, Amani: Michelle.

Michelle Hill: Demonstration of knowledge and then the specific language would be CFP Council II Allergen Committee 2023, "major food allergen framework" - that's the document. And then we gonna provide the link to the CFP website where the document will be hosted and it must be the HTTP, the full link printed which makes sense. And then here's the public health significance again.

Babekir, Amani: You'd like to give it like a couple of minutes just for the people.

Michelle Hill: Sure. [a few minutes pass]

Babekir, Amani: Yes, David – are you speaking? We cannot hear you …

David Read: I'm sorry, I was on mute. I have a quick question on where it says "a reference could be added in the following places within next two ..." Are you considering one of those places or in each of those places?

Michelle Hill: No, you're right. That's a good catch. So we should say the reference could be added in one place.

David Read: One of the following places, OK.

Michelle Hill: Thank you. We did contemplate asking for our own Annex, but we think because there's already these - we fit well within the information already provided in these sections that it wouldn't, it didn't seem like it was a real complicated ask to insert this language.

Babekir, Amani: Yes.

Michelle Hill: In the Annex.

Vinson, Scott: So under Section 1 here, we are just providing FDA options of places to put the reference to the framework in the Annex, A, B and C are just options.

Michelle Hill: Correct.

Vinson, Scott: With that, they could consider …

Michelle Hill: We wanted to be specific around this because it has a better chance - as what we've been told - if we have very specific placement in mind.

Vinson, Scott: Yeah. Well, and that obviously required a lot of work on ...

Michelle Hill: Both of us. Yeah, we were busy.

Vinson, Scott: Someone spent time, probably yours, Michelle, and I just wanna recognize that work and you know, commend you both for a job well done.

Michelle Hill: Well, thank you. We had other people involved too, but thank you, yeah.

Babekir, Amani: Amber also was included, though. Yeah.

Michelle Hill: Now, thanks for that, Scott. Yeah, it's a lot to get your head around the CFP language stuff too. You gotta be right about that or it'll just come right back to you so had to be pretty decisive with wording.

Babekir, Amani: Do we have anyone from FDA today?

Michelle Hill: I thought I saw Greg - Greg, are you on the call?

Greg Abel: Yes, I joined via phone. I could not get on Teams.

Michelle Hill: That's what I thought. I saw a 612-area code and I thought "that might be Greg." Good.

Babekir, Amani: Do you have any comments about this one? Do you see those suggested areas?

Greg Abel: So I'm on the phone so I can't see. I'm sorry I could not log on video for some reason.

Babekir, Amani: No problem. So if you've got a chance, just look at Issue #3. See if you have any comments that would be great.

Greg Abel: Yeah, yes, that'll work … e-mail.

Babekir, Amani: Thank you. You could proceed, Michelle.

Michelle Hill: Thank you. This next section is the "public health significance". So we had to state our case as to why we'd wanna do these things. We lifted the language from the first part of the Food Code. It's actually the preamble that talks about what is the purpose of the code? I just didn't think we could say it any better than it had been said.

So the next statement here is of my creation and it's in addition … the FDA Food Code contains a series of Annexes which provide the backup information, Scientific data, references, rationale, etcetera, for the guidance guidelines in each chapter. If you want to further understand the why behind something in the food code, the annexes give you that information."

So here we point out, "Why would we even choose the annex?" And then we say here "by publishing the major food allergen framework within the Annex of the Food Code, FDA would be further clarifying its satisfaction of CFP Issue 2008-III-06, which has to do with allergen control and educating people around food allergens and promoting awareness. So, once included, as are part of an annex, additional framework documents could be listed, including any future CFP-published documents around allergy control and the prevention of cross contact. You think of any better way or different things to add there, let me know it this is good enough.

Babekir, Amani: Any comments, suggestions? OK, I think that's good.

Michelle Hill: I have nothing for attachments for this document. I don't know that we need attachments. Maybe we attach the actual printed pages with our language inserted into that area, of what we'd like so they know how we'd look depending on where they choose to put it. Other than that I can't think of anything else we could add, so open to ideas. Or maybe we leave it blank, I don't know.

Babekir, Amani: Yes, Christine.

Christine Sylvis: Hello. I was wondering, for the attachments. I think I've seen it before where you can cross reference the framework from the other Issue.

Michelle Hill: Yes, that's a good idea.

Christine Sylvis: So I think they'll be able to do that. And then I'm sorry it took me a few minutes to go through all the pages and the Food Code. So let me get back to the PDF or the Word document? So when we're asking … location on page 309 of the PDF.

Michelle Hill: Yes.

Christine Sylvis: We're asking for #5 entitled "Food allergen".

Michelle Hill: Yes, so instead of it just being four items, there would be 5 on that list.

Christine Sylvis: I've lost pages … now the very last thing in Annex 2, so it would be listed there as a #5, but then it would be #5 …. It would have to go at the end Annex 2 … I was looking at #4 where it says, "Food defense". So if we are doing that, we might need to say "#5 food allergens" and have an introductory statement about that and then have it listed as a reference publication. So actuality it would be listed as #5 on that page, but it would be inserted on page like 336. And we might, if we're going to do that, we might want to have "introduction" language prepared.

Michelle Hill: And so let me see if I'm understanding this correctly. Listing it as a fifth item on the list will necessitate that we actually have the framework published or is that not what you're asking?

Christine Sylvis: No, it could still be a reference.

Michelle Hill: OK.

Christine Sylvis: I'm just looking at #4 where it has the “food defense” guidance from farm to table, which is #4 on page. I think it was 309. I don't have enough screens. And then that is actually on page 333, where it's mentioned, and it has an introductory statement and then a list of reference publications.

Michelle Hill: Yes.

Christine Sylvis: So I think we would follow that same framework. Is that right, Greg?

Greg Abel: Yes.

Christine Sylvis: Is where it would go as #5, but the content would go under #4 which is on page 336.

Michelle Hill: While the PDF has its own pagination and then there's the printed number on the bottom of the page and what I'm having trouble with is that bottom number is not 306, maybe the printed number is 306 ...

Christine Sylvis: It's 336.

Michelle Hill: Yeah, here we go. 336. OK, now, now we're talking. Yes, yes. Right here. You got it. That's what you're saying. We need language around. Yes, yes.

Christine Sylvis: So if you scroll up just a little bit, you'll see where number four starts, right there. Ohh yes. So you would need a number five with the little introductory paragraph and then have the reference, as a link.

Michelle Hill: So the PDF is 389, and the code is page 333. I'm just writing this down, so I know where to start, and then we'll have a #5. So, d you think we should have language around that already prepared? I think you're right. Good. Thank you. I didn't even ... I can't believe we didn't even extrapolate out to that point. We should have done that because you know it's important, well, necessarily, where we could also drop in, any future guidance too if we get a #5 … this I really like.

Christine Sylvis: Yeah, I like that idea.

Michelle Hill: Yes, I like the fact that this is like a little house for it. I feel like it could really live here and make sense.

Babekir, Amani: And we could make that introduction a more generic introduction so be open to host other documents related to ...

Christine Sylvis: So yeah, it is when you're searching for the page number, it is 309 which is 253.

Michelle Hill: Thank you. There you go. Bless you.

Christine Sylvis: So it would be #5 there. At the very top. Would be food allergens or?

Michelle Hill: So it's page 309 of the PDF 253 of the code. OK. And that's why we when we run out the Issues, we've got very specific language. Well, this will require an introductory paragraph. Since we've got this up, maybe we should look at Page 320 as well, which was another place we thought maybe this could live. Under “management and personnel”, it would be number #8.

Babekir, Amani: Yes.

Michelle Hill: Chapter 2 ... Management personnel … demonstration. That's right, under “demonstration of knowledge”. OK. Yeah, it would be a #8. And it would just reference our document. I guess we could put it … I don’t wanna muddy the waters, but this is the other place ... I really like the other place better. And then we had a third place ... let's look at that real quick too, page 375. And this would be adding after “the bad bug book”. It'd be letter “W”.

Babekir, Amani: Yes.

Michelle Hill: So it's under supporting documents, and they're supporting documents to … this is the FDA list of guidance for reference - so it's a long, long list. So we'd be letter “W”.

Babekir, Amani: We have 12 minutes left. We could spend like 5 minutes just working on the language we wanna add as an introduction.

Michelle Hill: Yes. It's got to get done, so yes. All right, so I'm going to just start typing it here so that we can all see it and we'll figure out where it lands later.

Babekir, Amani: Just asking for volunteer. We just, we just need couple of sentences just to introduce whatever content is related to allergens. That might be referenced on that section.

Michelle Hill: Here we go …

Babekir, Amani: We're still looking for the section.

Michelle Hill: I am … I finally found it.

Babekir, Amani: OK.

Michelle Hill: So here's Section 4. So we'd be looking to write a similar paragraph like this, and then list our publications.

Babekir, Amani: So let's give it a minute. Yeah, let's give it a minute for the people just to look at that section and then we could articulate something related. Do you think people would say something similar like “the following summary of available resources around Allergy?”

Michelle Hill: I'm just going to start by cutting and pasting that statement. Keeping it simple sometimes is best.

Babekir, Amani: Christine, do you think that's enough?

Christine Sylvis: And I'm looking at the other four sections. They are very short. Just saying, “here's a list of resources” for the most part.

Michelle Hill: I'm really glad you brought this up ...

Christine Sylvis: I was looking for the other ones for some inspiration.

Michelle Hill: Yeah. I didn't even think about where it would actually, what that #5 meant. It's just too much. So I guess what we'd be saying here is that if we do list it as #5, we would say … “proposed language ...”

Christine Sylvis: Looking at, I was looking at writing some other Issues for a different committee. I think we would put that at the bottom in the recommended solution part, so the recommended solution there is a template for just adding it in with the underlying language.

Michelle Hill: Yeah, I saw that too.

Christine Sylvis: Language to be added.

Michelle Hill: We should do that. We should have it be like we exactly how we want it to appear. Like #5, blah, blah blah, OK. Yeah, that makes sense. OK. I saw that there is a template or guidance on how to write all that out appropriately.

Babekir, Amani: Any suggestions about the language? OK. And then we could work on the formatting. OK, we're gonna have up to Friday, we probably need to finalize everything by Wednesday afternoon, so if you have any comments, any suggestions, feel free to e-mail us by Wednesday, by next Wednesday afternoon.

Michelle Hill: November 16th. I think that I think that's reasonable.

Babekir, Amani: And also, as Michelle said, we're going to send out the minutes of all meetings we have. I think around 5 minutes from our previous meetings need approval.

Michelle Hill: Well, yeah, that's only 100 pages Amani.

Babekir, Amani: Yeah, we haven’t approved them. It's a little bit hectic to go over it because what we've done in most part of those most recent meeting is we use the transcript of the Teams – now it is word by word.

Michelle Hill: It's a good read, it's an interesting read.

Babekir, Amani: We’re going to need your approval. The other thing is we were gonna have four meetings, I think. Nothing left for meetings in November because we have Thanksgiving. And then we have, I think one or two meetings in December.

Yeah, we gonna receive the review because we're gonna send those documents to Courtney, and we're gonna receive feedback from them and we have up to December the 2nd to send it back to them. We will look have meeting in between, but if we need the Committee opinion on any update or change, if it is not like formatting on stuff like that, you might hear from us, we're gonna send you an e-mail and we need your response, if you want to make any change on the on our documents.

Michelle Hill: I was gonna say and just so you all know, we'll be very specific on our ask. And it would just be only for substantiative stuff that you know, content that matters kind of questions.

Babekir, Amani: Then for the meetings in January, there is 3 meetings in January. I'm just gonna keep them in the calendar in case we need them, but you're gonna see me, cancel them if we've done all the review and we submitted our documents, we don't have any standing Issues, I'm gonna cancel those. I want to close by just saying big “Thank you” to all of the committee members. It's great work. Very good job. It was my pleasure and my honor to work with all of you on the Committee.

Michelle Hill: I second that Amani, and I think we've had a very active group. I'm really glad that we were all able to treat this as a consensus forming process throughout and I found that we all dealt with each other with great respect, even though there might have been disagreement over content, so it has been my pleasure as well and I loved being your Co chair Amani. I really have enjoyed my time with you.

Babekir, Amani: Thank you, me too.

Babekir, Amani: Thank you. And I hope to see you at the Conference of Food Protection next year.

Michelle Hill: Yeah, that'd be nice, everybody. Alright.

Babekir, Amani: Thank you everyone.

Meeting Number 25	Meeting Date **12/05/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Issues points	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

Amani Babekir This meeting is called to order. We have asked you to meet with us today to finalize the four Issues we will be submitting to the CFP for consideration. Michelle could you please display the Issues for consideration?

Michelle Hill Yes, my pleasure.

Eisner, Crystal Is this the way it was brought it to us when we first got the charges?

Michelle Hill It may have been. It's been through a couple different rounds already with Courtney and Wendy, so I can't guarantee that this is the same language. We ended up re-working the Issues. It was three and then we were told to split Issue 01 into two separate Issues.

Babekir, Amani But the main language is the same to what we discussed in our meeting and we approved so you don't see very major changes here. The one that cross contact is being recommended by Devin Dutilly, I know he was not able to join us, but if you think there is more clarification we could add from your prospective.

Abel, Greg A When did Devin make that recommendation? Long time ago?

Babekir, Amani Yes - for this one, while we were working on our subgroups.

Abel, Greg A A long time ago. OK.

Babekir, Amani Uh, yeah. A long time ago. He suggested to have this charge for the future committee in order to address cross contact, so I guess we're trying to understand what do you think are the main concerns when it comes to cross contact from the FDAs perspective.

Abel, Greg A Well, probably more or less just advice on how to manage food allergens. And, I think to identify the non major food allergens and to be aware of cross contact scenarios, as there's so many of them.

Babekir, Amani So we include examples of ...

Abel, Greg A Uh, depending on, I mean could be shared equipment, shared oils, shared surfaces. It’s more … I don't know what Devin had in mind about controlling cross-contact.

Babekir, Amani Thank you. Yeah, it was actually.

Abel, Greg A But what do we have in our … what’s some of the … isn't some of that advice already in what the Committee has prepared?

Babekir, Amani So we have, yes that’s what we had - there's like one extra or something.

Michelle Hill Yes. However, this is kind of two requests in a way because it's asking it to identify the non-major food allergens and how to control for those, in addition to expanding that to be included in the framework.

Abel, Greg A What would that be? To me it'd be like, OK, so here are the major food allergens, the 9 coming up in 2023. And if you get a request by consumer that something else might be a food allergen to them, that chef for those food service workers could use some of the same knowledge for that particular allergen.

Babekir, Amani This correct, yeah. Crystal, I think I saw your hand up. I mean Christine.

Christine Sylvis Hi, this is Christine Sylvis. I had it up and I took it down. I was just confirming that A, B, and C relate only to non-major food allergens.

Babekir, Amani Yes … the thing is … this came up while we were working on our actual major food allergens which includes, you know, the nine major.

Babekir, Amani But things, yeah, but since in number one, we are talking here about non-major food allergy, and probably that includes expanding cross contact to include the non-major food allergens. We did touch on cross contact in our framework, but I guess we need extra more detailed information about it … it seems especially for receiving and storage, and preparation.

Michelle Hill Also, I'd like to point out that this is actually a huge ask. If you read #1 "using existing research and resource to identify the non-major food allergens and how to control for them", that's telling our next committee that they need to identify what the non-major food allergens are. Am I wrong in reading that?

Christine Sylvis That's definitely how it reads. So there are, of course, other countries that have additional allergens then eight or nine, but people can have allergens to all different types of food, so I'm just not really understanding what food establishments would be expected to do … control cross-contact just for the identified non-major food allergens or for any allergen that somebody might have. You would think that the process would be about the same as what they would do for the identified allergens.

Michelle Hill Except that they take big steps to control for the big nine and if they're not aware of an allergen present, it will cross-contact throughout the flow. You can't like, let's say, if somebody says I can't have.

Michelle Hill I don't know. I can't even fill the blank. I'm sorry.

Abel, Greg A Broccoli.

Michelle Hill Umm, thank you. Broccoli. Yeah and.

Michelle Hill So I think that's what drove this bus was, how do we control for the stuff that people tell to us after the fact? It's as simple as. "you can't eat that."

Abel, Greg A But I think it's just a matter, I think when I'm trying to go back to those comments back in June when this type of stuff came up. The framework worked on the 9 major food allergens, but making sure that people know that there are several other food allergens out there, like Christine mentioned, there's 163 plus possible foods that some people has been allergic to at one time or another. Maybe just raising awareness that there may be a request or a concern from a patron that they might be allergic to something else, that is not a major food allergen and the controls would be the same. And if there's no controls in place for them already, well, like Michelle said, "you best not eat that food."

Maybe it's a simple answer that "hey, these are the major food allergens defined by FALCPA, and these are non-major foods, but they still can be a problem for certain people.

Michelle Hill Yes.

Abel, Greg A Just to be aware.

Seymour, Jennifer So it does seem like they're probably like assuming the 163. We're not just going to list all of those various foods - I doubt that that would be helpful. It seems to me, from having experiences with people who have these problems with non-major allergens, that what they really need is staff and restaurants to really understand what is in their food, understand the names, the ingredients to be able … there's so many restaurants you walk in and they have such lacking information about allergens. I've a friend who has a severe dairy allergy and you go in and people say, oh, "well, you can't eat that cause eggs in it." They just don't understand food in some fundamental ways. And maybe it's more about that dealing with the other … those outside of these really controlled strictures is about just being able to have some basic understanding of what various foods are. Having some way for someone to look that up to be able to know what is in every food that they have if they need to. I mean that's becoming fairly common in chain restaurants where you walk in, you say something strange and they pull out a book and you know, have pages and pages of notes about what is in every food. I see that more and more often.

Babekir, Amani That is what I'm talking about …

Michelle Hill Me too. And I think that you've hit upon a very important part of this, as far as just everybody being better educated about derivation of ingredients and how they can be depicted on a label or, having good working knowledge of what's in the food that people are serving. Transparency.

Michelle Hill Maybe that's maybe when you just say …

Babekir, Amani What would you do?

Michelle Hill Something different than what we've said.

Babekir, Amani And then have that sort of be like just this …

Abel, Greg A But wouldn't it be? I think in the future, wouldn't it be nice to have a requirement that places keep a list of ingredients in a book right in a binder, so everything they have in stock would be a resource that you could look up the ingredients. This is the product ... this is what's in it, right?

Babekir, Amani Right.

Michelle Hill So an allergen matrix for all product on hand?

Abel, Greg A Yeah, I think in Minnesota there is one Deli chain where they do keep that matrix. A folder of "OK, they're getting this deli salad, but they have a garlic allergy, so let's look in this 3-ring binder of everything that goes into each salad.

Babekir, Amani So for the points A, B, and C, to make logic out of it is to make it related to the non-major food allergens. The points A, B, C, that are addressing the non-major food allergens, in which we said it is a limitation when it comes to our framework. We did not address the non-major food allergy. Do we agree with that … that A, B and C, are asking them to focus on the named major food allergen and address A, B, and C, and then we could add the recommendations which you just discussed, to add more clarification.

Michelle Hill So do we need to rephrase this or is it clear enough that we're speaking directly about this being our big goal? Maybe what we do is we say existing research and resources to identify non-major food allergens and how to control for them, period. And then a second part of the charge would be to include the request to update the framework. Maybe that makes it easier.

Babekir, Amani Yes.

Amber Thompson You could even just leave it like that and then put D as that. Is that what you meant? OK, sorry. Yeah.

Michelle Hill No, no, you got it. No, that was good ... I did not know where it was going so …. it's awesome. Thank you.

Babekir, Amani So do you want to add the extra points? That's Michelle and Jennifer, I think. Yes, Greg and Jennifer, they said about the awareness and all of these points under "A".

Michelle Hill I feel like by striking the word "the" from this main sentence, now we don't give a quantity to it, it's just to identify non-major food allergens versus all allergens. To me, "the" means "this is a definitive list."

Amber Thompson Yes, that's better.

Seymour, Jennifer Just one point that has come up … a weird allergen of someone that I know. You know right there preparation comes into it, but it looks like that word preparation is just In terms of cross-contact, but I think there also are some issues with preparation that might not go into ingredient lists. And what I mean by that is I know someone who can't eat vinegar, and vinegar is put in water sometimes to cook things. So it's this idea of even understanding preparation methods. I could easily see that not being on an ingredient list. Another one that has come up because of this allergen is that most chicken is brined in pickle juice, and people don't think about that and don't know that. And it doesn't seem again to be on the ingredient list or it's on the ingredient list as only "brine". People don't think of that as being vinegar, so I've encountered a lot of these weird things. It's about the way people do things to make cooking work better, but it doesn't really get considered as an ingredient to a lot of people.

Abel, Greg A Well, that would be education, right? Because it has to be excluded, right? If it's going to be packaged. Then, though, if it's a major food allergen, it has to be included on the label.

Seymour, Jennifer Right, right. It's just this is an example of one that isn't a major food allergen.

Abel, Greg A Right.

Seymour, Jennifer And I would be surprised if it's even listed in the 163 ... never encountered another person with that problem.

Abel, Greg A Don't hold the 163 as the magic number ... I just threw that out. I don't know if that's the actual ...

Michelle Hill No, it's in excess of 170.

Seymour, Jennifer Yes.

Abel, Greg A OK, I remember hearing 163 maybe 15 years ago, so ...

Michelle Hill Yeah, FAARP is a really good place to get that number.

Michelle Hill How about if we drop in here preparation, including knowledge of preparation methods? I don't know if that helps alleviate that issue.

Babekir, Amani So it should be a big issue. And when it comes to receiving, I think, Greg, you said something about the matrix or something, I can't recall it ...

Michelle Hill An allergen matrix?

Babekir, Amani Mm-hmm.

Michelle Hill When you are in the act of receiving large bulk food, sometimes you stack it wrong or you put it in the fridge and it spills or drips causing cross-contact.

Abel, Greg A During receiving, OK.

Michelle Hill Umm. Yes.

Michelle Hill "How to prepare" no, how about including using an allergen matrix or is that too prescriptive?

Abel, Greg A I think that's too prescriptive. We'd have to define what we mean by a matrix. I mean, a matrix could be a suggestion as a helpful hint, "right now, here's a way to manage … "

Michelle Hill How about including "during receiving"? Maybe that helps too … that's what we mean during the act of receiving.

Abel, Greg A Right - because once you receive it, now it becomes the storage.

Michelle Hill Yes. OK.

Babekir, Amani What about the storage? Do you need to define "Dry" and "Cold" storage or as you said …

Michelle Hill When I teach about storing, it implies any type of storage, whether it's hot or cold. But that's from my perspective as somebody teaching CFPMs … that's our audience.

Abel, Greg A Storage to me means anything regardless of temperature, right?

Michelle Hill Being held properly, is all we worry about, right?

Babekir, Amani I remember we wanted to add more clarification to them to make it very obvious.

Michelle Hill Yes.

Amber Thompson Receiving, storage, holding. We call it holding. Like you know, especially if it's like a salad bar. You don't want to drop peanuts in the, you know, cheese or whatever it is …

Michelle Hill Excellent.

Michelle Hill And that's a great example. When we set up a salad bar, it's always the allergen is in front so you don't drip, drip, drip from the back. This only helps if you know what the allergen is, so …

Babekir, Amani If we are good with this one, we could go to the next one.

Michelle Hill This is a huge ask … this is a very big ask.

Eisner, Crystal For #1, because anyone can be allergic to anything.

Babekir, Amani It's more. It's more for style, so we probably need to define what is the objective of this allergen control toolkit. So they will have a clear idea what is the purpose behind it.

Michelle Hill Yeah, maybe we should say the allergen control toolkit would include information or methods of food preparation ...

Amber Thompson More specific even, cover the major food allergens.

Michelle Hill Well, I think it would include both major and non-major allergens.

Babekir, Amani We might need to give an example of what is the toolkit we are talking about. Is it just a document? Is it checklist?

Amber Thompson Yeah, it could be …

Eisner, Crystal … Infograms …

Amber Thompson Yes, that's what I was thinking.

Michelle Hill And an allergen matrix …

Amber Thompson Yes … you could say, "For the purpose of ..." That way we know what for the purpose of.

I don't know how you would say this, but basically, that the food workers can easily identify … not identify, but easily ...

Amber Thompson

Michelle Hill … support which could …

Amber Thompson Digest this information or something like that.

Eisner, Crystal Identify, no.

Amber Thompson For ease of use for food service workers, or for ease of implementation, or something like that. Better understanding of controlling allergens.

Michelle Hill OK. Yeah, that's awesome. Makes me feel a lot better. What do you all think?

Amber Thompson Well, have an idea, but this will kind of change the format, but it may be more helpful overall … if we said ... "use the existing research and resources to expand upon the major food allergen framework, and is guidance on how to control non-major food allergen cross-contact. That way this allergen control toolkit is for both major and non-major food allergens.

Michelle Hill Yes.

Amber Thompson Because we really like that idea of a toolkit, but we just don't have time to put something like that together.

Michelle Hill Right. OK. Did I get this first part right … "to expand upon the major food allergen framework to include cross-contact"?

Amber Thompson Yes, to include A, B, C, then we don't need D. You could say "guidance on how to control non major food allergens."

Michelle Hill OK, run that by me again. I missed what you said.

Amber Thompson Yeah, "guidance on how to control non-major food allergen cross contact"

Michelle Hill Awesome.

Amber Thompson Would you consider Celiac part of the non-major food allergens?

Michelle Hill Umm, I would.

Amber Thompson How to control non-major food allergen and … ?

Abel, Greg A You think in the, you know, we kind of made a point to keep the guidance to just "allergens".

Amber Thompson OK.

Michelle Hill Because dealing with Celiac didn't change behavior was our rationale for that, right?

Amber Thompson Right, right. OK.

Babekir, Amani Along with you. OK, good.

Michelle Hill Just want to make sure we have the right reason for not expanding.

Abel, Greg A I think a lot of lot of celiac people just say "I have a wheat allergy". It's too hard to explain.

Babekir, Amani Yes, that's the case. And it seems we are almost out of our time. We can extend the meeting extra half an hour. So, if you are free please stay on the line, OK.

Babekir, Amani Thank you. So we could proceed.

Michelle Hill Are we all good with this revised number one statement?

Babekir, Amani Looks good to me.

Amber Thompson I don't need a comma there … Use existing research and resources to expand upon the major food allergen.

Michelle Hill Thank you.

Amber Thompson Framework to include.

Michelle Hill Awesome.

Amber Thompson Service, identify. Gather at some research.

Amber Thompson Yeah, I like the way … I like this.

Babekir, Amani Are we asking them to update the "major food allergen framework" document?

Michelle Hill I think we say that the first part, don't we here, "using existing research resources to expand upon" … you know, you're right, we don't talk about it actually improving the document.

Babekir, Amani We just ask them to update the document to make it ... part of our toolkit.

Amber Thompson Umm, no, I feel like the toolkit is for the food workers to understand allergen control.

Michelle Hill OK.

Amber Thompson Umm, not necessarily about notifying customers.

Michelle Hill Good point.

Amber Thompson I'm curious about compliance when notifying a consumer. Compliance implies that there's ordinance in place, so I don't know if there's codified language in the food code about notifying consumers. I know there's for labeling. But I don't know if that's expanded to restaurants.

Abel, Greg A There's nothing to notify consumers in the food code.

Amber Thompson OK, maybe we can change that word "compliance" to … Umm … "established tools to ensure …"

"Abel, Greg A How would you want to notify them? And if that's the case, what's the danger when you miss something? So I look at it from another point. As a note, I think it's great for large franchises that have controls in place that can list all the ingredients. But what if you have an independent? I mean, look how much trouble our …

Amber Thompson Umm.

Abel, Greg A As it is now, and if it's required to inform the consumer, they're going to say, "oh, no, this has nothing in it", but someone's going to forget something and then that person's going to have to suffer a reaction.

Amber Thompson Right, right.

Abel, Greg A You see the danger? I think that's dangerous. I would never trust it. Except for maybe a large chain that has the resources to actually have a standardized menu.

Amber Thompson Umm.

Abel, Greg A And look at all the times I messed up, with my even my home cooking, you know?

Amber Thompson Right.

Abel, Greg A So compliance we're "notifying the consumer about ..." but a compliance can indicate there is a regulation.

Amber Thompson Right.

Michelle Hill Yes … as well as a way to assess their ability to comply.

Abel, Greg A Yes.

Amber Thompson The allergen framework has a section about notifying consumers, right?

Michelle Hill It does, yes.

Abel, Greg A And how does it? Is it suggestion or how does? How is it suggested that they be notified?

Michelle Hill It's a whole section. Hang on I can bring that up.

Babekir, Amani And I think this one came up when we were working on the notification section.

Is to have those. tools, I think. And we said, B is a charge for the next committee.

Amber Thompson OK.

Michelle Hill So here's the framework on tools to notify. Here's menu item self-service. Here is the Allergen Matrix, menus, and signage …

Abel, Greg A OK, so in this situation we're just providing a toolkit if someone chooses to notify. These are some examples and how it can be done, right?

Michelle Hill Right.

Abel, Greg A Versus making it a requirement so.

Michelle Hill Correct.

Abel, Greg A You know, I think that's fine because it's the suggest it's toolkit. Hey, if you want to take the extra level, here's how you can notify your consumers.

Amber Thompson We could maybe say was meant for non-major food allergens. Maybe that's what this meant.

Babekir, Amani Yes.

Amber Thompson When notifying consumers about non-major food allergens.

Babekir, Amani Yes, as I recall, this came up when we were discussing, the notification section, so it wasn't part of the non-major food allergy.

Amber Thompson OK. I just don't like the word compliance. I think maybe if we can find a different word that would be fine.

Michelle Hill How about support? "Support tools to identify," "tools to support food workers when notifying customers about food allergens …"

Babekir, Amani To notify a consumer on how to ensure … that's compliance with this is standard operating procedure ….

Michelle Hill I see.

Babekir, Amani Maybe here, next to the tools, we say, "This includes standard operating procedures."

Michelle Hill Yep.

Amber Thompson Yeah, standardized menus or something like this. Full ingredient lists.

Babekir, Amani But I think also here on this one we want to have the restaurant make sure that their workers comply with whatever standard they have there to notify the customer.

Amber Thompson Right. They support and educate. Yeah, that's a hard one because it's really the restaurants, and that may be included in the framework under "training".

It's actually codified language that says, in the food code, that the person in charge is to ensure that food employees know about the major food allergens as it relates to their duties or something like that.

Michelle Hill Right.

Abel, Greg A Yeah, but that's not, I think, how that was written. It wasn't intended to make an allergen free entree safely.

Amber Thompson Right, right, right.

Abel, Greg A Yeah.

Babekir, Amani And I think to that piece, I remember when I walked into a restaurant and I ordered pizza, which is, you know, the gluten free one. And then they brought me the dish. I ate it and it wasn't the gluten free one.

Michelle Hill Oh my God.

Babekir, Amani So yeah, there is a missing piece here … how do you track ...

Amber Thompson Yeah, you. Yeah, right.

Abel, Greg A I think there's when you're working with humans, there's missing pieces everywhere. I remember Buffalo Wild Wings having a gluten free menu item on the menu and my son would order certain wing coating. Then the person at the different store said “well, you can't have this because it's has gluten in it” and my son says “well, it's advertised gluten free and we eat it up in the north location.” She said, “Yeah, it says that on the menu but our chef does it different, so there's gluten in it.”

Amber Thompson Yeah. Well, that's liability right there.

Babekir, Amani Yes!

Abel, Greg A Isn't that crazy? Even they're not conforming to their own standardized recipes?

Babekir, Amani Umm. Yeah. And maybe we need to help them establish some kind of standard to make sure if they have a gluten free thing on the menu it is actually gluten free.

Abel, Greg A Well, that's just that person not caring or understanding … just adapting the menu, the recipe to their own liking.

Michelle Hill And it even happens with school lunch. A lot actually. They want to add cheese to everything, so it is no longer dairy free … You need standardized recipes. You have to follow the recipe.

Amber Thompson Yeah, I'm curious if Buffalo Wild Wings corporate knew about that chef because that would be a fired chef, if that was my chef.

Abel, Greg A Yeah, exactly right.

Michelle Hill Me too. Me too. Yeah.

Amber Thompson That's ridiculous beyond all.

Abel, Greg A Mm-hmm.

Amber Thompson You can't choose what you how you want to prepare something. Open your own restaurant. The frustrates me.

Michelle Hill Especially when it's off menu like that. Yeah, that's not OK.

Amber Thompson That's a lack of education.

Babekir, Amani And maybe we need some kind of like a controlled checklist to ensure before you serve the dish, it is really gluten free, or whatever, as it's announced on the menu.

Abel, Greg A I think I think Scott came up with some language on one of the subcommittees about that exact thing, right?

Babekir, Amani Yes.

Abel, Greg A I thought we worked on something that I forget what Amber was at on the committee we were on. I forget all the committees and all their little pieces to the puzzle, but one of them was kind of having an assurance that the food that the food going out, there's a checks and balance and the food goes, goes out, that it is truly.

Amber Thompson Umm. Like a QA, right?

Abel, Greg A Yes.

Michelle Hill Like a final allergen plate check or something.

Amber Thompson Right.

Abel, Greg A We worked on that concept, yeah.

Michelle Hill I don't know if that's new concept and people are going to be like, what are you talking about. But I did drop that in.

Babekir, Amani Hmm.

Amber Thompson You could just put quality, QA person, or quality assurance person, then?

Michelle Hill Oh, there you go. Quality assurance.

Abel, Greg A But isn't what, but this is this A, B, C ,D and all relates to non-major food allergens not defined right?

Michelle Hill No, we define that. So now up here we start our charge with, we're going to “expand upon” and then we dropped in “non-major food allergen” under “Control for”. So all the rest of B, C and D - all apply too. Including major food. Am I wrong about that? You guys OK? Good. OK.

Amber Thompson Right, right, including the non.

Abel, Greg A But wasn't some of that stuff already developed this year? But we've talked about some of the stuff. So you're saying just review it and expand on it?

Michelle Hill Mm-hmm.

Abel, Greg A Just continue the work is what you're saying.

Babekir, Amani And I think to your point, some of these ideas have been touched on in the "Preparation" section, I think, but it's not too much, so it was probably one or two points about that.

Abel, Greg A Hey, did you guys know when FALCPA got passed in 2004, got implemented 2006? There was a charge in there, a part of the law, that FDA was supposed to work with the Conference for of Food Protection, to produce a food allergen control manual.

Amber Thompson Umm.

Abel, Greg A I worked on that from 2007, for couple several years. And it just never got past. We were going to submit it, but it never got past our executive leadership of FDA.

Michelle Hill Boy, that would be a valuable tool because that's something you could share with people.

Abel, Greg A Right? It was so disheartening not to have it be put out there. But no I can't share it. I don't even have it.

Michelle Hill OK.

Abel, Greg A I mean, it wasn't even passed, so it's not even a final document. But and I forget the reasons why it never … because what if FDA authored it … would someone take it as a standard of, you know, a certain level when it's was meant to be guidance not …

Michelle Hill Not the law.

Abel, Greg A Not the law, right. You know, it's like, "well, FDA says so" - it could have been some of that. There were seven of us that were working together. We talked everything - about these concepts here. Now, what, 10-1/2 years later, we're doing it again, but in a different format. I just think how far we could have been ahead in this country if we would have had that 10 years ago, 15 years ago.

Michelle Hill Well, Greg, you, and I both know that we've been spinning the same wheel, and that's why I write my food blogs too. I write "9allergens.com" where you can print out all the derivations for all nine major allergens as ingredients and how they might appear on a label because there's no other place to find that. I think that's something FDA should house, too. Tear sheets of their allergy section could be better, like "this is how it can appear on a label …" and list every instance.

Michelle Hill Like whoever thought sesame would be lurking in tomato products. But it is.

Abel, Greg A Oh my gosh, I never thought that really.

Michelle Hill It's in the base product. They add sesame in, as part of tomato paste, and it's not on the label as such, it is listed as "extracts, spices" because it is an antioxidant and it doesn't impart serious flavor. It happens when they cook tomatoes during the first cook, so it gets distributed to other purveyors with it as part of it the tomato product and it is not labeled for sesame. I wonder … I'd love to know somebody in the tomato world because I know people in the bun world and it split that world in half, you know, sesame, no sesame seed bun ...

Amber Thompson Ohh wow.

Michelle Hill Yeah.

Amber Thompson There's gonna be a lot of non-sesame buns soon.

Amber Thompson We're not wanting to support the Food service worker, we're wanting to support the person in charge who's in control of the food service workers job, of notifying the consumer, which is a very long sentence …

Amber Thompson Person in charge. When training, yeah, there we go. Training, I would say employees.

Michelle Hill Ohh OK well, if I say food workers that include people that don't get paid … like volunteers at food shelf?

Amber Thompson Oh, that's a good point.

Michelle Hill I had to go through and standardize the whole document, so it's in my head.

Abel, Greg A But we I guess in the food code, we call the "food employees."

Michelle Hill Oh, you do? OK.

Abel, Greg A Yeah.

Michelle Hill Even if they're not being paid.

Abel, Greg A Umm, Yeah.

Babekir, Amani So I have to jump to another meeting at 3 … so if we could finalize this and then just jump to the other to the other issue.

Michelle Hill OK , Let's go to Issue 3. This deals with how to amend the food code.

Amber Thompson OK.

Michelle Hill Umm, we have to pick a spot – as we offer three options listed and there can only be one.

Babekir, Amani Yeah. We suggested the three options, so have to pick one and then also and then give FDA the flexibility to pick wherever they want.

Michelle Hill And all of the discussions we had around this and this is just me talking. I love #1A.

Abel, Greg A Can you blow that up?

Michelle Hill Umm yeah.

Amber Thompson Letter “A.”

Michelle Hill Yes

Abel, Greg A Yes.

Amber Thompson Yes, I like this one too. Make it its own #5 dedicated section to everything we want to add, including all the future work. Sure.

Michelle Hill Yep. And then letters “B” and “C” are listed within Annex 2, just not is such a prominent spot.

Amber Thompson Yeah, yeah. I'm. I'm. I'm down with a there or 1A. Yeah.

Babekir, Amani Yep.

Michelle Hill How about everybody else? Anybody objecting to that? All right.

Babekir, Amani Yeah, I'm with you on that one.

Michelle Hill Good, that's done. And I won't even say “A”, I'll just say ...

Amber Thompson There we go.

Michelle Hill Yes. And I must cite this right, I'll make sure it's cited. There’s a big document on how to make things look right issued by CFP that I will check. OK, so that is done.

Babekir, Amani Remember to add “or a location where deemed appropriate by FDA.”

Michelle Hill Yeah, I have Courtney's e-mail saved in another file so … Amani, I'll make … I'll fly speck this ... I'll send it to you and then forward on ... OK, awesome.

Babekir, Amani Umm. Yes. And do we feel good about the one which we were working on?

Michelle Hill Should I bring it back up?

Abel, Greg A As far as food employee as defined in the food code, it means “an individual working with unpackaged food, equipment and utensils are food contact surfaces,” so the food code defines it as a “food employee.”

Michelle Hill OK. Thank you.

Michelle Hill Are we OK with this letter C?

Amber Thompson Training. Workers are notifying consumers about food allergens.

Amber Thompson I like it the way it's re-worded with training because we're supporting the training.

Michelle Hill Yes. OK. I don't want us to feel super rushed. I know its due today …

Amber Thompson No pressure.

Michelle Hill Uh-huh.

Babekir, Amani Good, good. That's great.

Michelle Hill We did it.

Amber Thompson Yes, looks good.

Babekir, Amani Thank you for joining and thank you for your input - it's really valuable.

Michelle Hill We could not have done it without you. Really appreciate everything.

Babekir, Amani This meeting is asjourned.

CFP - Council II - Allergen Committee **Meeting Attendance** **2022 Biennium**

Position	First	Last	1 11/12/21	2 11/23/21	3 12/09/21	4 01/06/22	5 01/20/22	6 02/03/22	7 02/17/22	8 03/03/22	9 03/17/22	10 03/31/22	11 04/14/22	12 04/28/22
C II Co-Chair	Joetta	DeFrancesco		1	1		1	1		1		1		
C II Co-Chair	Wendy	Bell												
C II Co-Chair	Courtney	Halbrook	1									1		
Co-Chair	Amani	Babekir	1	1	1	1	1	1	1	1	1	1	1	1
Co-Chair	Michelle	Hill	1	1	1	1	1	1	1			1	1	1
Voting	James	Baldwin	1	1	1	1	1	1		1				1
Voting	Anne	Dolhanyk	1	1	1	1			1	1				
Voting	Crystal	Eisner	1	1	1	1	1	1	1			1	1	1
Voting	Amanda	Garvin	1		1	1	1		1	1	1	1		
Voting	Vy	Goddard / Truong	1	1	1	1	1	1	1	1	1		1	
Voting	Darby	Greco	1	1	1				1					1
Voting	DeBrena	Hilton		1	1									
Voting	Cassandra	Mitchell	1	1	1	1	1	1	1		1	1	1	
Voting	James	Oneal	1	1	1	1	1	1	1	1	1	1	1	1
Voting	Amber	Potts - Thompson		1	1	1	1	1		1	1	1		
Voting	David	Read	1	1	1	1	1	1	1	1	1	1	1	1
Voting	Libby	Thoma	1	1	1	1	1	1	1	1	1	1	1	
Voting	Scott	Vinson	1	1	1	1	1	1		1		1	1	
Voting	Steven	von Bodungen	1		1	1	1	1	1	1	1			
Voting	Ben	Wagner	1	1	1	1		1	1		1		1	1
		Invited Total Voting:	17	17	17	17	17	17	17	17	17	17	17	17
			15	15	17	15	13	13	13	11	10	10	10	8
		Required for Quorum:	10	10	10	10	10	10	10	10	10	10	10	10
Advisor	Greg	Abel		1	1	1		1		1	1	1		
Advisor	Mary	Cartagena	1	1	1		1	1						
Advisor	Devin	Dutilly								1	1	1	1	1
Advisor	*Jennifer*	*Green*		*1*		*1*		*1*		*1*			*1*	*1*
Advisor	Erin	Moritz	1	1	1		1	1		1	1	1		1
Advisor	Beth	Wittry	1											
Advisor	Jenna	Seymour			1	1	1	1		1	1	1	1	1
At Large	Susan	Algeo	1	1	1	1					1			
At Large	Janice	Brady		1										
At Large	Nicole	Lapore	1		1	1	1	1		1	1			1
At Large	Tom	Larsen*												
At Large	Susan	Leaverton	1											
At Large	Christina	Meinhardt	1	1		1		1		1				1
At Large	Aubrey	Noller	1	1	1	1		1		1	1	1	1	
At Large	Christine	Sylvis	1	1	1	1	1	1		1		1		1
		Invited Total:	14	14	14	14	14	14	14	14	14	14	14	14
			9	9	8	8	5	9	0	9	7	6	4	7

CFP - Council II - Allergen Committee **Meeting Attendance** **2022 Biennium**

Position	First	Last	13 05/12/22	14 06/09/22	15 06/23/22	16 07/07/22	17 08/04/22	18 08/18/22	19 09/01/22	20 09/29/22	21 10/27/22	22 11/10/22	23 12/05/22
C II Co-Chair	Joetta	DeFrancesco									0		0
C II Co-Chair	Wendy	Bell	1			1		1		1			0
C II Co-Chair	Courtney	Halbrook		1								1	0
Co-Chair	Amani	Babekir	1	1	1	1	1	1	1	1	1	1	1
Co-Chair	Michelle	Hill	1	1		1	1	1	1	1	1	1	1
Voting	James	Baldwin		1	1						0	0	
Voting	Anne	Dolhanyk									0	0	
Voting	Crystal	Eisner			1	1	1	1	1		1	0	1
Voting	Amanda	Garvin	1		1	1				1	0	0	
Voting	Vy	Goddard / Truong	1		1						0	0	
Voting	Darby	Greco									0	0	
Voting	DeBrena	Hilton									0	0	
Voting	Cassandra	Mitchell									0	0	
Voting	James	Oneal	1	1	1	1	1	1	1	1	1	1	
Voting	Amber	Potts - Thompson	1	1	1	1	1	1	1	1	1	0	1
Voting	David	Read	1	1	1	1	1	1	1	1	1	1	
Voting	Libby	Thoma		1		1	1		1		0	1	
Voting	Scott	Vinson		1	1	1	1	1	1	1	0	1	1
Voting	Steven	von Bodungen									0	0	
Voting	Ben	Wagner	1	1	1	1				1	1	1	
		Invited Total Voting:	17	17	17	17	17	17	17	17	17	17	
			8	9	10	10	8	7	8	8	7	7	
		Required for Quorum:	10	10	10	10	10	10	10	10	10	10	
Advisor	Greg	Abel		1	1	1	1		1				1
Advisor	Mary	Cartagena											
Advisor	Devin	Dutilly	1		1	1	1	1	1				
Advisor	*Jennifer*	*Green*	*1*	*1*	*1*	*1*	*1*		*1*				*1*
Advisor	Erin	Moritz		1		1	1	1	1		1		
Advisor	Beth	Wittry											
Advisor	Jenna	Seymour	1			1	1	1	1		1		1
At Large	Susan	Algeo	1	1	1	1	1		1				
At Large	Janice	Brady			1								
At Large	Nicole	Lapore		1	1	1							
At Large	Tom	Larsen*											
At Large	Susan	Leaverton											
At Large	Christina	Meinhardt						1			1		
At Large	Aubrey	Noller	1	1									
At Large	Christine	Sylvis					1	1	1			1	1
		Invited Total:	14	14	14	14	14	14	14	14	14	14	
			5	6	6	7	7	5	7	0	3	1	

Major Food Allergen Framework

Conference for Food Protection
2023 Biennium
Council II: Allergen Committee
Publication Date: _____

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Contents

Introduction

PURPOSE This document is to serve as a voluntary operational framework for FOOD ALLERGY[1] prevention and control of the MAJOR FOOD ALLERGENS[2] (as defined below) using existing research and other evidence-based materials for FOOD ESTABLISHMENTS[3] and OTHER COMMUNITY FOOD SOURCES[4]. Readers should be aware, however, that people may have other allergies beyond the major food allergens, and food establishments may employ the same practices outlined in this document to assist CONSUMERS[5] with allergies, FOOD INTOLERANCE/SENSITIVITY[6] beyond those listed herein.

Readers should be aware that consumers may have other food allergies, intolerances, or sensitivities (such as celiac disease, Crohn's disease, IBS/IBD, and others) which, although not technically allergies, are triggered by ingestion of particular foods.

SCOPE This document covers food allergy training of FOOD HANDLERS[7]; food handling policies and practices; consumer notification tools for food allergens; a food allergy reaction and emergency response guide; and equal consideration for other community food sources.

BACKGROUND A food allergy happens when a person's immune system overreacts to a food protein. Approximately thirty million people in the U.S. have food allergies, leading to 200,000 emergency department visits per year. FOOD ALLERGIC REACTIONS[8] vary in severity, from mildly itchy skin and lip swelling to severe, life-threatening symptoms (ANAPHYLAXIS[9]) and death. In the United States, 51% of adults and 42% of children with food allergies have experienced a severe reaction.

1 "Food allergy" means the reaction of the body's immune system to certain proteins in food. Reactions can vary in severity from mild symptoms involving hives and lip swelling to severe, life-threatening symptoms, called anaphylaxis, which may involve shock and fatal respiratory problems.

2 "Major Food Allergen" mean the allergens in foods that cause over 90% of allergic reactions: milk, egg, fish (such as bass, flounder, or cod), crustacean shellfish (such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame.

3 "Food establishment" means an operation that (a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; institution; or food bank; and (b) relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

4 "Other community food sources" means food sources that are made available to the public on a need basis, e.g., food bank, food shelf, food pantry.

5 "Consumer" means a person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale

6 An adverse reaction to a substance in food that does not involve the immune system, e.g., the inability to process or breakdown a certain food such as the milk sugar lactose which can lead to discomfort or have ill effects.

7 "Food handler" means a person who handles food utensils or who prepares, processes, or serves food or beverages for people other than members of their immediate household.

8 "Food allergic reaction" means an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food. The immune response can be severe and life-threatening.

9 "Anaphylaxis" means a life-threatening allergic reaction due to over-release of certain chemicals in the body resulting in shock when a person with an allergy is exposed to an allergen. Allergies to food, insect stings, medications, and latex, are most frequently associated with this type of severe response, and may include skin symptoms or swollen lips, difficulty breathing, reduced blood pressure, and gastrointestinal symptoms.

The **Major Food Allergens** that cause over 90% of all allergic reactions in people are these types of food:

- Milk
- Eggs
- Fish (such as bass, flounder, or cod)
- Crustacean shellfish (such as crab, lobster, or shrimp)
- Tree nuts (such as almonds, pecans, or walnuts)
- Wheat
- Peanuts
- Soybeans
- Sesame[10]

This guide includes example procedures, considerations, and resources that a food establishment can use to respond when someone notifies the food establishment about a food allergy or reports an allergic reaction. It also provides a framework for providing consumers accurate information about food ingredients so they can make informed decisions when ordering.

Although comprehensive, this guide might not provide everything that needs to be considered for a food allergy reaction and emergency response plan. It might also contain materials that are not relevant to every food establishment, so please consider internal procedures or standard operating procedures when using this material.

10 Sesame has been added to the list of Major Food Allergens via the FASTER Act of 2021, effective January 1, 2023.

A. Training

PURPOSE This is a framework to educate food handlers about (1) the Major Food Allergens – milk, egg, fish (such as bass, flounder, or cod), crustacean shellfish (such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame; and (2) other allergy and intolerance issues they may encounter.

Duties in food establishment (intensity of training increases with responsibility)

1. PIC - Person in Charge (PIC)[11]

Training should include

a) Definitions for food allergy, food intolerance/sensitivity, and CROSS-CONTACT[12].
b) List of the symptoms of a food allergic reaction, including anaphylaxis.
c) List of the Major Food Allergens in FDA's Food Code.
d) Dangers of food allergens and how to prevent cross-contact.
e) Using proper cleaning methods, such as wash, rinse, and sanitize, to prevent cross-contact.
f) How and when to communicate with consumers and staff about food allergens.
g) Special considerations related to food allergens for workstations and SELF-SERVICE[13] areas.
h) How to handle food allergy requests.
i) How to deal with food allergy emergencies.
j) Proper food preparation for guests with food allergies.
k) How to read a food LABEL[14] and understand the importance of food labels.
l) Personal hygiene practices to prevent cross-contact.
m) How to receive and store foods that contain Major Food Allergens to prevent cross-contact.

2. Front of house; wait staff, hostess/host, to-go personnel

Training should include

a) Definitions for food allergy, food intolerance/sensitivity, and cross-contact.
b) List of the symptoms of a food allergic reaction, including anaphylaxis.
c) List of the Major Food Allergens in FDA's Food Code.
d) How to handle food allergy requests.
e) How to deal with food allergy emergencies.

3. Back of house; Food handler *(as defined in FDA's Food Code)*

Training should include

a) List of the Major Food Allergens in FDA's Food Code.
b) Dangers of food allergens and how to prevent cross-contact.
c) Cleaning and personal hygiene practices to prevent cross-contact.
d) In-depth knowledge of MENU[15] items and preparation as it relates to assigned duties.
e) Proper food preparation for consumers with food allergies.
f) How to read a food label and understand the importance of food labels.

11 "Person in Charge (PIC)" means the person present at a food establishment who is responsible for the operation at the time of inspection.

12 "Cross-contact" means the unintentional transfer of an allergen from a food or food-contact surface containing an allergen to a food or food-contact surface that does not contain the allergen.

13 "Self-service" means areas where a food handler is not present to serve a consumer and the consumer is responsible for serving themselves. Examples: buffets, salad bars, sushi bars, or display cases.

14 "Label" means a display of written, printed, or graphic matter upon the immediate container of any article; and any word, statement, or other information that appears on the outside container or wrapper of the retail package.

15 "Menu" means all written and verbal lists of foods prepared and offered in a food establishment.

4. Understanding Labels

a) Manufacturers of PACKAGED FOOD[16] products that contain a Major Food Allergen are required by law to list that allergen on the product label – including if they are, or are a component of, a flavor, color, incidental additive, or spice (i.e., sesame paste).
b) There are several ways the allergen can be listed, so CONSUMERS[17] must read product labels carefully.
   i. The allergen may be listed in a 'Contains' statement.
   ii. If the product does not have a 'Contains' statement, consumers should review the entire ingredient list.
   iii. A 'may contain' or 'produced in a facility' marking is a voluntary, separate allergen advisory statement when there is a chance that a food allergen could be present. Anything labeled in this manner should be considered to have an allergen present.
c) Common allergens can have other names. For example, caseinates (in all forms), and whey (in all forms) are all milk proteins.
d) Although the same allergen can be present in multiple ingredients, its "food source name" (for example, milk), or common or usual name, must appear in the ingredient list just once to comply with LABELING[18] requirements.

SUPPLY CHAIN CONSIDERATIONS Manufacturers change their ingredients and production methods continually and without warning; it is especially important to read the ingredient label, and ingredient statement, for the presence of major food allergens with each shipment. Contact the manufacturer in advance if you have questions about food allergens that may be in a product.

e) Major food allergen labeling information can be found within:
   - FDA's "21 CFR 101", https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101
   - USDA's "Allergens – Voluntary Labeling Statements," https://www.fsis.usda.gov/guidelines/2013-0010
   - USDA's **"**FSIS Compliance Guidelines: Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling," https://www.fsis.usda.gov/sites/default/files/import/Allergens-Ingredients.pdf

16 "Packaged" means bottled, canned, cartoned, bagged, or wrapped, whether packaged in a food establishment or a food processing plant. "Packaged" does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food handler, upon consumer request.

17 "Consumer" means a person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale.

18 "Labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article.

B. Food-Handling Policies & Practices to Help Consumers with Food Allergies

PURPOSE Example policies and practices are provided here that will reduce the risk of a consumer being exposed to a food allergen.

With food allergens, it is **very important** to avoid having **even small amounts** of an ingredient to which a consumer is allergic come into contact with their food, utensils, tableware, and packaging. The unintentional transfer of an allergen from a food or food-contact surface containing an allergen to a food or food-contact surface that does not contain the allergen is called **cross-contact**. Sometimes it is obvious when an allergy-causing ingredient has gotten into a food through cross-contact because the ingredient can be easily seen, but other times it is not obvious, and great care should be taken to avoid these situations.

Following these guidelines, which apply to **all food handlers** who come into contact with food, beverages, and any food preparation surface, can help consumers with allergies avoid potentially life-threatening allergic reactions.

Train relevant staff in the following procedures

1. Food & Ingredient Storage

a) **Label** and segregate unpackaged foods containing one or more of the Major Food Allergens away from each other, and store separately from other foods and ingredients. *Make sure to read ingredient labels to check for the presence of allergens before labeling and segregating.
b) Spills of any of the Major Food Allergens should be cleaned up immediately, following the usual cleaning procedures used in the food establishment. If any Major Food Allergen accidentally comes into contact with other food ingredients that do not contain that allergen, these ingredients should be excluded from use.

2. Self-Service Items

a) For food items that were made on site, **label** the food items, or place **signs** next to the food items, that clearly identify the presence of one or more of the Major Food Allergens, or keep ingredient lists on site that identify the presence of one or more of the Major Food Allergens.
b) Labels and signage should be in both English and Spanish, and/or other languages appropriate to either the establishment, or the geographic area.

3. Taking a Food Order

a) When a consumer informs staff they have a food allergy, intolerance, or sensitivity, immediately **notify** the Person in Charge (PIC) or designated person (manager, chef, or key employees).
b) Help the consumer **identify** menu items that contain ingredients to which they are allergic and offer suggestions for alternative menu items.
c) If no alternative menu options are available, politely **inform** the consumer.
d) If it is possible to **modify** a menu item so that it does not include ingredients the consumer must avoid, inform the consumer, and ask if the modification would suit their needs.
e) **Verify** with the food handler that the proposed menu item modification is possible, feasible, and can be done safely for the consumer.
f) Make a **note** on the consumer's order that they have a food allergy/intolerance/sensitivity and which ingredients they must avoid so that other food handlers are aware.

4. Preparing a Food Order

a) Thoroughly clean all areas and equipment that will be used for preparing the allergic consumer's meal, even if those areas had already been cleaned for normal use.
b) Wash hands thoroughly before preparing the allergic consumer's meal. In some situations it may be necessary to change apron/chef coat, if previously soiled with potential allergens.
c) Use dedicated equipment or physically separate products to prevent cross-contact.

i. Use color-coded or specially marked supplies, uniforms, equipment, and utensils designated for preparing allergen-free meals.
ii. Avoid using the same cooking medium (e.g., oil or water) and surface (e.g., grill, prep table) when handling ingredients with and without allergens.

d) Use ingredients that do not contain the allergen(s) to which the consumer is allergic. Check ingredient labels for packaged foods.
e) Prepare food in a manner that eliminates cross-contact. All preparation, including garnishes, should be done by only one food handler who is dedicated to ensuring the meal is allergen-free, and who is not preparing other consumers' meals at the same time.

i. **If a mistake is made**, and an ingredient to which the consumer is allergic is accidentally included in the meal, it is **not sufficient** to simply remove the offending ingredient, because cross-contact will have occurred. In case this happens, **re-make** the consumer's meal.
ii. Wash your hands with soap and water before continuing preparation to avoid potential, or additional, cross-contact.

f) Cover the meal with a clean lid to prevent cross-contact and mark the meal as "allergy" so other staff are aware.
g) Notify the PIC, or designated food handler once the allergen-free meal is prepared and ready for service.
h) Wash, rinse, and store special equipment for allergen-free meals to be ready for next use.
i) Wash your hands with soap and water before touching anything else if you have handled a food allergen.

5. Delivering a Food Order

a) Verify with the food handler who prepared the meal that it does not contain the allergen specified by the consumer.
b) Ensure no cross-contact with other meals occurs during transport of the meal to the consumer.
c) Use a separate meal tray to deliver the meal.
d) VERIFY with the consumer that the meal meets their needs.
e) Discard the meal and offer to re-make it for the consumer if the meal contains ingredients to which the consumer is allergic. **Notify** the PIC. **Review** procedures and **retrain** the food handler(s) who prepared and handled the meal on these procedures **before** allowing them to re-make the consumer's meal.

C. Tools to Notify Consumers about Major Food Allergens

PURPOSE The purpose of this guidance is to provide examples of how to give consumers accurate information about food ingredients that are, or that contain, Major Food Allergens so they can make informed decisions when ordering. Giving incorrect or incomplete information can put consumers at risk for allergic reactions.

Consumers with food allergies depend on accurate allergen information when deciding what to eat. It is most effective to tell the consumer both verbally and in writing (e.g., on labels and menus) about the presence of food allergens and the risks of cross-contact.

1. Food Allergens in Menu Items & Self-Served Food[19] Items

a) Review your menu and source ingredients.
b) Use a table (see "Figure 1: Example Food Allergen Matrix" below), listing each menu item and noting the presence of major food allergens including all ingredients such as egg washes, sauces, garnishes, etc. Remember, a food might have more than one allergen.
c) Print "Figure 2. Allergen Matrix – Major Food Allergens Present in Menu Items" (following page) and use it for staff and consumers.
d) Assign a person in charge to regularly, at least once a year, review the food allergen table and update it as needed to verify the ingredients have not changed. Review and update when ingredients, suppliers or processes have changed, and/or a new item has been added to the menu. Consider off-menu items, seasonal and specialty items.
e) Have accessible the full list of ingredients for menu items for consumers with allergies or intolerances beyond the top nine. Consumers may be allergic to ingredients beyond the Major Food Allergens, like gluten. Understanding the full list of ingredients may help you better assist these consumers.

2. Create a Food Allergen Matrix *(based upon your current menu items)*

Figure 1. Example Food Allergen Matrix

Food Items*		Major Food Allergens								
		Egg	Fish	Milk	Peanut	Sesame	Shellfish	Soybean	Tree Nut	Wheat
Breads or Breaded	Bagels	X		X		m		m		
	Gluten Free biscuit	X		X				m	m	
	Sourdough bread									
	Croutons	X		m		m			m	
	Onion rings	X		X						
	Chicken nuggets	X						m		
	Mac and cheese	X		X						
Cheese	American			X						
	Provolone			X						
	Cheddar			X						
	Peanut oil in fryer				X			X		
Lettuce Salad	no Dressing									
	with Dressing	X		X				X		

"X" Contains this allergen.

"m" May contain this allergen or is processed in a facility with this allergen.

19 "Self-served food" means Restaurant-type food that is available at a salad bar, hot food bar, buffet line, cafeteria line, or similar self-service facility, and is served by the consumers themselves. Self-service food also includes self-service beverages, such as drinks dispensed from a soda fountain and coffee available on a self-service basis

Figure 2. Allergen Matrix[20]

Major Food Allergens Present in Menu Items

Food Items *	Major Food Allergens									Other Components			
	Egg	Fish	Milk	Peanut	Sesame	Shellfish	Soybean	TreeNut	Wheat				

"X" Contains this allergen.
"m" May contain this allergen or is processed in a facility with this allergen.
** Include off-menu items, seasonal and specialty items.*

Created on:_____ Reviewed on:_____ Next review:_____

20 A table such as this could be customized for gluten-free and other food intolerances and sensitivities by utilizing the “Other Components” column.

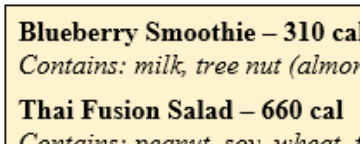
3. Menus & Signage

Design and update existing menus (including those for online ordering, catering, specials, and take-out) to ensure names and descriptions of **all** food items include Major Food Allergens present in each food. For example:

a) Have signage to notify consumers and food handlers an allergen menu exists.
b) Next to each menu item, include text to specify allergens (e.g., *Contains egg, milk*).
c) Use images (or "icons") of food allergens next to menu items where they are present. Include a key so consumers know what the icons represent. Links to websites with pre-made icons are included below.

Figure 3. Examples of notifications

Example 1: In-menu allergen notification.



Example 2: Allergen icons.

4. Talk with Consumers

a) Encourage staff to **ask consumers** about any food allergies they might have.
b) **Provide a list** of menu items and their ingredients for food handlers and consumers as a reference.
c) **Appoint at least one trained food handler per shift** to respond to consumer requests and questions about food allergens.

5. Other Ways to Inform Consumers

a) **Static clings** on display cases provide Major Food Allergen information in consumer view. **Tags or tents** next to food items also work well.
b) **Counter cards, table-talkers, or signs** at the point-of-sale or pick-up to inform consumers.
c) Consider **placing a sign in a prominent location**, when contact with a Major Food Allergen is possible or unavoidable (e.g., French fries prepared in the same fryer as breaded [wheat-containing] items).
d) **Websites** where you can find graphics and other icons for food allergens include:

i. International Association for Food Protection (IAFP) Food Allergen Icons
https://www.foodprotection.org/resources/food-allergen-icons/
ii. StateFoodSafety Allergen Icons
https://drive.google.com/drive/folders/1z_Ie5yxvWq5vFLnWnR7FeIXZDQePhygI?usp=sharing
iii. Erudus Food Allergy Icons
https://erudus.com/standardised-food-allergy-icons/

D. Food Allergy Reaction & Emergency Response Guide

PURPOSE This section is to serve as a resource for food establishments when writing a food allergy reaction and emergency response plan. This guide includes example procedures, considerations, and resources that a food establishment can use to respond when someone reports an allergic reaction. Although this section was written specifically for food allergies, some parts are applicable to reactions caused by other exposures, such as bee stings. Example informational posters are included for you to use within your food establishment.

1. What an allergic reaction may look like

Allergies are complex and allergic reactions can vary from person to person.

Allergic reactions can present in many ways. Food allergic reactions vary in severity, from mildly itchy skin and lip swelling to severe, life-threatening symptoms (anaphylaxis) and death. Some signs and symptoms only affect one part of the body (for example, hives around the mouth). Some signs and symptoms mean that multiple areas of the body are affected (for example, dizziness).

Even within the same person, reactions can differ from food-to-food and day-to-day. For example, a person might experience itching around the mouth after eating an almond, but they could have difficulty breathing and require emergency care after eating a peanut. Even reactions to the same food on different eating occasions can cause different symptoms in the same person.

Different people, including children, experience different symptoms too. For example, not everyone experiences nausea or diarrhea during a reaction. Likewise, it is possible to have a severe life-threatening reaction (anaphylaxis) without any skin symptoms, such as a rash or hives.

2. Allergic reactions in children and adolescents

Children can experience serious food allergic reactions, with an alarming number of fatal anaphylactic reactions occurring during adolescence. Milk, egg, wheat, and soy allergies are more common in childhood than adulthood.

Children can have difficulty communicating what they are experiencing during a reaction. Some children put their hands in their mouths or scratch at their tongues. Their voices may change (for example, becoming hoarse or squeaky), and they might slur their words.

3. If someone reports an allergic reaction

These are **examples** of potential actions to take when a person reports an allergic reaction. Procedures may differ depending on the severity of the reaction. Food establishments should evaluate their need for internal procedures or additional steps. based on corporate policies or other circumstances.

*** When in doubt, call 911 ***

a) Clearly direct one person to dial 911 and report an allergic reaction.
b) Follow the directions of emergency services personnel and the food establishment's food allergy emergency response plan.

4. Epinephrine auto-injectors

a) What is an auto-injector?
EPINEPHRINE AUTO-INJECTORS[21] are medical devices for injecting a measured dose of epinephrine directly into a person experiencing an allergic reaction. The devices are designed to be given through clothing. Multiple brands of auto-injectors are available in the United States, and other countries, and may look slightly different. In the U.S., you cannot buy an epinephrine auto-injector unless you have a prescription from a health care provider. Food establishments will not be able to stock an auto-injector for general use.
Epinephrine auto-injectors have specific directions for use printed directly on the device. **Always follow the instructions printed on the auto-injector**. Always call emergency services when an auto-injector needs to be administered, as a relapse is possible.

b) Here are some example images of what an epinephrine auto-injector might look like; not all auto-injectors will look like these.

Figure 4. Examples of Epinephrine auto-injectors (EAIs)

5. Additional considerations for the food establishment

The following questions and scenarios may be used to develop a detailed food allergy reaction and emergency response plan and/or can be used as a practice drill. Not all questions and scenarios will apply to a food establishment and some food establishments might have additional questions to consider.

a) What ingredient information will be provided to a consumer if they ask? Will this information be written or verbal?

i. If a person experiences a reaction, their first question will be if the allergen was present in any of the food(s) they ate.

b) The exact numbers to dial to reach emergency services should be clearly posted by all telephones.

i. Is there an additional number to dial or extra step to get an outside line?

c) Each person should be aware of any role they play during an emergency. You may consider who will:

i. Be the primary person in charge and ensure each person is performing their duties.

21 A device for injecting oneself with a single, preloaded dose of a drug. The device typically consists of a spring-loaded syringe activated when the device is pushed firmly against the body.

ii. Call emergency services and relay information.
iii. Direct and meet emergency medical services? Are there clear instructions available on how to find the food establishment?
iv. Interact with and physically assist the consumer, if necessary.
v. Keep the area around the person experiencing the reaction clear.

d) Will the food establishment keep any allergy-specific supplies (for example, antihistamines or itch creams) on hand? If yes, when will they be used?

REMINDER Epinephrine is the only medication that can treat a severe allergic reaction and must be prescribed by a health care provider.

e) Will staff have permission to search a person's belongings for an epinephrine auto-injector if they are unable to assist?
f) Can staff administer epinephrine auto-injectors? If yes, which people have permission?
g) Is there an automated external defibrillator ("AED") available? If yes, are staff trained to use it?
h) What are the procedures if the person experiencing a reaction does not want to call an ambulance? If the person leaves before the ambulance arrives, who will pay for any charges incurred?
i) Is there a debriefing and/or reporting requirement after the incident? If yes, include those steps in the allergic reaction response plan.
j) Modify the response plan, as necessary, to better prepare for future incidents.

6. Examples of Posters *(that can be placed within your food establishment to support food allergy preparedness and emergencies)*

E. Equal Consideration for Other Community Food Sources

Other community food sources provide healthy, nutritious food to those in need. For individuals with food allergies, it can be difficult to find safe foods. People with food allergies may need additional support and it is important to consider the food sources' ability to do the following:

- Have at least one well-trained person that is available to speak with those who have allergy concerns. It is important to identify foods that do not contain *at least* the Major Food Allergens so appropriate suggestions can be made.
- Allow consumers the opportunity to review original food packaging so they can read the labels. Know the importance of reading every label, every time, as ingredients can change without warning.
- Make sure staff understand the dangers of cross-contact and how to avoid it. Find out what procedures are in place to avoid cross-contact in the storage and/or preparation of food, if it is being prepared on site, so it can be shared readily.
- If food is cooked and/or served on the premises, be sure workers knows how to recognize the signs and symptoms of anaphylaxis and what the protocols are for a food-allergic emergency.

When offering foods/meals to large groups, encourage preparation of meals that are free of the Major Food Allergens.

- If foods or meals with food allergens are served, provide materials (e.g., signage, labels, tags, tents) in prominent and visible locations to inform consumers.
- While most sections of this document are applicable to both food service venues as well as other community food sources, special attention should be paid to the understanding of how allergens are listed on food labels and the availability of food label information.

Food Sources During an Emergency and Disaster Preparedness

Whether an earthquake, hurricane or wildfire, natural disasters, in addition to man-made ones, can happen at any time, often with little notice. Establish procedures for accessing allergen-friendly foods during an emergency. A crisis is never a time to experiment with a new food or product.

Fig

Food Allergy Reactions

Nine Major Food Allergens

- Milk
- Eggs
- Fish
- Shellfish
- Tree nuts
- Peanuts
- Wheat
- Soybeans
- Sesame

Symptoms of a Severe Allergic Reaction

LUNG
Short of breath, wheezing, repetitive cough

HEART
Pale, blue, faint, weak pulse, dizzy

THROAT
Tight, hoarse, trouble breathing/ swallowing

MOUTH
Significant swelling of the tongue and/or lips

SKIN
Many hives over body, widespread redness

GUT
Repetitive vomiting, severe diarrhea

OTHER
Feeling something bad is about to happen, anxiety, confusion

OR A COMBINATION
of symptoms from different body areas.

FOR **MILD SYMPTOMS** FROM **MORE THAN ONE** SYSTEM AREA, GIVE EPINEPHRINE.

If someone is having a SEVERE ALLERGIC REACTION…

INJECT EPINEPHRINE IMMEDIATELY

Follow the instructions on the device.

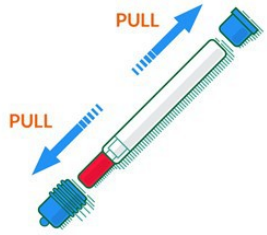
CALL 911

Tell them the individual is having an allergic reaction.

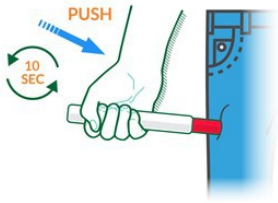
LAY them down.

If breathing is difficult or they are vomiting, let them sit up or lie on their side.

STEP 1. Prepare the epinephrine auto injector for injection by following the instructions on the device.



STEP 2. Administer the injection by firmly push the needle into the leg until a click is heard or felt. Hold the device there.



Written allergic reaction response plan is can be found here: _____

Adapted from Michigan Department of Agriculture and Rural Development, Michigan Restaurant Association, https://www.foodallergy.org/living-food-allergies/food-allergy-essentials/food-allergy-anaphylaxis-emergency-care-plan, and https://www.fda.gov/food/food-labeling-nutrition/food-allergies

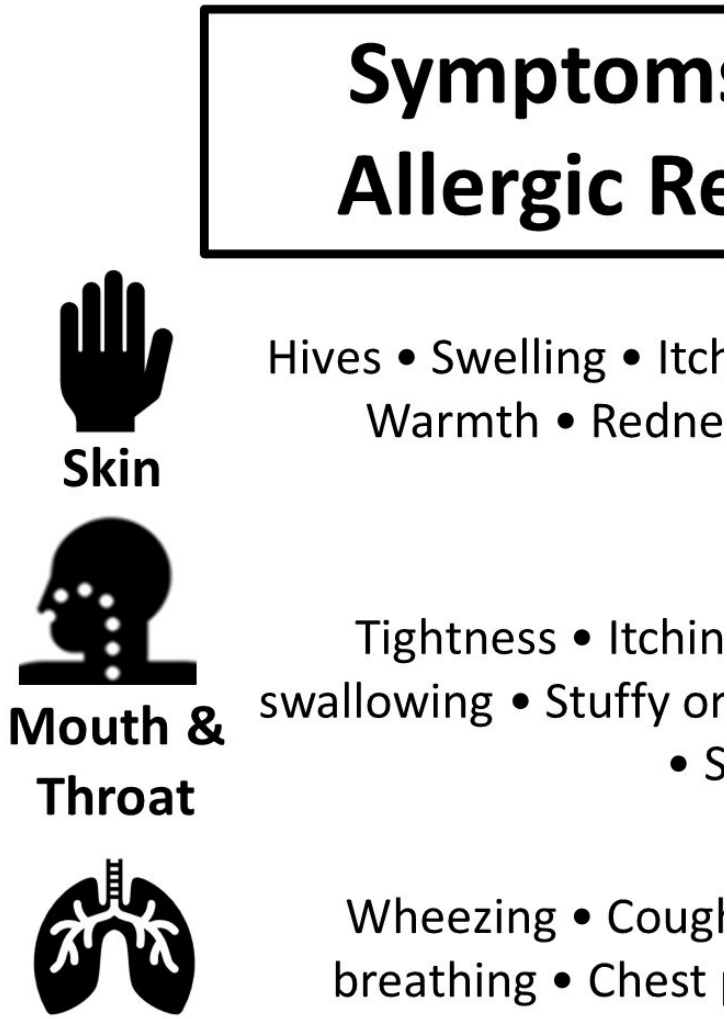


Figure 6. Symptoms of an Allergic Reaction

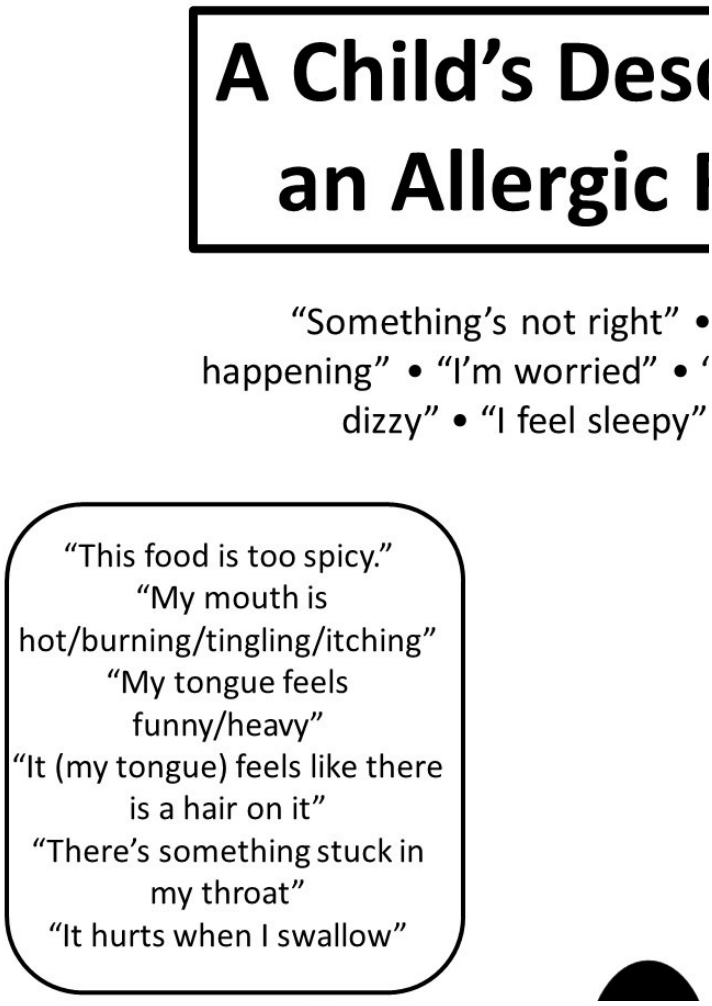


Figure 7. A Child's Description of an Allergic Reaction

Figure 8. Food Allergy Aware - Six that save lives

FOOD ALLERGY AWARE

SIX THAT SAVE LIVES

1

The Symptoms

Signs of a serious food allergy reaction – known as anaphylaxis – are 2 or more of the following after eating a suspect food:

- Hives, itching and/or skin redness
- Swelling of the tongue, lips or throat
- Breathing difficulty, wheezing or coughing
- Stomach cramps or vomiting or diarrhea
- Feeling faint / drop in blood pressure (If only this 1 symptom, it is still anaphylaxis.)

2

In Anaphylaxis: Use the auto-injector right away. Call 911 and report a food allergy emergency.

Epinephrine shots are given via the auto-injector to the outer thigh muscle. This is considered a very safe drug. Antihistamines are acceptable as secondary medication only. They won't halt anaphylaxis. Allergists say: err on the side of using the auto-injector.

3

Time is of the Essence

In studies of those who have died of anaphylaxis, they did not receive an epinephrine injection, or they got it too late, after a reaction had progressed. In anaphylaxis, prompt use of the shot is always essential.

4

Go to the Hospita

A person who had an eme epinephrine shot must be to hospital for observation. transport, IF symptoms ha improved within 10 to 15 n a second auto-injection s be given.

5

Reclining is Best

During the ambulance r the person having the se reaction should be lying d with the legs raised (this im blood flow). NIAID guidel recommend the patient re oxygen and IV fluid.

6

Don't Go It Alone

No person should be exp to be fully responsible fo administration of an epine auto-injector. Assistance anaphylaxis is crucia

From allergicliving.com. Based on guidelines from NIAID and the Canadian Society of Allergy and Clinical Immunology.

Definitions

Anaphylaxis
A life-threatening allergic reaction due to over-release of certain chemicals in the body resulting in shock when a person with an allergy is exposed to an allergen. Allergies to food, insect stings, medications, and latex, are most frequently associated with this type of severe response, and may include skin symptoms or swollen lips, difficulty breathing, reduced blood pressure, and gastrointestinal symptoms.

Consumer
A person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale.

Cross-contact
The unintentional transfer of an allergen from a food or food-contact surface to a food or food-contact surface that does not contain the allergen.

Epinephrine auto-injector
A device for injecting oneself with a single, preloaded dose of a drug. The device typically consists of a spring-loaded syringe activated when the device is pushed firmly against the body.

Food allergic reaction
An adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food. The immune response can be severe and life-threatening.

Food allergy
The reaction of the body's immune system to certain proteins in food. Reactions can vary in severity from mild symptoms involving hives and lip swelling to severe, life-threatening symptoms, called anaphylaxis, which may involve shock and fatal respiratory problems.

Food establishment
An operation that (a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; institution; or food bank; and (b) relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

Food handler
A person who handles food utensils or who prepares, processes, or serves food or beverages for people other than members of his or her immediate household.

Food intolerance/sensitivity
An adverse reaction to a substance in food that does not involve the immune system, e.g., the inability to process or breakdown a certain food such as the milk sugar lactose which can lead to discomfort or have ill effects.

Label
A display of written, printed, or graphic matter upon the immediate container of any article; and any word, statement, or other information that appears on the outside container or wrapper of the retail package.

Labeling
All labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article.

Major Food Allergen
The allergens in foods that cause over 90% of allergic reactions: milk, egg, fish (such as bass, flounder, or cod), Crustacean shellfish (such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, sesame, and soybeans.

Menu
All written and verbal lists of foods prepared and offered to consumers.

Other community food sources
Food sources that are made available to the public on a need basis, e.g., food bank, food shelf, food pantry.

Packaged food
"Packaged" means bottled, canned, cartoned, bagged, or wrapped, whether packaged in a food establishment or a food processing plant. (2) "Packaged" does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food handler, upon consumer request.

Person in Charge (PIC)
The person present at a food establishment who is responsible for the operation at the time of inspection.

Self-served food
Restaurant-type food that is available at a salad bar, hot food bar, buffet line, cafeteria line, or similar self-service facility, and is served by the consumers themselves. Self-service food also includes self-service beverages, such as drinks dispensed from a soda fountain and coffee available on a self-service basis.

Self-service
Areas where a food handler is not present to serve a consumer and the consumer is responsible for serving themselves, such as at a buffet, salad bar, sushi bar, or display case.

References

Conference For Food Protection. (2021). Food allergen notifications: A guidance for industry. http://www.foodprotect.org/media/guide/cfp-allergen-notification-guidance-8-22-2019-10-27-21.pdf
FARE: Facts and Statistics
https://www.foodallergy.org/resources/facts-and-statistics
UC Davis: Food allergies in children: Pediatric guidelines, diagnosis and more (ucdavis.edu)
https://health.ucdavis.edu/blog/good-food/food-allergies-in-children-pediatric-guidelines-diagnosis-and-more/2021/07
Serbes 2022: Serbes et al. Clinical features of anaphylaxis in children. Allergy Asthma Proc.
FARE/Child: How a Child Might Describe a Reaction | Food Allergy Research & Education
https://www.foodallergy.org/resources/how-child-might-describe-reaction
SNHD: HACCP-Based SOPs (southernnevadahealthdistrict.org)
https://www.southernnevadahealthdistrict.org/download/FERL-Resources/SOP-ALLERGY-TRAINING-AND-RESPONSE-20190102.pdf
Significant portions of this guidance were informed by materials developed by the Southern Nevada Health District.
https://www.southernnevadahealthdistrict.org/permits-and-regulations/food-establishment-resource-library/food-allergy-awareness-materials/
FARE: Navigating Food Assistance Programs with Food Allergies
https://www.foodallergy.org/resources/food-banks-and-soup-kitchens
FDA: Have Food Allergies? Read the Label
https://www.fda.gov/consumers/consumer-updates/have-food-allergies-read-label

Train relevant staff in the following procedures:

1. Food & Ingredient Storage

a) Label and segregate unpackaged foods containing one or more of the Major Food Allergens away from each other, and store separately from other foods and ingredients. *Make sure to read ingredient labels to check for the presence of allergens before labeling and segregating.

b) Spills of any of the Major Food Allergens should be cleaned up immediately, following the usual cleaning procedures used in the food establishment. If any Major Food Allergen accidentally comes into contact with other food ingredients that do not contain that allergen, these ingredients should be excluded from use.

2. Self-Service Items

a) For food items that were made on site, label the food items, or place signs next to the food items, that clearly identify the presence of one or more of the Major Food Allergens, or keep ingredient lists on site that identify the presence of one or more of the Major Food Allergens.

b) Labels and signage should be in both English and Spanish, and/or other languages appropriate to either the establishment, or the geographic area.

3. Taking a Food Order

a) Encourage staff to ask consumers about any food allergies they might have.

b) When a consumer informs staff they have a food allergy, intolerance, or sensitivity, immediately notify the Person in Charge (PIC) or designated person (manager, chef, or key employees).

c) Provide a list of menu items and their ingredients for food handlers and consumers as a reference.

d) Help the consumer identify menu items that contain ingredients to which they are allergic and offer suggestions for alternative menu items.

e) If no alternative menu options are available, politely inform the consumer.

f) If it is possible to modify a menu item so that it does not include ingredients the consumer must avoid, inform the consumer, and ask if the modification would suit their needs.

g) Verify with the food handler that the proposed menu item modification is possible, feasible, and can be done safely for the consumer.

h) Make a note on the consumer's order that they have a food allergy/intolerance/sensitivity and which ingredients they must avoid so that other food handlers are aware.

4. Preparing a Food Order

a) Thoroughly clean all areas and equipment that will be used for preparing the allergic consumer's meal, even if those areas had already been cleaned for normal use.

b) Wash hands thoroughly before preparing the allergic consumer's meal. It is necessary to change apron/chef coat, if previously soiled with potential allergens.

c) Use dedicated equipment or physically separate products to prevent cross-contact.

   i. Use color-coded or specially marked supplies, uniforms, equipment, and utensils designated for preparing allergen-free meals.

   ii. Avoid using the same cooking medium (e.g., oil or water) and surface (e.g., grill, prep table) when handling ingredients with and without allergens.

d) Use ingredients that do not contain the allergen(s) to which the consumer is allergic. Check ingredient labels for packaged foods.

e) Prepare food in a manner that eliminates cross-contact. All preparation, including garnishes, should be done by only one food handler who is dedicated to ensuring the meal is allergen-free, and who is not preparing other consumers' meals at the same time.

   i. If a mistake is made, and an ingredient to which the consumer is allergic is accidentally included in the meal, it is not sufficient to simply remove the offending ingredient, because cross-contact will have occurred. In case this happens, re-make the consumer's meal.

   ii. Wash your hands with soap and water before continuing preparation to avoid potential, or additional, cross-contact.

f) Cover the meal with a clean lid to prevent cross-contact and mark the meal as "allergy" so other staff are aware.

g) Notify the PIC, or designated food handler once the allergen-free meal is prepared and ready for service.

h) Wash, rinse, and store special equipment for allergen-free meals to be ready for next use.

i) Wash your hands with soap and water before touching anything else if you have handled a food allergen.

5. Delivering a Food Order

a) Verify with the food handler who prepared the meal that it does not contain the allergen specified by the consumer.

b) Ensure no cross-contact with other meals occurs during transport of the meal to the consumer.

c) Use a separate meal tray to deliver the meal.

d) VERIFY with the consumer that the meal meets their needs.

e) Discard the meal and offer to re-make it for the consumer if the meal contains ingredients to which the consumer is allergic. Notify the PIC. Review procedures and retrain the food handler(s) who prepared and handled the meal on these procedures before allowing them to re-make the consumer's meal.

6. If someone reports an allergic reaction

*** When in doubt, call 911 ***

a) Clearly direct one person to dial 911 and report an allergic reaction.

b) Follow the directions of emergency services personnel and the food establishment's food allergy emergency response plan.

With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME **Committee for the Evaluation of Intended Use Hazards during Retail Meat Grinding**

DATE OF FINAL REPORT: *12/5/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☐ ***Council II*** ☒ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Hilary Thesmar, FMI and Ellen Shumaker, NCSU

COMMITTEE CHARGE(S):

Issue # 2020 III-015

1. Evaluate prior developed 'CFP Beef Grinding Log Template Guidance Document' to consider inclusion of information for the prevention of common hazards known to be associated with grinding processes:
   A.) "Intended Use" policy, purpose, and control measures including supply chain communication.
   B.) Examples of common control measures, such as supplier guarantees or certificates of analysis and ongoing verification;
   C.) Reference to FSIS guideline for minimizing STEC in Raw Beef Processing Operations (https://www.fsis.usda.gov/guidelines/2021-0007)
2. Consider developing educational materials (e.g., handout(s) to support grinding log assessment by regulatory authorities, industry personnel, and the public. Examples may include:
   A.) Educational fact sheets detailing hazards represented by the non-intact handling of beef intended for whole intact use;
   B.) Plain language explanations of "Intended Use" policy purpose.
3. Evaluating potential changes to the Food Code to address the hazards associated with establishments grinding of beef that is manufactured as "Intended for Intact Use".
4. Determining appropriate mechanisms for sharing the committee's work, and
5. Reporting progress back to the next Biennial Meeting in 2023 and the committee's findings and recommendations may be presented at the subsequent Biennial Meeting if necessary.

COMMITTEE WORK PLAN AND TIMELINE:

The committee was established in October 2021 and began work on the charges in early November 2021. The committee completed charge 1 and began work on charges 2 and 3.

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

1. ***Overview of committee activities:***

   The committee held calls via MS Teams every two weeks. Calls dates were 11/2/2021, 11/16/2021, 11/30/2021, 12/14/2021, 1/11/2022, 1/25/2022, 2/8/2022, 2/22/2022, 3/8/2022, 3/22/2022, 4/5/2022, 4/19/2022, 5/3/2022, 5/17/2022, 5/31/2022, 6/14/2022, 6/28/2022, 7/19/2022, 8/23/2022, 9/6/2022.

2. ***Charges COMPLETED and the rationale for each specific recommendation:***
   a. Charge 1- Guidance document was created and is complete
   b. Charge 2 – The committee considered developing educational material and determined that the committee lacked the qualifications and experience to develop educational materials. The committee had expertise in food safety management and mitigation of risk. The committee focused on the guidance document and encouraged food safety education experts to draft educational material based on the content in the guidance document.
   c. Charge 3 – The committee spent considerable time contemplating potential food code language changes and determined that the FDA Food Code Annex 2 section K is the appropriate location for the guidance document and to provide resources for regulatory officials and the industry. Recommending language in the Food Code was contemplated and many committee members expressed concern about the confusion with multiple agencies having regulatory authority as well as concerns about local and state resources to train regulatory officials appropriately. For all of these

reasons, the committee agreed that the FDA Food Code Annex 2 section K is the appropriate place for the reference to the guidance document.

d. Charge 4 – The committee recommends that the guidance document be posted on the CFP website for access by CFP stakeholders.
e. Charge 5 – Completed report and guidance document for CFP website

3. ***Charges INCOMPLETE and to be continued to next biennium:***

none

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***
☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

Issue #1: Report – Committee Name:
Committee for the Evaluation of Intended Use Hazards - Issue 1- Committee Report

a. **List of content documents submitted with this Issue:**

Report of the Committee for the Evaluation of Intended Use Hazards During Retail Meat Grinding

b. ***Committee Member Roster:***

☐ ***See attached revised roster PDF*** ☒ ***No changes to previously approved roster***
"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) ***Other content documents:***

Roster

List of supporting attachments: ☐ ***Not applicable***

(1) Committee Report
(2) Roster
(3) Guidance document created "Evaluation of Intended Use Hazards During Retail Meat Grinding"

Committee Issue #2:
Committee for the Evaluation of Intended Use Hazards - Issue #2– Approval of guidance "Evaluation of Intended Use Hazards During Retail Meat Grinding"

List of supporting attachments: ☐ ***Not applicable***

Guidance document created "Evaluation of Intended Use Hazards During Retail Meat Grinding"

Committee Issue #3:

Committee for the Evaluation of Intended Use Hazards -Issue #3 – Amend FDA Food Code Annex 2 to reference approved Guidance Document

List of supporting attachments: ☐ ***Not applicable***

Guidance document created "Evaluation of Intended Use Hazards During Retail Meat Grinding"

CFP Committee Membership Roster and Instructions

Committee for the Evaluation of Intended Use Hazards during Retail Meat Grinding

2022

Committee Name:									
Last Name	**First Name**	**Position (Chair, Member, etc.)**	**Voting Status**	**Constituency**	**Employer**	**City**	**State**	**Phone**	**Email**
Thesmar	Hilary	Chair		Industry	FMI	Arlington	VA		hthesmar@fmi.org
Shumaker	Ellen	Co-Chair		Academia	NCSU	Raleigh	NC		ellen_shumaker@ncsu.edu
Burgess	Victoria	Member	Yes	Industry	Pubix Super Markets, Inc	Boynton Beach	FL		Victoria.Burgess@Publix.com
Danos	Trista	Member	Yes	Industry	Whole Foods Markets	Austin	TX		trista.danos@wholefoods.com
English	Amber	Member	Yes	Regulatory - Local	Washoe County Health D	Reno	NV		aeenglish@washoecounty.us
Hess	Erich	Member	Yes	Industry	Jewel-Osco	Itasca	IL		erich.hess@jewelosco.com
Hofer	Vasanthi	Member	Yes	Regulatory - Local	MARICOPA COUNTY EN	Phoenix	AZ		vasanthi.hofer@maricopa.gov
Kendrick	Susan	Member	Yes	Regulatory - State	Oregon Department of Ag	Salem	OR		susan.kendrick@oda.oregon.gov
Mello	Wayne	Member	Yes	Industry	Ahold Delhaize/Retail Bu	Scarborough	ME		wayne.mello@retailbusinessservices.com
Otzenberger	Michael	Member	Yes	Regulatory- State	Wisconsin	Madison	WI		michael.otzelberger@wisconsin.gov
Pease	Robert	Member	Yes	Industry	HEB	San Antonio	TX		pease.robert@heb.com
Rivas	Rose	Member	Yes	Industry	Rivas	Pfafftown	NC		april@rivasranch.com
Moore	Veronica	FDA Consultant	No	Regulatory - Federal	FDA	College Park	MD		Veronica.Moore@fda.hhs.gov
Collaro	Thomas	USDA Consultant	No	Regulatory - Federal	USDA-FSIS	Washington	DC		Thomas.collaro@usda.gov
Barlow	Kristina	USDA Consultant	No	Regulatory - Federal	USDA-FSIS	Washington	DC		kristina.barlow@usda.gov
Beckett	John	alternate	No	Industry	Publix	Plantation	FL		john.beckett@publix.com
Hollingsworth	Jill	alternate	No	Industry	Ecolab	Winston Salem	NC		jill.hollingsworth@ecolab.com
Prince	Gale	alternate	No	Industry	SAGE Food Safety LLC	Cincinnati	OH		Gale@GalePrince.Com

Conference for Food Protection

Evaluation of Intended Use Hazards During Retail Meat Grinding
December 2022

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1. Charge of the Committee

Council III of the Conference for Food Protection (CFP) formed the Evaluation of Intended Use Hazards during Retail Meat Grinding committee with the directive to:

1.) Evaluate prior developed 'CFP Beef Grinding Log Template Guidance Document' to consider inclusion of information for the prevention of common hazards known to be associated with grinding processes

A.) "Intended Use" policy, purpose, and control measures including supply chain communication

B.) Examples of common control measures, such as supplier guarantees or certificates of analysis and ongoing verification

C.) Reference to FSIS guideline for minimizing STEC in Raw Beef Processing Operations (https://www.fsis.usda.gov/guidelines/2021-0007)

2.) Consider developing educational materials (e.g., handout(s) to support grinding log assessment by regulatory authorities, industry personnel, and the public. Examples may include:

A.) Educational fact sheets detailing hazards represented by the non-intact handling of beef intended for whole intact use

B.) Plain language explanations of “Intended Use” policy purpose.

3.) Evaluating potential changes to the Food Code to address the hazards associated with establishments grinding of beef that is manufactured as “Intended for Intact Use”.

4.) Determining appropriate mechanisms for sharing the committee's work, and

5.) Reporting progress back to the next Biennial Meeting in 2023 and the committee's findings and recommendations may be presented at the subsequent Biennial Meeting if necessary.

2. Introduction

This committee was charged with enhancing the Conference for Food Protection (CFP) "Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments"[1] to include information on how retail food establishments can prevent common hazards associated with beef grinding processes.

Shiga toxin-producing *Escherichia coli* (STEC) is estimated to cause 265,000 illnesses in the US annually, including 3,600 hospitalizations and thirty deaths. To date, at least four outbreaks have been associated with beef ground at retail that was not intended for grinding (e.g., trim from intact steaks or roasts, and "pull backs"). Inadequate grinding records and insufficient sanitation between source lots at retail have hindered public health investigators' ability to determine the ultimate source of the implicated beef.

After reviewing the 2014 CFP beef-grinding document, the United States Department of Agriculture, Food Safety Inspection Service (USDA, FSIS) guidance documents and beef supplier risk elimination program presentations, the committee proposes the following changes and additions to the guidance document including:

1. Definition of "Intended Use", its purpose and regulations,
2. Beef product examples in both categories (intended and not intended to be ground) and what risk is associated with each,
3. Recommended common control measures that can be done in a retail setting to reduce risk, such as supplier communication.

The Committee agreed that creating educational materials was out of the scope of the committee and should be created by experts in education based on the needs of their communities following the release of this guidance document.

This document is intended to be guidance for retail food establishments that grind beef and to assist with creating protocols and training materials for their establishments. The recommendations are not intended to replace, or otherwise serve as, the rules and regulations applicable to food establishments in any given federal, state, local or tribal jurisdiction. Please refer to the appropriate inspection authority in your jurisdiction for further guidance. Inspectors often have deep expertise and can assist with food safety management programs and compliance with existing regulations.

[1] CFP Beef Grinding Log Committee. "Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments". Conference for Food Protection. 2012-2014. Available from: http://www.foodprotect.org/guides-documents/cfp-beef-grinding-log-template-guidance-document/.

3. Definitions

Note – These definitions generally represent terms used in retail establishments. When multiple definitions are available from regulatory agencies applicable to retail establishments, references are provided.

Active Managerial Control
Active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.[2]

Batch/Set
An identified quantity of beef that is ground based on specific attributes, such as percent lean, which will all be labeled as the same product.

Bench Trim
Product derived from cattle not slaughtered at the establishment.[3] In retail establishments with meat cutting operations, bench trim is generated in store. (Retailers tend to use the terms bench trim and trim interchangeably)

Chub
Rolls of ground beef that have been packaged to keep air out.[4] Chubs come in a variety of packaged sizes.

Customer requested grinding
As a service to customers, retailers may offer grinding of a cut of beef selected by the customer from the service case or packaged product that was not originally intended to be ground. This product is subject to the recordkeeping requirements for ground beef.

Grind Cycle
The amount of ground beef (measured by quantity and/or time) for one **lot** of product as documented by complete sanitation cycles. A grind cycle may include multiple batches/sets within a sanitation cycle.

Ground Beef
Chopped fresh and/or frozen beef or veal with or without seasoning and without the addition of beef fat as such, will not contain more than 30% fat, and shall not contain added water, phosphates, binders, or extenders.[5]

[2] 2017 FDA Food Code Annex, page 551.
[3] FSIS Directive 10,010.1. Available from: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/10010.1.pdf
[4] "Ground Beef Packaging, What's the difference?" Meat Science Organization. 2017. Available from: https://meatscience.org/TheMeatWeEat/topics/fresh-meat/article/2017/04/26/ground-beef-packaging-what's-the-difference
[5] *9 CFR 319.15a*

Intact Meat
A cut of whole muscle(s) meat that has not undergone comminution, mechanical, tenderization, vacuum tumbling with solutions, or reconstruction, cubing or pounding.[6]

Intended Use
How the federal establishment (producer) intends the product to be safely consumed or if further processing or further controls are needed. *9 CFR 417.2(a)(2)* requires each establishment to identify the intended use or consumers of the finished product. The product's intended use may affect the **STEC** controls in place at both the shipping and receiving establishments. Establishments that purchase beef from slaughter establishments should be aware of the slaughter establishment's intended use for the specific products they receive. [7]

Lot
For the purposes of FSIS requirements in *9 CFR 320.1(b)(4),* a lot is defined as the amount of raw ground beef produced during particular dates and times, following clean-up and until the next clean-up, during which the same source materials are used.[8]

Lot code
Defined volume or timeframe of finished product.

Non-Intact
Non-intact beef products include: ground beef; chopped beef; flaked or, minced product; beef that is vacuum tumbled with solutions; beef that an establishment has mechanically tenderized by needling (including injecting with solutions), cubing, pounding devices (with or without marinade); beef that an establishment has reconstructed into formed entrees; beef with proteolytic enzymes applied; and diced beef less than ¾ inch (dial setting) in any one dimension on average.[9]

Mechanically tenderized (non-intact)
Manipulating meat by piercing with a set of needles, pins, blades or any mechanical device, which breaks up muscle fiber and tough connective tissue, to increase tenderness. This includes INJECTION, scoring, and processes which may be referred to as "blade tenderizing," "jaccarding," "pinning," or "needling."[10,11]

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[6] "Non-intact beef products". askUSDA. Available from: https://ask.usda.gov/s/article/Non-intact-beef-products
[7] "FSIS Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Processing Operations". 2021. Available from: https://www.fsis.usda.gov/guidelines/2021-0007
[8] *9 CFR 320.1(b)(4)(iii).*
[9] "FSIS Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Processing Operations". 2021. Available from: https://www.fsis.usda.gov/guidelines/2021-0007.
[10] U.S. Department of Health and Human Services, U.S. Food and Drug Administration. FDA Food Code. 2017 Available from: www.fda.gov/FoodCode.
[11] Federal Register Vol. 80, No. 95 Monday, May 18, 2015 (p. 28153-28172) Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products.

Primal cut
From FDA Food Code: A basic major cut into which carcasses and sides of meat are separated, such as a beef round, pork loin, lamb flank, or veal breast.[12]

From FSIS: Primal parts are the wholesale cuts of carcasses as customarily distributed to retailers. The round, flank, loin, rib, plate, brisket, chuck, and shank are primal parts of beef carcasses. Veal, mutton, and goat primal parts are the leg; flank, loin, rack, breast, and shoulder.[13] *(For the purpose of this document, only beef and veal are in scope.)*

Production Cycle
Consists of one or more **Grind Cycles.**

Production Log
Documents used to facilitate or supplement the recordkeeping requirement for ground beef. Some retailers find it helpful to maintain a production log that contains additional details on timing and products used to help with internal records. Production logs are not required in the FSIS regulation on recordkeeping, and do not take the place of the official records required by FSIS. See Appendix for a sample production log.

Pull backs
Retail packaged cuts, such as steaks or roasts, removed from the self- service refrigerated display cases and either reworked into smaller cuts, such as stew beef or cube steak, or ground product. “Pull-backs” can be ground separately but are sometimes co-mingled with in-store produced bench trim.

Recordkeeping requirements for beef (grinding log)
FSIS finalized a rule on December 21, 2015, requiring additional records be kept for establishments and retailers grinding beef. The rule is titled “Records to Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products.” [14]

Re-work
Changing the form of a meat or poultry cut by reprocessing it down into smaller pieces or transformed to a different product to maximize shelf life.

FDA Definition: Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.[15]

[12] U.S. Department of Health and Human Services, U.S. Food and Drug Administration. FDA Food Code. 2017.
[13] *9 CFR 316.9(b).*
[14] Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products. *Federal Register*.2015. Available from: https://www.federalregister.gov/documents/2015/12/21/2015-31795/records-to-be-kept-by-official-establishments-and-retail-stores-that-grind-raw-beef-products
[15] *21 CFR 117.3*.

Standard Operating Procedures (SOP)
Written procedures that an establishment develops and implements to prevent direct contamination or adulteration of product, internal protocols. [16]

Sanitation Standard Operating Procedures (SSOP)
Written procedures (specific to sanitation) that an establishment develops and implements to prevent direct contamination or adulteration of product, internal protocols. [17]

Subprimal cuts
The first division of a whole carcass is into primal cuts. The four major **primal cuts** into which beef is separated are chuck, loin, rib and round. All primal cuts may or may not be intended for use in ground products. **Primal cuts** are then divided into subprimal cuts. Examples of subprimal cuts of beef are the top round, whole tenderloin, and rib eye. Any subprimal cut may or may not be intended for use in ground products.[18]

STEC
FSIS uses the term STEC to refer to Shiga toxin-producing *Escherichia coli* (*E. coli*) O157:H7 and six non O157 serogroups O26, O45, O103, O111, O121, and O145 that are adulterants in raw non-intact beef and raw intact beef intended for non-intact use.[19]

Trim
Beef products produced from in-house source materials.[20] (Retailers tend to use the terms bench trim and trim interchangeably)

Vacuum packaged
Source product (**primal cuts**) packaged in vacuum packed bags from supplier are typically considered to be **intended for intact use**.

[16] FSIS Standard Operating Procedure Guide. *USDA*. Available from: https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/Sanitation-SOP-Guide.pdf
[17] FSIS Standard Operating Procedure Guide. *USDA.* Available from: https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/Sanitation-SOP-Guide.pdf
[18] "What are primal cuts?" AskUSDA. Available from: https://ask.usda.gov/s/article/What-are-the-primal-cuts
[19] "Expansion of FSIS Shiga Toxin-Producing Escherichia coli (STEC) Testing to Additional Raw Beef Products". Available from: https://www.fsis.usda.gov/node/2272
[20] FSIS Directive 10,010.1. available from: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/10010.1.pdf

4. Intended Use

Federally inspected beef suppliers (approved suppliers to retail food establishments) should determine the intended use of the products shipped including the determination if the product is meant to be safely consumed (following proper food handling practices) or if further processing or further controls are needed for the product to be safety consumed.

Through regulations specified in *9 CFR 417.2(a)(2),* FSIS requires each establishment (supplier) to identify the intended use or consumers of the finished product. The product's intended use may affect the STEC controls in place at both the shipping and receiving establishments. Intended use of beef products for use at retail should be known, communicated and considered when planning production of retail packaged products. The intended use for the purpose of this document is to facilitate the safe consumption of the beef product or to clarify if additional controls or treatment is needed.

STEC is not an adulterant on raw intact beef products, such as steaks and roasts, which are "intended" for intact consumer use. This is because STEC contamination would be limited to the exterior surfaces of intact beef products and, if these products remain intact, normal consumer cooking will destroy any STEC on the outer surfaces, even if the product is cooked to a rare or medium internal state. STEC is an adulterant in raw non-intact beef products (ground beef) and raw intact beef products intended for raw non-intact use because the same consumer cooking practice will not destroy any STEC that have been internalized by the non-intact processing. STEC is also considered an adulterant in products for which the intended use is not clearly defined or supported.[21]

USDA FSIS documentation in askFSIS states that regulated establishments (beef suppliers) should[22]:

- Identify the intended use of the product as per *9 CFR 417.2(a)(2).*
- Develop decision-making documents based on objective measures which identify the intended use of the product. A hazard analysis must be included with the documents and must be consistent with the establishment's assertion that the product in question is/is not for use in raw non-intact product.
- Have measures in place to restrict products that are for intact use only. Such measures may include letters to the purchasers, website postings, bill of lading communications, and a receipt of acknowledgement that the purchasers understand that this product is intended solely for intact use as described in detail by the posted askFSIS answer "Adequate Support for the Intended Use of Beef Primal and Subprimal Cuts".[23]

[21] "FSIS Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Processing Operations". Available from: https://www.fsis.usda.gov/guidelines/2021-0007
[22] "Adequate Support for the Intended Use of Beef Primal and Subprimal Cuts". AskUSDA. https://ask.usda.gov/s/article/Adequate-Support-for-the-Intended-Use-of-Beef-Primal-and-Subprimal-Cuts
[23] Supporting the supply of raw beef intended for intact use. AskUSDA. Available from: https://ask.usda.gov/s/article/Supporting

Some acceptable ways that the establishment can support that primal and subprimal cuts are intended for raw intact product include:

- The establishment communicates the intended use to the receiving establishment or facility by making the letter of intended use available on the producing establishment's company website and references the letter of intended use on bills of lading.
- The establishment receives letters of guarantee showing that all product is used in raw intact product only and maintains on-going communication with the receiving establishment or facility to verify that product is being processed as raw intact product only.
- The establishment has a contractual agreement with the receiving establishment or facility so the producing establishment has knowledge of the receiving establishment or facility's production process.[24]

Intended use should be considered when retailers are grinding primals, subprimals, purchased trim, boxed beef, or other components (e.g., mechanically separated beef or partially defatted beef fatty tissue) that are not accompanied by records of negative *E. coli* O157:H7 or other STEC test results.

Supplier labeling designating the intended use is not required. Therefore, retailers should work with their suppliers to be sure they understand how the supplier will communicate the intended use of beef products. There are various ways a supplier can communicate the intended use of beef to the retailer. Following are some examples:

- Direct communication with the supplier of raw beef products
- Receiving a letter identifying the intended use with each lot of product
- Contractual agreement with the supplying establishment
- Receiving a Certificate of Analysis (COA), testing results, or similar documentation showing the basis for the supplier’s designated intended use
- Documentation showing that the product has been tested and found to not contain *E. coli* O157:H7 or other STEC
- Other documents such as Bill of Lading or Letter of Guarantee
- Using a code or labeling to identify the intended use of the product

If the retailer is unclear on the intended use of a product, they should contact their supplier for further clarification.

[24] Adequate Support for the Intended Use of Beef Primal and Subprimal Cuts". AskUSDA. Available from: https://ask.usda.gov/s/article/Adequate-Support-for-the-Intended-Use-of-Beef-Primal-and-Subprimal-Cuts

5. Recordkeeping for Beef Ground at Retail

Existing regulations from FSIS require that all facilities grinding beef (including retail establishments) maintain records regarding the source materials and cleaning and sanitation practices. In a rule published in December 2015, FSIS specified the recordkeeping requirements in *9 CFR 320.1(b).*

Official establishments and retail stores are required to maintain records that fully disclose:

1. The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product;
2. All supplier lot numbers and production dates;
3. The names of the supplied materials, including beef components and any materials carried over from one production lot to the next;
4. The date and time each lot of raw ground beef product is produced; and
5. The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.

Records can be in any format but should be legible and accessible at all times. Records must be maintained for one year. When feasible, all retailers are encouraged to adopt electronic recordkeeping to collect and maintain this important data in a secure and usable format. Technology will facilitate accurate and timely tracebacks, although smaller retailers may find it challenging due to limited financial and human resources support to move to digital records. Retailers that adopt electronic recordkeeping should develop SOPs to address how to capture key grinding data for system issues or malfunction.

Template: Sample Recordkeeping Template for Grinding Beef

Retail Establishment Name: Store # **Retail Establishment Production Date**

Date and time of grind (required)	Manufacturer name of source material used for product produced (required)	Establishment number(s) of establishment providing source material (required)	Supplier lot #s, product code and/or pack date of source material used (required)	Date and time grinder and related Food Contact Surfaces cleaned and sanitized (required)	Comments	Information linking to the retail package (recommended)

6. Retail Practices, Risk Reduction, and Supplier Communications

Implementing retail practices and strategies for reducing risks in the retail meat department should be part of an Active Managerial Control program. Active Managerial Control is the purposeful incorporation of specific actions or procedures by management into the retail operations to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.

Beef Handling and Grinding Practices at Retail

A producer or supplier of beef cannot verify that all pathogens have been eliminated from raw beef. However, producers have procedures in place for handling, treating, and testing beef in accordance with a HACCP plan and under FSIS federal inspection oversight to minimize the risk of contamination. The risk control steps taken by a supplier are used to designate the intended use of the meat once that meat is in a retail facility.

The risks associated with beef at a retail establishment will depend on several factors including how the supplier intended the beef to be handled, processed, labeled, and sold at retail. When implementing retail practices, the risk should be considered based on product type and intended use.

All the practices in the following examples are permitted. Some of these practices are based on following the supplier's intended use designation for the product. Other retail practices may present additional risk because they are not in accordance with the supplier's intended use and these are designated as non-intended use practices.

1. Practices/Products Based on Intended Use

Beef products from a supplier that are intended to be consumed intact.

> Examples: Steaks, roasts, smaller cuts of beef such as stew beef or primals in vacuum packaging. It does not include meat that has been ground, comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded.
>
> Rationale: These products are least likely to have contamination. Contamination, if present, is on the cut surface only. These pieces of beef may have surface contamination, but the outside surfaces will receive sufficient heat treatment when cooked by the consumer to render them safe.

Beef products from a supplier that can be cut at the retail facility provided they retain an intact surface that will be heat-treated when cooked by the consumer.

> Examples: Primals, sub-primals, or large roasts that are cut into steaks or smaller pieces. It does not include meat that has been ground, comminuted, mechanically

tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded. Nothing has been done at retail to introduce pathogens into the interior of the meat and any contaminants will remain on an exterior surface.

Rationale: Contamination, if present, is on the cut surface only. These pieces of beef may have surface contamination, but the outside surfaces will receive sufficient heat treatment when cooked by the consumer to render them safe.

Beef that has been ground, comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded by the supplier. This is non-intact meat which the supplier intended to be consumed in this form.

Examples: Beef ground by the supplier (may be pre-packed or bulk), cubed steaks, mechanically tenderized steaks. In all these examples, the meat was converted into non-intact beef by the supplier.

Rationale: Although this meat is not intact, the supplier has taken additional steps for handling, treating, and testing this beef in accordance with a HACCP plan and under FSIS federal inspection oversight to minimize the risk of STEC contamination.

Beef that has been ground or comminuted by the supplier but will be re-ground at the retail establishment. This is non-intact meat which the supplier intended to be consumed in this form.

Examples: Large chubs or containers of ground beef or coarse ground beef that will be re-ground at the retail facility.

Rationale: The supplier has already converted this beef into non-intact product. The supplier has taken additional steps for handling, treating, and testing this beef in accordance with a HACCP plan and under FSIS federal inspection oversight to minimize the risk of STEC contamination.

Beef trimmings from the supplier that are intended to be ground at retail. This meat will be converted into non-intact beef at retail.

Examples: Combo bins of trimmings, fat, and other small pieces of beef intended by the supplier to be ground at retail.

Rationale: The supplier has taken additional steps for handling, treating, and testing this beef in accordance with a HACCP plan and under FSIS federal inspection oversight to minimize the risk of STEC contamination.

2. Practices Not Based on Intended Use

Non-intended use practices may require additional controls to help mitigate risk of cross contamination if STEC is present on the exterior portion of the beef prior to grinding. Although the controls will help mitigate cross contamination, they will not address the risk of STEC in the product. Examples of non-intended use include the following:

Beef that is intact and which the supplier did not intend to be ground at retail. Intact beef that is not intended by the supplier to be comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded at the retail establishment.

> Examples: Converting store-generated trim (bench trim, market trim, case trim, block trim), re-work, pull-backs, and customer orders into ground beef. Cubing steaks or needle tenderizing beef at the retail facility.
>
> Rationale: Although suppliers have procedures in place for handling, treating, and testing beef in accordance with a HACCP plan and under FSIS federal inspection, this product did not receive any additional treatment or testing to further reduce the risk of STEC contamination. The supplier did not intend for this meat to be converted into non-intact beef at retail.

Controls to Reduce Risk at Retail

There are steps that can be taken at retail to help reduce the risks of contamination of beef. These include developing a written beef grinding protocol that specifies, at a minimum, segregation, separation, grinding practices, lotting, recordkeeping, and labeling.

Retail practices may include:

- Grinding product in small batches to reduce co-mingling of different products
- Labeling products with different source materials to ensure proper identification
- Maintaining complete and accurate production logs and grinding logs
- Segregating products based on designation of intended use
- Establishing consistent grinding sequence (Examples: from intact to non-intact; from most lean to higher fat content)
- Separating production cycles based on type of products or species
- Designating shelf life and/or use by date
- Sourcing meat from approved suppliers following all FSIS regulations

Additional good retail practices include:

- Rotate supply first-in first-out and pay attention to dates.
- Avoid mixing species unless intentional and clearly labeled. Clean and sanitize equipment between species.
- All food contact surfaces should be cleaned and sanitized before use.
- All products should be held at proper temperatures.

- Properly label all products with source, date, time and other required information.
- Avoid mixing multiple products from different suppliers because it makes the recordkeeping and traceback difficult.
- Control other hazards including foreign material.
- Develop a written cleaning and sanitizing program.

The control program should address the cleaning and sanitizing of food contact surfaces, equipment, utensils, implements, and the meat processing areas including frequency of cleaning, cleaning/sanitizing chemicals and tools that will be used. The time of each cleaning and sanitizing should be documented in the recordkeeping system for beef ground at retail. Training is recommended for all employees with responsibilities for cleaning and sanitizing.

Refer to the FDA Food Code and your state, local, tribal or territory requirements for cleaning and sanitation best practices. Section 4-602.11 of the FDA Food Code states that all food contact surfaces shall be cleaned at least every four hours. The food code provides for cleaning less frequently than every four hours if the utensils and equipment are held in a refrigerated room and cleaned according to the frequencies provided in the food code. (See *2017 FDA Food Code* Section 4-602.11)

Temperature	Cleaning Frequency
5.0°C (41°F) or less	24 hours
>5.0°C -7.2°C (>41°F -45°F)	20 hours
>7.2°C -10.0°C (>45°F -50°F)	16 hours
>10.0°C -12.8°C (>50°F -55°F)	10 hours

Breaks in the grinding cycle

When grinding beef, intentional breaks in the grinding cycle are critical and should not be overlooked. A break in the grinding cycle is a combination of a complete cleaning and sanitizing step in conjunction with no carryover of product. Breaks should be used to separate lots, batches, or cycles of product to reduce the risk of cross-contamination. Breaks in the production of ground beef can be the difference between needing to recall product from only part of a day or all product produced over several days. The day and time of all cleaning and sanitizing breaks in the cycle should be documented and included as part of the grinding log.

Employee Training and Personal Health and Hygiene

Proper training of all employees with access to food production, storage, and packaging areas is essential. Only properly trained employees should be allowed in designated areas.

The Food Code and/or state and local regulations have guidelines for employee health and hygiene including illness procedures and policies for hand washing, proper clothing, coverings, hair restraints, gloves, etc. Local, state, and federal regulations should be followed at all times.

Retailers should develop specific training programs for the employees, certified food protection manager (CFPM), and person in charge (PIC) specific to working in the meat department. This includes grinding practices and protocols along with collecting, recording, and maintaining grind log data during their daily job duties.

Lotting at Retail

The package of beef produced at retail must be linked to the lot code(s) of the product from which it was made, i.e., the source product. The retail-ground lot should have a supportable definition and should link the packaged product to the source material.

Official establishments and retail stores are to define a lot of raw ground beef product as the amount of raw ground beef produced during particular dates and times, following clean-up and until the next clean-up, during which the same source materials are used. This ground beef recordkeeping lot definition is distinct from the STEC lot definition used by official establishments; the establishment lot may not be the same as retailer lot.)

The practices above also apply to product that is comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded at retail.

Communication with Suppliers

It is important that retailers understand how a supplier indicates the intended use of beef products. Suppliers should provide information on the intended use so retailers can assess the risk associated with grinding different types of beef products.

Intended use should be considered when retailers are grinding primals, sub-primals, purchased trim, boxed beef, or other components (e.g., mechanically separated beef or partially defatted beef fatty tissue).

Supplier labeling designating the intended use is not required. Therefore, retailers should work with their suppliers to be sure they understand how the supplier will communicate the intended use of beef products. There are various ways a supplier can communicate the intended use of beef to the retailer. Following are some examples:

- Direct communication with the supplier of raw beef products
- Receiving a letter identifying the intended use with each lot of product
- Contractual agreement with the supplying establishment
- Receiving a Certificate of Analysis (COA), testing results, or similar documentation showing the basis for the supplier's designated intended use
- Documentation showing that the product has been tested and found to not contain *E.coli* O157:H7 or other STEC
- Other documents such as Bill of Lading or Letter of Guarantee
- Using a code or labeling to identify the intended use of the product

7. Regulatory Requirements

Procedures outlined in this document are based on well-established food safety principles and set forth as guidance for planning and conducting safe grinding activities at retail. The use of this guidance is voluntary, and it is not a regulatory document. Retail food establishments that participate in beef grinding should operate in accordance with any applicable federal, state, and local food safety statutes and regulations. For example, retail food establishments conducting grinding activities may also be subject to the FDA Food Safety Modernization Act (FSMA) as well as applicable Current Good Manufacturing Practices (CGMPs) or USDA Food Safety Inspection Service's (FSIS) requirements. It is important that retail food establishments understand all legal and regulatory requirements, as well as industry guidelines, governing the safety of food throughout the grinding process

State, territorial, and local establishments with regulations modeled after the FDA model Food Code should include the following in their operations:

1. Presence of a Certified Food Protection Manager (U. S. Food and Drug Administration, § 2-102.12(A))
2. Compliance with Food Law (Approved Source) (U. S. Food and Drug Administration, §3-201.11(A))
3. Compliance with Food Law (Safe Handling Instructions) (U. S. Food and Drug Administration, §3-201.11(F))
4. Packaged and Unpackaged Food-Separation, Packaging, and Segregation (Food Storage) (U. S. Food and Drug Administration, §3-302.11)
5. Equipment Food-Contact Surfaces and Utensils. (Cleaning Frequency) (U. S. Food and Drug Administration, §4-602.11)
6. Employee Health (U. S. Food and Drug Administration, Subpart 2-201)
7. Hygienic Practices (U. S. Food and Drug Administration, Part 2-4)

It is strongly recommended that establishments focus on the following:

1. Establishing active managerial control, including developing policies, training staff, and maintaining detailed logs/records.
2. Understanding the concerns associated with using beef that is not intended for grinding.
3. Understanding the importance of having a clean break in the production cycle.

8. Other Resources and References

“Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments” CFP 2014
http://www.foodprotect.org/guides-documents/cfp-beef-grinding-log-template-guidance-document/

“Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations” FSIS 2021
https://www.fsis.usda.gov/guidelines/2021-0007

“FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations” FSIS 2021
https://www.fsis.usda.gov/guidelines/2021-0007

“Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products” Federal Register Vol. 80, No. 244 Monday, December 21, 2015 (p. 79231-79250)
https://www.govinfo.gov/content/pkg/FR-2015-12-21/pdf/2015-31795.pdf

“Best Practices for Raw Ground Beef Products” BIFSCo 2020
https://www.bifsco.org/Media/BIFSCO/Docs/bp_for_raw_ground_products_final_2020.pdf

9. Appendices

Appendix 1 - Production logs and additional records

A Beef Grinding Log may be used in conjunction with a company's beef production log (or cutting list) log. Production logs are used by retailers to project and produce specific types and amounts of steaks and roasts needed in a production cycle. A fall-out benefit of a production log is that they collect the source material of any bench trim that may have been produced by the retailer while fabricating steaks and roasts for the refrigerated display case. For those retailers grinding bench trim, this becomes the easiest way to collect the necessary data. Production logs or cutting lists will need to contain the supplier establishment number, manufacturer's name of the primal, and pack date and lot or serial number of the primal. (Note: Beef packers will reuse lot and serial numbers. However, documenting *both* the lot or serial number and pack date or use by date for a source material would make the lot or serial number unique.) Retailers will then need to file together both the production log and grind log for record keeping. The *Sample Primal Production Log for Retail Food Establishments below* shows the pertinent information that must be tracked on a production log if an establishment is grinding in-store produced bench trim and/or pull back material.

Completed grinding records must be maintained for a minimum of one year[25]. All such records should be accessible within 24 hours and are required to be maintained at the location where the raw beef was ground.

Production Log for Trim
Sample Primal Production Log for Retail Food Establishments

Examples for use include customer requested grinds and pull backs

Store Location: Store #55			**Production Date**: 08/04/2022	
Primal Product Name as Listed on the Box	**Vendor/Supplier Name**	**Establishment #**	**Lot Number**	**Pack Date**
BEEF KNUCKLE	Swift	3D	7846515	07/24/2022

*Note: This sample production log is being provided as an example to visually provide the pertinent information that must be tracked (in addition to a beef grinding log) if an establishment is grinding in-store produced bench trim and/or pull back material. This document must not be misconstrued to prohibit an establishment from keeping this information in a different manner or format.

[25] 9 CFR 320.1(b)4

Appendix 2 - Required and recommended information for records

Required Recordkeeping (9 CFR 320.1(b)	Recommended data elements for records
	Retail Establishment Name
	Supplier Name
(A) The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product;	Establishment Number(s) of Beef Supplier
(B) All supplier lot numbers and production dates;	Lot Number of product ground Pack Date of product ground
(C) The names of the supplied materials, including beef components and any materials carried over from one production lot to the next;	Common Name of Primal
	Common name of product made
(D) The date and time each lot of raw ground beef product is produced; and	Date and time of grind
(E) The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.	Date and time for cleaning and sanitation of grinding equipment
	Link to package label created by retailer

Appendix 3 - Examples of language for intended use from beef suppliers

Suppliers typically provided intended use information in letters of guarantee (LOG) or other information posted on their websites. The following are examples of LOG from beef suppliers:

https://www.cargill.com/doc/1432077201913/mfs-subprimal-fsis-mt65-ltr-pdf.pdf

https://pacfoods.com/wp-content/uploads/2021/02/JBS-Beef-Food-Safety-Letter-01.04.21.pdf

Disclaimer: These letters should not be considered an endorsement of any particular supplier or company.

10. Acknowledgements

Multiple CFP members, volunteers and external experts participated in the development of this document.

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Conference for Food Protection

Evaluation of Intended Use Hazards During Retail Meat Grinding
December 2022

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1. Charge of the Committee

Council III of the Conference for Food Protection (CFP) formed the Evaluation of Intended Use Hazards during Retail Meat Grinding committee with the directive to:

1.) Evaluate prior developed 'CFP Beef Grinding Log Template Guidance Document' to consider inclusion of information for the prevention of common hazards known to be associated with grinding processes

A.) "Intended Use" policy, purpose, and control measures including supply chain communication

B.) Examples of common control measures, such as supplier guarantees or certificates of analysis and ongoing verification

C.) Reference to FSIS guideline for minimizing STEC in Raw Beef Processing Operations (https://www.fsis.usda.gov/guidelines/2021-0007)

2.) Consider developing educational materials (e.g., handout(s) to support grinding log assessment by regulatory authorities, industry personnel, and the public. Examples may include:

A.) Educational fact sheets detailing hazards represented by the non-intact handling of beef intended for whole intact use

B.) Plain language explanations of “Intended Use” policy purpose.

3.) Evaluating potential changes to the Food Code to address the hazards associated with establishments grinding of beef that is manufactured as “Intended for Intact Use”.

4.) Determining appropriate mechanisms for sharing the committee's work, and

5.) Reporting progress back to the next Biennial Meeting in 2023 and the committee's findings and recommendations may be presented at the subsequent Biennial Meeting if necessary.

2. Introduction

This committee was charged with enhancing the Conference for Food Protection (CFP) "Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments"[1] to include information on how retail food establishments can prevent common hazards associated with beef grinding processes.

Shiga toxin-producing *Escherichia coli* (STEC) is estimated to cause 265,000 illnesses in the US annually, including 3,600 hospitalizations and thirty deaths. To date, at least four outbreaks have been associated with beef ground at retail that was not intended for grinding (e.g., trim from intact steaks or roasts, and "pull backs"). Inadequate grinding records and insufficient sanitation between source lots at retail have hindered public health investigators' ability to determine the ultimate source of the implicated beef.

After reviewing the 2014 CFP beef-grinding document, the United States Department of Agriculture, Food Safety Inspection Service (USDA, FSIS) guidance documents and beef supplier risk elimination program presentations, the committee proposes the following changes and additions to the guidance document including:

1. Definition of "Intended Use", its purpose and regulations,
2. Beef product examples in both categories (intended and not intended to be ground) and what risk is associated with each,
3. Recommended common control measures that can be done in a retail setting to reduce risk, such as supplier communication.

The Committee agreed that creating educational materials was out of the scope of the committee and should be created by experts in education based on the needs of their communities following the release of this guidance document.

This document is intended to be guidance for retail food establishments that grind beef and to assist with creating protocols and training materials for their establishments. The recommendations are not intended to replace, or otherwise serve as, the rules and regulations applicable to food establishments in any given federal, state, local or tribal jurisdiction. Please refer to the appropriate inspection authority in your jurisdiction for further guidance. Inspectors often have deep expertise and can assist with food safety management programs and compliance with existing regulations.

1 CFP Beef Grinding Log Committee. "Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments". Conference for Food Protection. 2012-2014. Available from: http://www.foodprotect.org/guides-documents/cfp-beef-grinding-log-template-guidance-document/.

3. Definitions

Note – These definitions generally represent terms used in retail establishments. When multiple definitions are available from regulatory agencies applicable to retail establishments, references are provided.

Active Managerial Control
Active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.[2]

Batch/Set
An identified quantity of beef that is ground based on specific attributes, such as percent lean, which will all be labeled as the same product.

Bench Trim
Product derived from cattle not slaughtered at the establishment.[3] In retail establishments with meat cutting operations, bench trim is generated in store. (Retailers tend to use the terms bench trim and trim interchangeably)

Chub
Rolls of ground beef that have been packaged to keep air out.[4] Chubs come in a variety of packaged sizes.

Customer requested grinding
As a service to customers, retailers may offer grinding of a cut of beef selected by the customer from the service case or packaged product that was not originally intended to be ground. This product is subject to the recordkeeping requirements for ground beef.

Grind Cycle
The amount of ground beef (measured by quantity and/or time) for one **lot** of product as documented by complete sanitation cycles. A grind cycle may include multiple batches/sets within a sanitation cycle.

Ground Beef

2 2017 FDA Food Code Annex, page 551.
3 FSIS Directive 10,010.1. Available from: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/10010.1.pdf
4 "Ground Beef Packaging, What's the difference?" Meat Science Organization. 2017. Available from: https://meatscience.org/TheMeatWeEat/topics/fresh-meat/article/2017/04/26/ground-beef-packaging-what's-the-difference

Chopped fresh and/or frozen beef or veal with or without seasoning and without the addition of beef fat as such, will not contain more than 30% fat, and shall not contain added water, phosphates, binders, or extenders.[5]

Intact Meat
A cut of whole muscle(s) meat that has not undergone comminution, mechanical, tenderization, vacuum tumbling with solutions, or reconstruction, cubing or pounding.[6]

Intended Use
How the federal establishment (producer) intends the product to be safely consumed or if further processing or further controls are needed. *9 CFR 417.2(a)(2)* requires each establishment to identify the intended use or consumers of the finished product. The product's intended use may affect the **STEC** controls in place at both the shipping and receiving establishments. Establishments that purchase beef from slaughter establishments should be aware of the slaughter establishment's intended use for the specific products they receive. [7]

Lot
For the purposes of FSIS requirements in *9 CFR 320.1(b)(4),* a lot is defined as the amount of raw ground beef produced during particular dates and times, following clean-up and until the next clean-up, during which the same source materials are used.[8]

Lot code
Defined volume or timeframe of finished product.

Non-Intact
Non-intact beef products include: ground beef; chopped beef; flaked or, minced product; beef that is vacuum tumbled with solutions; beef that an establishment has mechanically tenderized by needling (including injecting with solutions), cubing, pounding devices (with or without marinade); beef that an establishment has reconstructed into formed entrees; beef with proteolytic enzymes applied; and diced beef less than ¾ inch (dial setting) in any one dimension on average.[9]

Mechanically tenderized (non-intact)
Manipulating meat by piercing with a set of needles, pins, blades or any mechanical device, which breaks up muscle fiber and tough connective tissue, to increase tenderness.

5 *9 CFR 319.15a*
6 "Non-intact beef products". askUSDA. Available from: https://ask.usda.gov/s/article/Non-intact-beef-products
7 "FSIS Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Processing Operations". 2021. Available from: https://www.fsis.usda.gov/guidelines/2021-0007
8 *9 CFR 320.1(b)(4)(iii).*
9 "FSIS Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Processing Operations". 2021. Available from: https://www.fsis.usda.gov/guidelines/2021-0007.

This includes INJECTION, scoring, and processes which may be referred to as “blade tenderizing,” “jaccarding,” “pinning,” or “needling.”[10,11]

Primal cut
From FDA Food Code: A basic major cut into which carcasses and sides of meat are separated, such as a beef round, pork loin, lamb flank, or veal breast.[12]

From FSIS: Primal parts are the wholesale cuts of carcasses as customarily distributed to retailers. The round, flank, loin, rib, plate, brisket, chuck, and shank are primal parts of beef carcasses. Veal, mutton, and goat primal parts are the leg; flank, loin, rack, breast, and shoulder.[13] *(For the purpose of this document, only beef and veal are in scope.)*

Production Cycle
Consists of one or more **Grind Cycles.**

Production Log
Documents used to facilitate or supplement the recordkeeping requirement for ground beef. Some retailers find it helpful to maintain a production log that contains additional details on timing and products used to help with internal records. Production logs are not required in the FSIS regulation on recordkeeping, and do not take the place of the official records required by FSIS. See Appendix for a sample production log.

Pull backs
Retail packaged cuts, such as steaks or roasts, removed from the self- service refrigerated display cases and either reworked into smaller cuts, such as stew beef or cube steak, or ground product. “Pull-backs” can be ground separately but are sometimes co-mingled with in-store produced bench trim.

Recordkeeping requirements for beef (grinding log)
FSIS finalized a rule on December 21, 2015, requiring additional records be kept for establishments and retailers grinding beef. The rule is titled “Records to Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products.” [14]

Re-work

10 U.S. Department of Health and Human Services, U.S. Food and Drug Administration. FDA Food Code. 2017 Available from: www.fda.gov/FoodCode.

11 Federal Register Vol. 80, No. 95 Monday, May 18, 2015 (p. 28153-28172) Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products.

12 U.S. Department of Health and Human Services, U.S. Food and Drug Administration. FDA Food Code. 2017.

13 *9 CFR 316.9(b).*

14 Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products. *Federal Register.*2015. Available from: https://www.federalregister.gov/documents/2015/12/21/2015-31795/records-to-be-kept-by-official-establishments-and-retail-stores-that-grind-raw-beef-products

Changing the form of a meat or poultry cut by reprocessing it down into smaller pieces or transformed to a different product to maximize shelf life.

FDA Definition: Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.[15]

Standard Operating Procedures (SOP)
Written procedures that an establishment develops and implements to prevent direct contamination or adulteration of product, internal protocols. [16]

Sanitation Standard Operating Procedures (SSOP)
Written procedures (specific to sanitation) that an establishment develops and implements to prevent direct contamination or adulteration of product, internal protocols. [17]

Subprimal cuts
The first division of a whole carcass is into primal cuts. The four major **primal cuts** into which beef is separated are chuck, loin, rib and round. All primal cuts may or may not be intended for use in ground products. **Primal cuts** are then divided into subprimal cuts. Examples of subprimal cuts of beef are the top round, whole tenderloin, and rib eye. Any subprimal cut may or may not be intended for use in ground products.[18]

STEC
FSIS uses the term STEC to refer to Shiga toxin-producing *Escherichia coli* (*E. coli*) O157:H7 and six non O157 serogroups O26, O45, O103, O111, O121, and O145 that are adulterants in raw non-intact beef and raw intact beef intended for non-intact use.[19]

Trim
Beef products produced from in-house source materials.[20] (Retailers tend to use the terms bench trim and trim interchangeably)

Vacuum packaged

15 *21 CFR 117.3*.
16 FSIS Standard Operating Procedure Guide. *USDA*. Available from: https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/Sanitation-SOP-Guide.pdf
17 FSIS Standard Operating Procedure Guide. *USDA*. Available from: https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/Sanitation-SOP-Guide.pdf
18 "What are primal cuts?" AskUSDA. Available from: https://ask.usda.gov/s/article/What-are-the-primal-cuts
19 "Expansion of FSIS Shiga Toxin-Producing Escherichia coli (STEC) Testing to Additional Raw Beef Products". Available from: https://www.fsis.usda.gov/node/2272
20 FSIS Directive 10,010.1. available from: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/10010.1.pdf

Source product (**primal cuts**) packaged in vacuum packed bags from supplier are typically considered to be **intended for intact use**.

4. Intended Use

Federally inspected beef suppliers (approved suppliers to retail food establishments) should determine the intended use of the products shipped including the determination if the product is meant to be safely consumed (following proper food handling practices) or if further processing or further controls are needed for the product to be safety consumed.

Through regulations specified in *9 CFR 417.2(a)(2),* FSIS requires each establishment (supplier) to identify the intended use or consumers of the finished product. The product's intended use may affect the STEC controls in place at both the shipping and receiving establishments. Intended use of beef products for use at retail should be known, communicated and considered when planning production of retail packaged products. The intended use for the purpose of this document is to facilitate the safe consumption of the beef product or to clarify if additional controls or treatment is needed.

STEC is not an adulterant on raw intact beef products, such as steaks and roasts, which are "intended" for intact consumer use. This is because STEC contamination would be limited to the exterior surfaces of intact beef products and, if these products remain intact, normal consumer cooking will destroy any STEC on the outer surfaces, even if the product is cooked to a rare or medium internal state. STEC is an adulterant in raw non-intact beef products (ground beef) and raw intact beef products intended for raw non-intact use because the same consumer cooking practice will not destroy any STEC that have been internalized by the non-intact processing. STEC is also considered an adulterant in products for which the intended use is not clearly defined or supported.[21]

USDA FSIS documentation in askFSIS states that regulated establishments (beef suppliers) should[22]:

- Identify the intended use of the product as per *9 CFR 417.2(a)(2).*
- Develop decision-making documents based on objective measures which identify the intended use of the product. A hazard analysis must be included with the documents and must be consistent with the establishment's assertion that the product in question is/is not for use in raw non-intact product.
- Have measures in place to restrict products that are for intact use only. Such measures may include letters to the purchasers, website postings, bill of lading communications, and a receipt of acknowledgement that the purchasers understand that this product is intended solely for intact use as described in detail

21 "FSIS Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Processing Operations". Available from: https://www.fsis.usda.gov/guidelines/2021-0007

22 "Adequate Support for the Intended Use of Beef Primal and Subprimal Cuts". AskUSDA. https://ask.usda.gov/s/article/Adequate-Support-for-the-Intended-Use-of-Beef-Primal-and-Subprimal-Cuts

by the posted askFSIS answer "Adequate Support for the Intended Use of Beef Primal and Subprimal Cuts".[23]

Some acceptable ways that the establishment can support that primal and subprimal cuts are intended for raw intact product include:

- The establishment communicates the intended use to the receiving establishment or facility by making the letter of intended use available on the producing establishment's company website and references the letter of intended use on bills of lading.
- The establishment receives letters of guarantee showing that all product is used in raw intact product only and maintains on-going communication with the receiving establishment or facility to verify that product is being processed as raw intact product only.
- The establishment has a contractual agreement with the receiving establishment or facility so the producing establishment has knowledge of the receiving establishment or facility's production process.[24]

Intended use should be considered when retailers are grinding primals, subprimals, purchased trim, boxed beef, or other components (e.g., mechanically separated beef or partially defatted beef fatty tissue) that are not accompanied by records of negative *E. coli* O157:H7 or other STEC test results.

Supplier labeling designating the intended use is not required. Therefore, retailers should work with their suppliers to be sure they understand how the supplier will communicate the intended use of beef products. There are various ways a supplier can communicate the intended use of beef to the retailer. Following are some examples:

- Direct communication with the supplier of raw beef products
- Receiving a letter identifying the intended use with each lot of product
- Contractual agreement with the supplying establishment
- Receiving a Certificate of Analysis (COA), testing results, or similar documentation showing the basis for the supplier's designated intended use
- Documentation showing that the product has been tested and found to not contain *E. coli* O157:H7 or other STEC
- Other documents such as Bill of Lading or Letter of Guarantee
- Using a code or labeling to identify the intended use of the product

If the retailer is unclear on the intended use of a product, they should contact their supplier for further clarification.

23 Supporting the supply of raw beef intended for intact use. AskUSDA. Available from: https://ask.usda.gov/s/article/Supporting

24 Adequate Support for the Intended Use of Beef Primal and Subprimal Cuts". AskUSDA. Available from: https://ask.usda.gov/s/article/Adequate-Support-for-the-Intended-Use-of-Beef-Primal-and-Subprimal-Cuts

5. Recordkeeping for Beef Ground at Retail

Existing regulations from FSIS require that all facilities grinding beef (including retail establishments) maintain records regarding the source materials and cleaning and sanitation practices. In a rule published in December 2015, FSIS specified the recordkeeping requirements in *9 CFR 320.1(b).*

Official establishments and retail stores are required to maintain records that fully disclose:

1. The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product;
2. All supplier lot numbers and production dates;
3. The names of the supplied materials, including beef components and any materials carried over from one production lot to the next;
4. The date and time each lot of raw ground beef product is produced; and
5. The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.

Records can be in any format but should be legible and accessible at all times. Records must be maintained for one year. When feasible, all retailers are encouraged to adopt electronic recordkeeping to collect and maintain this important data in a secure and usable format. Technology will facilitate accurate and timely tracebacks, although smaller retailers may find it challenging due to limited financial and human resources support to move to digital records. Retailers that adopt electronic recordkeeping should develop SOPs to address how to capture key grinding data for system issues or malfunction.

Template: Sample Recordkeeping Template for Grinding Beef

Retail Establishment Name: Store # **Retail Establishment Production Date**

Date and time of grind (required)	Manufacturer name of source material used for product produced (required)	Establishment number(s) of establishment providing source material (required)	Supplier lot #s, product code and/or pack date of source material used (required)	Date and time grinder and related Food Contact Surfaces cleaned and sanitized (required)	Comments	Information linking to the retail package (recommended)

6. Retail Practices, Risk Reduction, and Supplier Communications

Implementing retail practices and strategies for reducing risks in the retail meat department should be part of an Active Managerial Control program. Active Managerial Control is the purposeful incorporation of specific actions or procedures by management into the retail operations to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.

Beef Handling and Grinding Practices at Retail

A producer or supplier of beef cannot verify that all pathogens have been eliminated from raw beef. However, producers have procedures in place for handling, treating, and testing beef in accordance with a HACCP plan and under FSIS federal inspection oversight to minimize the risk of contamination. The risk control steps taken by a supplier are used to designate the intended use of the meat once that meat is in a retail facility.

The risks associated with beef at a retail establishment will depend on several factors including how the supplier intended the beef to be handled, processed, labeled, and sold at retail. When implementing retail practices, the risk should be considered based on product type and intended use.

All the practices in the following examples are permitted. Some of these practices are based on following the supplier's intended use designation for the product. Other retail practices may present additional risk because they are not in accordance with the supplier's intended use and these are designated as non-intended use practices.

1. **Practices/Products Based on Intended Use**

Beef products from a supplier that are intended to be consumed intact.

> Examples: Steaks, roasts, smaller cuts of beef such as stew beef or primals in vacuum packaging. It does not include meat that has been ground, comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded.
>
> Rationale: These products are least likely to have contamination. Contamination, if present, is on the cut surface only. These pieces of beef may have surface contamination, but the outside surfaces will receive sufficient heat treatment when cooked by the consumer to render them safe.

Beef products from a supplier that can be cut at the retail facility provided they retain an intact surface that will be heat-treated when cooked by the consumer.

Examples: Primals, sub-primals, or large roasts that are cut into steaks or smaller pieces. It does not include meat that has been ground, comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded. Nothing has been done at retail to introduce pathogens into the interior of the meat and any contaminants will remain on an exterior surface.

Rationale: Contamination, if present, is on the cut surface only. These pieces of beef may have surface contamination, but the outside surfaces will receive sufficient heat treatment when cooked by the consumer to render them safe.

Beef that has been ground, comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded by the supplier. This is non-intact meat which the supplier intended to be consumed in this form.

Examples: Beef ground by the supplier (may be pre-packed or bulk), cubed steaks, mechanically tenderized steaks. In all these examples, the meat was converted into non-intact beef by the supplier.

Rationale: Although this meat is not intact, the supplier has taken additional steps for handling, treating, and testing this beef in accordance with a HACCP plan and under FSIS federal inspection oversight to minimize the risk of STEC contamination.

Beef that has been ground or comminuted by the supplier but will be re-ground at the retail establishment. This is non-intact meat which the supplier intended to be consumed in this form.

Examples: Large chubs or containers of ground beef or coarse ground beef that will be re-ground at the retail facility.

Rationale: The supplier has already converted this beef into non-intact product. The supplier has taken additional steps for handling, treating, and testing this beef in accordance with a HACCP plan and under FSIS federal inspection oversight to minimize the risk of STEC contamination.

Beef trimmings from the supplier that are intended to be ground at retail. This meat will be converted into non-intact beef at retail.

Examples: Combo bins of trimmings, fat, and other small pieces of beef intended by the supplier to be ground at retail.

Rationale: The supplier has taken additional steps for handling, treating, and testing this beef in accordance with a HACCP plan and under FSIS federal inspection oversight to minimize the risk of STEC contamination.

2. Practices Not Based on Intended Use

Non-intended use practices may require additional controls to help mitigate risk of cross contamination if STEC is present on the exterior portion of the beef prior to grinding. Although the controls will help mitigate cross contamination, they will not address the risk of STEC in the product. Examples of non-intended use include the following:

Beef that is intact and which the supplier did not intend to be ground at retail. Intact beef that is not intended by the supplier to be comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded at the retail establishment.

> Examples: Converting store-generated trim (bench trim, market trim, case trim, block trim), re-work, pull-backs, and customer orders into ground beef. Cubing steaks or needle tenderizing beef at the retail facility.
>
> Rationale: Although suppliers have procedures in place for handling, treating, and testing beef in accordance with a HACCP plan and under FSIS federal inspection, this product did not receive any additional treatment or testing to further reduce the risk of STEC contamination. The supplier did not intend for this meat to be converted into non-intact beef at retail.

Controls to Reduce Risk at Retail

There are steps that can be taken at retail to help reduce the risks of contamination of beef. These include developing a written beef grinding protocol that specifies, at a minimum, segregation, separation, grinding practices, lotting, recordkeeping, and labeling.

Retail practices may include:

- Grinding product in small batches to reduce co-mingling of different products
- Labeling products with different source materials to ensure proper identification
- Maintaining complete and accurate production logs and grinding logs
- Segregating products based on designation of intended use
- Establishing consistent grinding sequence (Examples: from intact to non-intact; from most lean to higher fat content)
- Separating production cycles based on type of products or species
- Designating shelf life and/or use by date
- Sourcing meat from approved suppliers following all FSIS regulations

Additional good retail practices include:

- Rotate supply first-in first-out and pay attention to dates.
- Avoid mixing species unless intentional and clearly labeled. Clean and sanitize equipment between species.
- All food contact surfaces should be cleaned and sanitized before use.
- All products should be held at proper temperatures.
- Properly label all products with source, date, time and other required information.
- Avoid mixing multiple products from different suppliers because it makes the recordkeeping and traceback difficult.
- Control other hazards including foreign material.
- Develop a written cleaning and sanitizing program.

The control program should address the cleaning and sanitizing of food contact surfaces, equipment, utensils, implements, and the meat processing areas including frequency of cleaning, cleaning/sanitizing chemicals and tools that will be used. The time of each cleaning and sanitizing should be documented in the recordkeeping system for beef ground at retail. Training is recommended for all employees with responsibilities for cleaning and sanitizing.

Refer to the FDA Food Code and your state, local, tribal or territory requirements for cleaning and sanitation best practices. Section 4-602.11 of the FDA Food Code states that all food contact surfaces shall be cleaned at least every four hours. The food code provides for cleaning less frequently than every four hours if the utensils and equipment are held in a refrigerated room and cleaned according to the frequencies provided in the food code. (See *2017 FDA Food Code* Section 4-602.11)

Temperature	Cleaning Frequency
5.0°C (41°F) or less	24 hours
>5.0°C -7.2°C (>41°F -45°F)	20 hours
>7.2°C -10.0°C (>45°F -50°F)	16 hours
>10.0°C -12.8°C (>50°F -55°F)	10 hours

Breaks in the grinding cycle

When grinding beef, intentional breaks in the grinding cycle are critical and should not be overlooked. A break in the grinding cycle is a combination of a complete cleaning and sanitizing step in conjunction with no carryover of product. Breaks should be used to separate lots, batches, or cycles of product to reduce the risk of cross-contamination. Breaks in the production of ground beef can be the difference between needing to recall product from only part of a day or all product produced over several days. The day and time of all cleaning and sanitizing breaks in the cycle should be documented and included as part of the grinding log.

Employee Training and Personal Health and Hygiene

Proper training of all employees with access to food production, storage, and packaging areas is essential. Only properly trained employees should be allowed in designated areas.

The Food Code and/or state and local regulations have guidelines for employee health and hygiene including illness procedures and policies for hand washing, proper clothing, coverings, hair restraints, gloves, etc. Local, state, and federal regulations should be followed at all times.

Retailers should develop specific training programs for the employees, certified food protection manager (CFPM), and person in charge (PIC) specific to working in the meat department. This includes grinding practices and protocols along with collecting, recording, and maintaining grind log data during their daily job duties.

Lotting at Retail

The package of beef produced at retail must be linked to the lot code(s) of the product from which it was made, i.e., the source product. The retail-ground lot should have a supportable definition and should link the packaged product to the source material.

Official establishments and retail stores are to define a lot of raw ground beef product as the amount of raw ground beef produced during particular dates and times, following clean-up and until the next clean-up, during which the same source materials are used. This ground beef recordkeeping lot definition is distinct from the STEC lot definition used by official establishments; the establishment lot may not be the same as retailer lot.)

The practices above also apply to product that is comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded at retail.

Communication with Suppliers

It is important that retailers understand how a supplier indicates the intended use of beef products. Suppliers should provide information on the intended use so retailers can assess the risk associated with grinding different types of beef products.

Intended use should be considered when retailers are grinding primals, sub-primals, purchased trim, boxed beef, or other components (e.g., mechanically separated beef or partially defatted beef fatty tissue).

Supplier labeling designating the intended use is not required. Therefore, retailers should work with their suppliers to be sure they understand how the supplier will communicate the intended use of beef products. There are various ways a supplier can communicate the intended use of beef to the retailer. Following are some examples:

- Direct communication with the supplier of raw beef products
- Receiving a letter identifying the intended use with each lot of product
- Contractual agreement with the supplying establishment
- Receiving a Certificate of Analysis (COA), testing results, or similar documentation showing the basis for the supplier's designated intended use
- Documentation showing that the product has been tested and found to not contain *E.coli* O157:H7 or other STEC
- Other documents such as Bill of Lading or Letter of Guarantee
- Using a code or labeling to identify the intended use of the product

7. Regulatory Requirements

Procedures outlined in this document are based on well-established food safety principles and set forth as guidance for planning and conducting safe grinding activities at retail. The use of this guidance is voluntary, and it is not a regulatory document. Retail food establishments that participate in beef grinding should operate in accordance with any applicable federal, state, and local food safety statutes and regulations. For example, retail food establishments conducting grinding activities may also be subject to the FDA Food Safety Modernization Act (FSMA) as well as applicable Current Good Manufacturing Practices (CGMPs) or USDA Food Safety Inspection Service's (FSIS) requirements. It is important that retail food establishments understand all legal and regulatory requirements, as well as industry guidelines, governing the safety of food throughout the grinding process

State, territorial, and local establishments with regulations modeled after the FDA model Food Code should include the following in their operations:

1. Presence of a Certified Food Protection Manager (U. S. Food and Drug Administration, § 2-102.12(A))
2. Compliance with Food Law (Approved Source) (U. S. Food and Drug Administration, §3-201.11(A))
3. Compliance with Food Law (Safe Handling Instructions) (U. S. Food and Drug Administration, §3-201.11(F))
4. Packaged and Unpackaged Food-Separation, Packaging, and Segregation (Food Storage) (U. S. Food and Drug Administration, §3-302.11)
5. Equipment Food-Contact Surfaces and Utensils. (Cleaning Frequency) (U. S. Food and Drug Administration, §4-602.11)
6. Employee Health (U. S. Food and Drug Administration, Subpart 2-201)
7. Hygienic Practices (U. S. Food and Drug Administration, Part 2-4)

It is strongly recommended that establishments focus on the following:

1. Establishing active managerial control, including developing policies, training staff, and maintaining detailed logs/records.
2. Understanding the concerns associated with using beef that is not intended for grinding.
3. Understanding the importance of having a clean break in the production cycle.

8. Other Resources and References

"Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments" CFP 2014
http://www.foodprotect.org/guides-documents/cfp-beef-grinding-log-template-guidance-document/

"Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations" FSIS 2021
https://www.fsis.usda.gov/guidelines/2021-0007

"FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations" FSIS 2021
https://www.fsis.usda.gov/guidelines/2021-0007

"Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products" Federal Register Vol. 80, No. 244 Monday, December 21, 2015 (p. 79231-79250)
https://www.govinfo.gov/content/pkg/FR-2015-12-21/pdf/2015-31795.pdf

"Best Practices for Raw Ground Beef Products" BIFSCo 2020
https://www.bifsco.org/Media/BIFSCO/Docs/bp_for_raw_ground_products_final_2020.pdf

9. Appendices

Appendix 1 - Production logs and additional records

A Beef Grinding Log may be used in conjunction with a company's beef production log (or cutting list) log. Production logs are used by retailers to project and produce specific types and amounts of steaks and roasts needed in a production cycle. A fall-out benefit of a production log is that they collect the source material of any bench trim that may have been produced by the retailer while fabricating steaks and roasts for the refrigerated display case. For those retailers grinding bench trim, this becomes the easiest way to collect the necessary data. Production logs or cutting lists will need to contain the supplier establishment number, manufacturer's name of the primal, and pack date and lot or serial number of the primal. (Note: Beef packers will reuse lot and serial numbers. However, documenting *both* the lot or serial number and pack date or use by date for a source material would make the lot or serial number unique.) Retailers will then need to file together both the production log and grind log for record keeping. The *Sample Primal Production Log for Retail Food Establishments below* shows the pertinent information that must be tracked on a production log if an establishment is grinding in-store produced bench trim and/or pull back material.

Completed grinding records must be maintained for a minimum of one year[25]. All such records should be accessible within 24 hours and are required to be maintained at the location where the raw beef was ground.

Production Log for Trim
Sample Primal Production Log for Retail Food Establishments

Examples for use include customer requested grinds and pull backs

Store Location: Store #55			**Production Date**: 08/04/2022	
Primal Product Name as Listed on the Box	**Vendor/Supplier Name**	**Establishment #**	**Lot Number**	**Pack Date**
BEEF KNUCKLE	Swift	3D	7846515	07/24/2022

*Note: This sample production log is being provided as an example to visually provide the pertinent information that must be tracked (in addition to a beef grinding log) if an establishment is grinding in-store produced bench trim and/or pull back material. This

25 9 CFR 320.1(b)4

document must not be misconstrued to prohibit an establishment from keeping this information in a different manner or format.

Appendix 2 - Required and recommended information for records

Required Recordkeeping (9 CFR 320.1(b)	**Recommended data elements for records**
	Retail Establishment Name
	Supplier Name
(A) The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product;	Establishment Number(s) of Beef Supplier
(B) All supplier lot numbers and production dates;	Lot Number of product ground Pack Date of product ground
(C) The names of the supplied materials, including beef components and any materials carried over from one production lot to the next;	Common Name of Primal
	Common name of product made
(D) The date and time each lot of raw ground beef product is produced; and	Date and time of grind
(E) The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.	Date and time for cleaning and sanitation of grinding equipment
	Link to package label created by retailer

Appendix 3 - Examples of language for intended use from beef suppliers

Suppliers typically provided intended use information in letters of guarantee (LOG) or other information posted on their websites. The following are examples of LOG from beef suppliers:

https://www.cargill.com/doc/1432077201913/mfs-subprimal-fsis-mt65-ltr-pdf.pdf

https://pacfoods.com/wp-content/uploads/2021/02/JBS-Beef-Food-Safety-Letter-01.04.21.pdf

Disclaimer: These letters should not be considered an endorsement of any particular supplier or company.

10. Acknowledgements

Multiple CFP members, volunteers and external experts participated in the development of this document.

Sherri Trujillo, JBS and Mandy Carr Johnson, BIFSCo provided valuable information during the development of this document on industry practices and scientific insights related to grinding raw beef and risk management.

2021-2023 CFP Intended Use Committee

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Rossow, Todd	CFP Vice Chair
Schaffner, Donald	CFP Council III Chair
Manuel, Chip	CFP Council III Vice Chair

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COMMITTEE NAME Retail Sushi HACCP Standardization Committee Final Report

DATE OF FINAL REPORT: 11/10/2022

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☐ ***Council II*** ☒ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Veronica Bryant, Chair and Rupesh Modi, Vice Chair

COMMITTEE CHARGE(S):

Issue # 2020 III-017 stated that a Retail Sushi HACCP Standardization Committee be formed with the following charges:

1. Review current industry practices, collect available guidance documents, and current state codes pertaining to the production of sushi prepared at retail establishments.
2. Update the current CFP guidance document for production of sushi prepared at retail establishments.
3. Referencing the guidance document in the Food Code Annex, or wherever the committee deems appropriate.
4. Identifying whether the Food Code adequately addresses sushi production at retail as a whole and make suggestions for changes (if necessary) at the next CFP Biennial Conference.
5. Identifying the recommended methods to disseminate the committee's findings.
6. Reporting the committee's findings at the next CFP Biennial Conference

COMMITTEE WORK PLAN AND TIMELINE:

Initial Committee Meeting held November 10, 2021. Regular monthly meetings were held on the second Wednesday of each month

1. Work plan was discussed with full committee, decision was made to work on charges sequentially.
2. First charge was completed between November and December meetings.
3. Charge #2 to update guidance will take most of the time for the committee. Guidance document was discussed during December, January, and February meetings.
4. Committee has agreed to split topics to be covered in the guidance document among members and work in small groups to write sections of the documents and create infographics and decision trees.
5. Guidance document will be assembled with a target date of July 1.
6. Editing and review of the document will be completed with target date of August 1. Actual editing and review were not completed until September 14 meeting. Vote on the final version of the document was completed at the end of October via email vote.
7. Recommendations to the FDA from the committee were discussed and submitted via email vote.
8. The chair and co-chair will monitor attendance of voting and non-voting members and voting members of the full committee will vote to excuse members if unexcused absence of the voting member becomes a pattern.
9. Periodic reports will be submitted by March 1, 2022 and July 1, 2022 to the Council Chair.
10. Final guidance document to be submitted to Council Chairs by November 15, 2022.

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls: 11/10/21, 12/15/21, 1/12/22, 2/9/22, 3/9/22, 5/11/22, 6/8/22, 7/13/22, 8/10/22. 9/14/22, 10/12/22

1. ***Overview of committee activities:***

   Committee completed review of existing sushi guidance. Research was compiled, trends and discrepancies were noted, and a summary of the research will be included in the background of the guidance document.

   Committee has determined content to be discussed in guidance document, and what additional tools may be included.

   Committee has provided feedback on which section of the guidance document they are interested in writing, and groups of committee members were formed to prepare guidance document.

   Committee members wrote draft language for sections of the document, document was then combined.

   Committee members worked to provide edits and prepare a final document with a decision tree and checklist included

   Draft guidance document was submitted to committee at the May 11 meeting. Meetings in June, July, August and September were used to discuss the document and edits to be made.

Additional charges and recommendations to FDA were discussed during the September and October meetings.

Final edits were completed, and vote was taken via email vote. Vote was 20 for, 1 against, 2 abstained. Two abstained votes were committee members who were no longer regularly participating in meetings.

Final votes were taken on additional issues to be submitted by committee. Vote was 19 for, 2 against, 2 abstain for issue on requesting FDA to streamline chain HACCP process and 18 for, 3 against, 2 abstain for issue on adding acidification of rice directly to the Food Code.

Committee work was completed as of 11/7/2022 and committee will request to be disbanded at the 2023 Annual Meeting.

2. ***Charges COMPLETED and the rationale for each specific recommendation:***
   a. Review current industry practices, collect available guidance documents, and current state codes pertaining to the production of sushi prepared at retail establishments.
   Review was completed and document that summarizes findings is attached to this report.
   b. Update the current CFP guidance document for production of sushi prepared at retail establishments.
   Committee determined that guidance needed was not able to be included in the current CFP document. The committee created a separate document that will be submitted. Guidance document is attached to this report.
   c. Referencing the guidance document in the Food Code Annex, or wherever the committee deems appropriate.
   Issue will be submitted by the committee asking for the document to be posted on the website and included in resources provided for acidification of foods, specifically Annex 2 – Supporting Documents or Annex 3 in Section 3-502.11.
   d. Identifying whether the Food Code adequately addresses sushi production at retail as a whole and make suggestions for changes (if necessary) at the next CFP Biennial Conference.
   Two additional issues were voted to be submitted to the 2023 meeting based on discussions of this charge. Committee will ask for letter to be sent to the FDA to review and streamline process for chain HACCP review, and for FDA to include acidification of rice parameters in 3-502.11.
   e. Identifying the recommended methods to disseminate the committee's findings.
   f. Reporting the committee's findings at the next CFP Biennial Conference

3. ***Charges INCOMPLETE and to be continued to next biennium:***

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

1.
2.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. ***Issue #1:*** **Report – Retail Sushi HACCP Standardization Committee (RSRHSC) 1**

b. **List of content documents submitted with this Issue:** ***Committee Member Roster:***

☐ ***See attached revised roster PDF*** ☒ ***No changes to previously approved roster***

"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) ***Other content documents:***
Guidance Document
Review of National Requirements for HACCP/Variance for Acidification of Rice

c. **List of supporting attachments:** ☐ ***Not applicable***

(1) **Final Roster**

(2) **Roster with attendance**

1. ***Committee Issue #2***: **RSHSC 2– Approval of Guidance Document**
2. **Committee Issue #3**: **RSHSC 3 – Amend Food Code Annex to Reference Approved Document**
3. **Committee Issue #4*:*** **RSHSC 4 – Review and Streamlining of Retail Sushi HACCP Process**
4. **Committee Issue #5**: **RSHSC 5 – Including Rice Acidification Parameters in Food Code**

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Guidance Document for Retail Sushi HACCP Standardization

Prepared By the CFP Council III Retail Sushi HACCP Standardization Committee

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- A – Food Flow Diagram for Sushi Process
- B – Example Permitting Scenarios
- C – Decision Tree for When a HACCP Plan in Needed
- D – Food Flow and Hazard Analysis for Sushi Rice
- E – Checklist for HACCP Plan Review and Verification

Introduction

Preface

Council III of the Conference for Food Protection created the Standardization of HACCP Plans for Sushi at Retail Committee in response to Issue 2020-III-017. The committee was charged with:

1. Reviewing current industry practices, collecting available guidance documents, and current state codes pertaining to the production of sushi prepared at retail establishments.
2. Updating the current CFP guidance document for the production of sushi prepared at retail establishments.
3. Referencing the guidance document in the Food Code Annex, or wherever the committee deems appropriate.
4. Identifying whether the Food Code adequately addresses sushi production at retail as a whole

The committee reviewed the current CFP guidance document related to sushi created by the 2016-2018 Special Process Controls Committee titled "Single Hazard Special Process HACCP Template" and it was determined that the information prepared by the committee is not easily integrated into the existing document. This document was created to supplement the templates and guidance provided for acidified rice in that document. This document is intended to provide guidance for food service operators and regulators, is not binding and does not replace regulatory requirements.

Note: This summary was developed around the 2017 FDA Model Food Code. Not all jurisdictions will have adopted this version of the Food Code, however, the references will be similar among versions of the Food Code. Be sure to verify your regulatory authority's requirements.

Sushi Background

The word "sushi" describes the specific preparation of the rice used in formed sushi-making. Sushi rice is a specific variety of rice that has its own unique flavor and ability to stick together to form finished products when combined with vinegar or other acidic products. In its conventional usage, sushi is described as cooked rice that has been acidified with vinegar solutions and formed with raw or cooked fish other seafood, imitation crabmeat, shellfish and fish egg, surimi, fresh chopped vegetables, produce, pickles, tofu, etc.

Sushi products may be formed manually using mats made of bamboo or plastic, specialized tools, or mechanically using sushi forming machines. Popular product forms can include:

- Nigiri, small balls of rice with raw or cooked fish or shellfish, optionally held in place with strips of dried seaweed (nori).
- Maki Rolls, layers of rice and nori sheets rolled with a bamboo or plastic mat to form cylinders that contain various seafood, vegetables, and other ingredients, [i.e., California roll cucumber, avocado and surimi or imitation crab, Philly roll with cream cheese, Tekka maki raw tuna)]; and
- Hand rolls, cone shaped rolls formed by a sheet of nori filled with various ingredients."

Sashimi is a separate food from sushi, even though the two are often used interchangeably. Sashimi, loosely translated, means "pierced body "and it refers to a delicacy of thinly sliced fish or other types of meat. Sashimi is eaten plain, without rice or other foods. Sashimi-grade fish is not a regulatory term but is used as a culinary one. Some of the most popular varieties of sashimi include salmon, fatty tuna, yellowtail, and squid.

An example of a food flow diagram that outlines the entire process of preparing sushi can be found in Appendix A.

Existing Problem

Due to the number and types of local regulatory agencies responsible for food safety across the country, there is inconsistent interpretation and enforcement of existing Food and Drug Administration (FDA) Model Food Code, herein called Food Code, requirements for specialized processes. Establishments that operate in multiple jurisdictions with separate regulatory agencies may be required to provide different documentation for the same food item produced the same way. Examples of these inconsistencies include, but are not limited to:

- When a full HACCP plan and/or variance may be required
- Requirements for variance submittal
- pH value for acidification of rice
- Requirements for submitting sample to lab for pH verification
- Final cooling temperature of rice
- Labeling requirements
- Additional regulatory requirements, such as when seafood HACCP is required

Audience and Benefits of Document

This document provides standardized information for reference and use by both regulatory agencies and retail food establishments that make and sell sushi. Providing standardized guidance for sushi and acidified rice should not only shorten plan review and approval times but would greatly reduce the number of HACCP plans that each retail food establishment or sushi company must create and maintain.

The goal of this guidance is to help jurisdictions achieve a more standardized review of HACCP Plans. Uniform criteria for retail sushi HACCP plans allow for more consistent oversight for regulatory agencies and allows for training of food safety regulators on established critical control points across all facilities. Furthermore, this approach would help ensure that risks associated with the production of sushi at retail and food establishments were properly identified and addressed.

Purpose and Limitations of Guidance Document

This guidance document addresses the specialized process of acidifying rice to make it a non-time/temperature control for safety (TCS) food. This process requires a variance in the current version of the Food Code. This document does not address the requirement of seafood HACCP for fish used as an ingredient in sushi. Seafood HACCP is a requirement for reputable suppliers, and since requirements for approved/reputable suppliers are outlined in the Food Code, adherence to regulation is sufficient for retail HACCP.

Sushi Preparation Food Code References

The application of the Food Code requirements to sushi will vary depending on methods the establishment utilizes to prepare sushi products. Just like all TCS food, the Food Code requirements for parasite destruction, consumer advisory, cold holding, and cooling need to be considered for all sushi operations. Depending on the establishment's operation, time as a public health control or the special process of acidification of rice may also need to be addressed. The establishment's choice of sushi products served, and methods of operation will guide their best approach to meeting the Food Code requirements.

References for all sushi operations:
Parasite Destruction 3-402.11
Cooling 3-501.14
Temperature Control 3-501.16
Consumer Advisory 3-603.11

Additional Considerations for some operations:
Date Marking 3-501.17
Time as a Public Health Control 3-501.19
Special Process (Acidification) 3-502.11
Labeling 3-602.11

References that Apply to all Sushi Operations

Parasite Destruction 3-402.11

Sushi products that include raw or undercooked fish may have naturally occurring parasitic hazards that need to be controlled. The Food Code requires fish that will be served raw or undercooked to be frozen to specific time and temperature parameters found in 3-402.11, unless an exemption is met. Exemptions include molluscan shellfish, shucked scallop adductor muscle, select tuna species [*Thunnus alalunga, Thunnus albacares* (Yellowfin tuna), *Thunnus atlanticus, Thunnus maccoyii* (Bluefin tuna, Southern), *Thunnus obesus* (Bigeye tuna), or *Thunnus thynnus* (Bluefin tuna, Northern)], and fish raised under specified aquaculture practices. Retail establishments commonly rely on suppliers to address parasite controls. Documentation of proper parasite control is required which may include in-house freezing records or letters of guarantee from suppliers.

Cooling 3-501.14

TCS foods held in the Danger Zone have the potential to cause foodborne illnesses. To help control these foodborne illnesses, the Food Code requires rapid cooling of TCS foods, such as cooked rice, cooked fish products, and assembled finished products. TCS food must be rapidly cooled using a two-tiered cooling system that includes cooling TCS from 135°F (57°C) to 70°F (21°C) within 2 hrs., then to 41°F (5°C) within a total of 6 hours.

Sushi usually contains multiple components that include both TCS and non-TCS ingredients. The TCS ingredients and TCS containing finished products must be rapidly cooled to prevent foodborne illness. Sushi rice when acidified below 4.2 is not considered a TCS food. However, the finished, assembled sushi roll containing TCS foods must be rapidly cooled in accordance with 3-501.14.

Temperature Control 3-501.16

Cold holding may occur at several different steps in the production of sushi products. This commonly includes cold holding of fish, some sushi ingredients and sauces, non-acidified cooked rice, and the assembled sushi product if not immediately served. Keeping TCS food at or below 41°F (5°C) reduces opportunity for pathogen growth and/or toxin formation. Keeping TCS foods at 135°F (57°C) or above additionally controls pathogen growth. In sushi operations, hot holding may not be a feasible option due to quality.

Consumer Advisory 3-603.11

The Food Code requires that the consumer be informed about the risks of consuming undercooked or raw animal foods, including raw or undercooked fish often found in sushi. The consumer advisory requires 1) **disclosure** identifying any raw or undercooked animal foods and 2) **reminder** of risks associated with consuming undercooked or raw animal foods such as fish. Consumer advisories are commonly placed on menus, signage at place of order, or on label of packaged product.

References for Some Operations (based on preparation methods)

Date Marking 3-501.17

Date marking in the Food Code applies to ready-to-eat, TCS foods held cold for more than 24 hours within the establishment. Food components that go into finished sushi products, as well as the completed rolls, may require date marking if held over 24 hours. Fish used in sushi products is considered ready-to-eat even if it remains in an undercooked or raw form. Date marking for these ready-to-eat fish components would begin when removed from manufacturers' packaging or removal from in-house freezing for parasite destruction step. When food items are combined, the oldest date needs to be used for the new item. Many sushi products are prepared and sold to consumers the same day, so date marking may not apply.

However, all sushi operations should review use of components that were opened in advance and possible end of day carry-over to determine if the Food Code date marking requirements would apply.

Time as a Public Health Control 3-501.19

Time as a public health control (TPHC) is an option under the Food Code 3-501.19. This can allow use of food products for up to four hours after being cooked without temperature control or control of pH, with any remaining product being discarded. This practice requires written procedures, labeling food when removed from temperature control, and discarding unlabeled products and any remaining at the end of four hours. This option does not allow for saving or restarting once a TPHC procedure is started. This approach works frequently for finished sushi rolls intended for immediate consumption. However, retail establishments packaging sushi for to-go service methods will find TPHC impractical.

Special Process - Acidification of Rice 3-502.11

Acidification of TCS foods with the intent of making them non-TCS is considered a special process in the Food Code. In the case of sushi rice, this process takes a TCS food (cooked rice) and adds acid (typically vinegar) to drop the pH and allow the cooked rice to be held without time or temperature controls. This acid addition needs to adjust the equilibrium pH to less than 4.2 to control the identified hazards.

Addition of vinegar for flavor only, when pH is not monitored, is not considered a special process and rice must be temperature controlled just like any other TCS food. It is also important to remember once the acidified rice is combined with other sushi ingredients the final product would be considered TCS again requiring time and temperature control.

Retail food operations who wish to handle food outside the Food Code parameters can do so by use of a Variance and HACCP Plan. HACCP plan (discussed following sections) specifies the process and how food safety hazards will be controlled. The Food Code 8-103.11 outlines requirements for obtaining a regulatory variance, and 8-201.14 identifies required elements of HACCP plans. The variance issued by the regulatory authority allows the establishment to implement a reviewed HACCP plan which controls food safety hazards in an alternate manner. The Food Code 8-103.10 has additional information about variances.

Labeling 3-602.11

Sushi that is packaged for retail sale, for example clam shell packaged sushi products in a consumer display case, will also require labeling. Package labeling is required to allow the consumer to make informed decisions on food selections and avoid major food allergens. The definition of “packaged” is included in the Food Code and excludes over wraps or carry-out containers facilitating service of food upon consumer request. Basic elements required on label include identity statement, ingredient list, net quantity, major allergens, and name and place of business. In addition to the Food Code, labeling may meet 21 CFR 101.

When a Variance and HACCP Plan is Needed

Based on the food process the establishment has chosen, a variance and HACCP Plan may be required for a retail sushi establishment. As noted above, the Food Code requires a variance and HACCP when acidifying rice to render it non-TCS; however, regulations will vary with jurisdictions. In determining whether a HACCP Plan is needed, the establishment needs to consult with the regulatory authority for specific requirements and procedures for receiving a variance. This document is intended for retail food service establishments and does not cover food processing plants. Example scenarios to help determine whether a food business is a retail food establishment, or a food processing plant can be found in Appendix B. A decision tree is included in Appendix C to assist in determining if a variance and HACCP approval is needed. The sections below provide guidance for creating the HACCP plan for acidified rice only.

Contents of a Sushi Rice HACCP Plan

There are seven principles of HACCP: Hazard Analysis, Determine Critical Control Point, Establish Critical Limit, Establish Monitoring Procedures, Establish Corrective Action, Verification and Record Keeping. A Sushi Rice HACCP Plan should address each of these principles. Additional items are required for a HACCP Plan as stated in 8-201.14, such as general information regarding the operation, recipes, flow diagrams, sample blank log forms, and Standard Operating Procedures.

- **General Information:** General information should be included on the plan to include the owner/operator's name, location of business, Person-In-Charge (PIC), and contact information.
- **Recipe(s)**: Included in your HACCP Plan should be the recipe for your sushi rice. Include each different sushi rice recipe, including alternative grains such as quinoa, brown rice, or similar.
- **Flow Diagram or Chart**: A flow diagram will visually explain the exact process of preparing the sushi rice. Your plan should include a flow diagram or chart. The first step in the flow of food should be receiving ingredients and the last step is consumption or sale of sushi rice. An example food flow can be found in Appendix D.
- **Sample log form**s: A copy of the blank logs should be attached to the HACCP plan. There should be at least one log for each of the critical control points.
- **Standard Operating Procedure**s: Standard operating procedures (SOPs), are written procedures that provide specific instructions on performing food safety tasks related to the HACCP plan.

Hazard Analysis

A hazard analysis identifies the known or reasonably foreseeable hazards associated with a specific food. There are two main biological hazards associated with sushi rice held at room temperature: *Bacillus cereus (B. cereus) and Staphylococcus aureus*. If they are allowed time to grow in the rice, both bacteria can form toxins that cause vomiting and diarrhea. *B. cereus* is a spore forming bacteria often associated with rice. The spores may be present in rice and other grains, and then survive the cooking step. *S. aureus* is associated with food preparation environments and may be introduced to sushi rice due to the amount of handling throughout the sushi preparation process. These bacteria can produce toxins when left for too long in temperature danger zone, of above 41°F- below 135°F (5°F - 57°C). These bacteria are commonly associated with unacidified or improperly acidified sushi rice because it is typically kept in the temperature danger zone. A full hazard analysis for sushi rice process can be found in Appendix D.

Control Measure

Control measures are those processes or procedures put into place to control, reduce, or inactivate pathogens. The main control for the growth of *B. cereus* and *S. aureus*, aside from time/temperature control, is acidification. In the preparation of sushi rice, vinegar is typically mixed thoroughly into cooked sushi rice to reduce the pH of the rice to less than 4.2. This pH threshold meets the definition of a non-TCS food, found in Table B of the FDA Model Food Code (note that water activity of cooked rice is greater than 0.88, and so is not a factor in this determination). This control is effective only when the pH of the rice is correctly monitored by using a pH meter. Colorimetric methods for the determination of pH may be allowed in some instances when the pH is 4.0 or lower.

Critical Control Point (CCP)

The critical control point, or CCP, is the point in the flow of the process at which there is control over the identified hazard, typically the growth of pathogens. If not done correctly, pathogens could grow and/or produce toxins, resulting in consumer illness. The step in which vinegar is added to the rice is the critical control point for sushi rice. This is the step where the two hazards of concern, *Bacillus cereus and Staph aureus*, must be controlled to prevent illness.

Critical Limit(s)

Critical limits are those measurable parameters and values that are based on science that demonstrate a critical control point is effective controlling the identified hazard. In the case of acidified sushi rice the critical limit is a pH of below 4.2to be considered non-TCS. When using FDA Interaction Table B, rice acidified to below 4.2 would not need further evaluation and would be considered non-TCS. Cooked short grain white rice has available water measurement (known as water activity, a_w) of approximately 0.98.

Alternative grains such as brown rice or wild rice, quinoa, couscous, cauliflower rice, are sometimes proposed to be used instead of sushi rice. Any alternate grains are required to meet this same pH critical limit unless alternate science is provided.

Monitoring

A HACCP Plan must include information on how the production of the acidified rice will be monitored. An example monitoring procedure is included in this document. When preparing the sample, 21 CFR 114.90 states that a ratio of 10-20 mL of water to 100 grams of product should be used. Both the acidification of the rice and the final pH of the rice should be monitored. The plan will indicate what is being monitored, how it will be monitored, what is the frequency of monitoring, and who will do the monitoring. With sushi rice, monitoring should be done by a trained individual using a calibrated pH meter.

Corrective Action

Corrective actions are steps taken when a critical limit is not met during the preparation process. It is important that any time a corrective action is needed it must be recorded on a log sheet. If the pH of the measurement is 4.2 or greater; then repeat the measurement with a new sample. If that sample reads 4.2 or greater; add more vinegar to the acidified rice. Mix well and repeat the pH measurement. Repeat this corrective action until the pH is below 4.2. The rice can also be held using time as a public health control, cooled, and held cold, or discarded as a corrective action. Additional long term corrective actions should be applied, including reviewing the process, adjusting recipe, or substituting vinegar type. Note all corrective actions applied in a corrective action log.

Verification vs Validation

Verification and Validation are not the same thing. **Verification** is making sure the HACCP Plan is working as written. **Validation** is making sure the HACCP Plan will work to control the hazards identified based on science. Most sushi rice HACCP plans are written based on already validated science (i.e., pH below 4.2), because of this, scientific validation is not required. If a method is used that is not already recognized in the scientific literature as controlling the identified hazard, a validation (other science or challenge studies) may be required.

Verification

The Person-in-Charge (PIC) is responsible for reviewing and signing the sushi rice acidification log and making sure the HACCP plan is being followed as written. This is considered a verification of the HACCP plan. The HACCP plan should indicate who will do the verification, the frequency of the verification and what verification activities are taking place. The PIC should also observe employees performing the pH measurement and recording required data periodically. All verification activities should be noted in the appropriate log notes along with the signature of the PIC performing the verification activities. An example checklist can be found in Appendix E that can help with verification activities.

Record Keeping

Records (logs or log forms) are an integral part of the HACCP Plan and should be kept for all monitoring of critical control points. Required records include pH meter calibration logs, sushi rice pH measurement logs, corrective action logs, PIC verification logs, and training logs.

Note: Once records are created, they must be kept for at least six months or as otherwise specified by the jurisdiction based on inspection frequency and made available to the Regulatory Authority upon inspection request.

Training

Any employee involved in the acidification of rice is required to receive training to show that they understand the hazards and controls associated with making acidified rice. The training plan must address any food safety issues of concern as stated in 8-201.14(F) (1) and should include training on all facility standard operating procedures. The PIC must review sections relating to the flow diagram, hazards, control measures, CCPs, critical limits, verification and record keeping. Hands-on training is essential. A blank training log form should be attached to the HACCP Plan. The training sessions must be recorded in the log, and must include date, employees present, and instructor.

Standard Operating Procedures

Standard operating procedures, or SOPs, are an important part of a HACCP Plan. These are specific written instructions that give details on how to perform tasks associated with food safety and the sushi rice HACCP Plan. SOPs should already align with the regulation unless a variance is in place. SOPs should include pH meter calibration, cleaning and sanitizing food contact surfaces, personal hygiene and employee health policies, hand washing, eliminating bare hand contact, and proper chemical storage. Many of the SOPs needed for sushi rice acidification are contained within the Food Code, but should include the following (these are examples only, additional SOPs may be needed):

- **Bare hand contact:** Clarify that bare hand contact with ready to eat (RTE) food is not permitted at any time and what is done with RTE food touched with bare hands
- **Employee health policy:** Address the symptoms of foodborne illness, pathogens associated with illness, symptom and illness reporting requirements, exclusion/restriction plan, return to work criteria, etc.
- **Personal hygiene:** Address wounds/sores, jewelry, fingernails, hair restraints, clothing (i.e., uniform, apron), tasting food, eating/drinking, what is done when employees do not follow the personal hygiene information
- **Hand washing:** Clarify when, how, and where to wash hands, and any corrective actions
- **Labeling:** Include details of all applicable dates (packaging, expiration), consumer advisory (if applicable), and what is done with food that is not labeled or is incorrectly labeled
- **Cleaning and sanitizing food contact surfaces:** Specify how to properly clean and sanitize food contact surfaces, and what to do with food contact surfaces that have not been properly cleaned and sanitized
- **Thermometer use and calibration:** Address the method and frequency of thermometer calibration and what is done with thermometers that cannot be calibrated, and provide details of documenting thermometer calibration
- **pH meter use and calibration:** Address the method and frequency of pH meter use; calibration, verification of accuracy of calibration and what is done with pH meters that cannot be calibrated and provide information on calibration and use logs.
- **Cold holding:** Address proper cold holding temperatures and corrective actions if food is found to be out of temperature, including allowances for cooling or discarding food
- **Transporting:** Address proper cold holding temperatures and applicable corrective actions if food is found to be out of temperature, including allowances for cooling or discarding food

Example Standard Operating Procedures

The following are examples of standard operating procedures that can be used for thermometer calibration, pH meter calibration, and pH monitoring. Be sure to follow any manufacturer's instructions related to specific equipment. *****These are only examples; sushi operations may choose another SOP to align with business needs. *****

Standard Operating Procedure for Thermometer Calibration

- Thermometers used for specialized processes should meet the same requirements as outlined in the Food Code Sections 4-201.12, 4-203.11 and 4-302.12.
- All thermometers must be accurate to +/-2 degrees Fahrenheit.
- Thermometers must be calibrated according to the Food Code Section 4.502.11(B). Thermometers should be calibrated at least once per day and whenever they are exposed to extreme temperatures or dropped.
- The ice water calibration method is the most common and reliable, and is outlined below:
- Fill a cup with ice, preferably crushed, with enough ice so the thermometer remains upright.
- Add cold water to the cup and stir, allowing the temperature to equilibrate.
- Place the thermometer probe in the cup. Temperature should read at 32°F, if it does not, adjust the thermometer according to manufacturer's instructions.
- When taking product temperature, the probe should be placed in the thickest portion of the food. For rice and other grains, it is recommended to stir first before taking temperature.

Standard Operating Procedure for pH meter Calibration

- The pH meters used for sushi rice should be designed for food and not designed simply for water or liquids. Appropriate meters will be portable, able to be calibrated and read to at least two decimal points
- pH should be calibrated daily and according to the manufacturer's instructions. Typically, pH meters come with 2-3 buffer solutions which are typically pH 4, pH 7 and pH 10. These solutions may be in aqueous or powder form and will come with any applicable mixing and handling instructions.
- The following outlines a basic calibration procedure, but always follow specific manufacturer's guidance.
    1. Prepare buffer solutions according to the package instructions.
    2. Remove the electrode from the storage solution, rinse thoroughly with distilled water and carefully blot (do not wipe) dry with a lint-free wipe.
    3. Turn the pH meter on and submerge the probe in the pH 7 solution, gently moving the probe around until the pH reading stabilizes. Select the calibrate button and then rinse the probe with distilled water and blot dry.
    4. Repeat step 3 with the pH 4 buffer solution.
- After calibration is complete, check the pH in the 4.0 buffer solution to make sure it reads correctly. The reading should be within 0.1 pH units of its true value (for example, the 4.0 buffer should read between 3.9 and 4.1).
- If results aren't within 0.1 pH unit of the true value for the buffer, the meter must be recalibrated.
- Record the calibration in your pH meter calibration log. You are now ready to test product samples.
- A second pH meter will ensure acidification operation can continue if there is failure of the pH meter. Having an additional pH meter for use as a backup is recommended.

Standard Operating Procedure for pH monitoring

- Each batch of acidified rice must be measured for pH as follows.
- Prepare rice and acidify according to the approved recipe. Allow rice to sit so vinegar can uniformly penetrate the rice. The pH is typically measured within 30 minutes or within timeframe specified in HACCP plan
- Prepare and calibrate the pH meter according to the manufacturer's directions. Record the calibration of the pH meter in the log. Calibration should be done daily or as required to maintain calibration.
- One quarter cup of rice should be collected from various locations in the batch of sushi rice. Press the rice down during sampling in the measuring cup so that it is flat and level. Repeat the procedure so there are two different samples.
- Add ¾ cup of distilled water to the ¼ cup of sushi rice for each sample. Mix the rice and water until a consistent slurry develops. The cooked and acidified grains will need to be crushed, mashed or blended with distilled water to reach a semi-liquid consistency.
- Insert the pH electrode into the first rice slurry and press the button to measure the pH. The electrode should be fully submerged in the sample and should be gently and slowly stirred until the probe reading is complete.
- Record your measurement on in your log, including the signature of the person who performed the acidification/monitoring. Take the pH of the second sample. Record it.
- **If either sample has a pH of 4.2 or above, corrective action is required**.

Prerequisite Programs

PARASITE DESTRUCTION

- Raw, ready-to-eat seafood, except for those exempt under 3-402.11(B), require freezing utilizing one of the following options: frozen and stored at a temperature of -20 ˚C (-4 ˚F) or below for a minimum of 168 hours (7 days) in a freezer, frozen at -35 ˚C (-31 ˚F) or below until solid and stored at -35 ˚C (-31 ˚F) or below for a minimum of 15 hours; or frozen at -35 ˚C (-31 ˚F) or below until solid and stored at -20 ˚C (-4 ˚F) or below for a minimum of 24 hours.
- In addition to exempt tuna species, some aquacultured fish products that have met specific requirements in 3-402.11(B) are exempt from freezing.
- The Food Code requires that "If the fish are frozen by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified under § 3-402.11" be provided. A similar written agreement is required to verify aquacultured fish products have met exemption requirements.
- Either purchase specifications or a letter of guarantee would be an acceptable way to verify the parasite destruction requirement.
- A document containing the following information would meet the requirement for verifying parasite destruction.
- Name of processing facility, or other entity, that has documented and carried out the freezing process.
- Draft date (within one year of purchase)
- Seafood item name
- Clear description of master cartons, or packaging, logo/brand reference to aid in cross referencing the letter to the item.

- One of the following specifications, depending on whether fish has been frozen or is exempt from parasite destruction
    - For fish that has been frozen: specific freezing process (one of the above) used to destroy parasites
    - For exempt/aquacultured fish: specifics on feed type and farm type (open water, net-pens, ponds, tanks, etc.)

- Where freezing is not applied for raw ready-to-eat seafood, and a parasite destruction exemption exists, documentation shall be secured from the supplier/processor to include, at a minimum, the following:
- Additionally, fish served raw in sushi products should be labeled as "ready-to-eat." Retail sushi operations should read packaging and labels as all fish and fish products are not intended for raw consumption. If the label or package does not state information about whether it is intended for raw consumption, the sushi operator should verify the intended use with the supplier.

REFERENCES

- FDA Food Code 2017: 3-402.11 Parasite Destruction
- Fish and Fish Products Hazards and Controls Guidance – Fourth Edition – June 2021
- FDA Appendix 1 - https://www.fda.gov/media/99581/download

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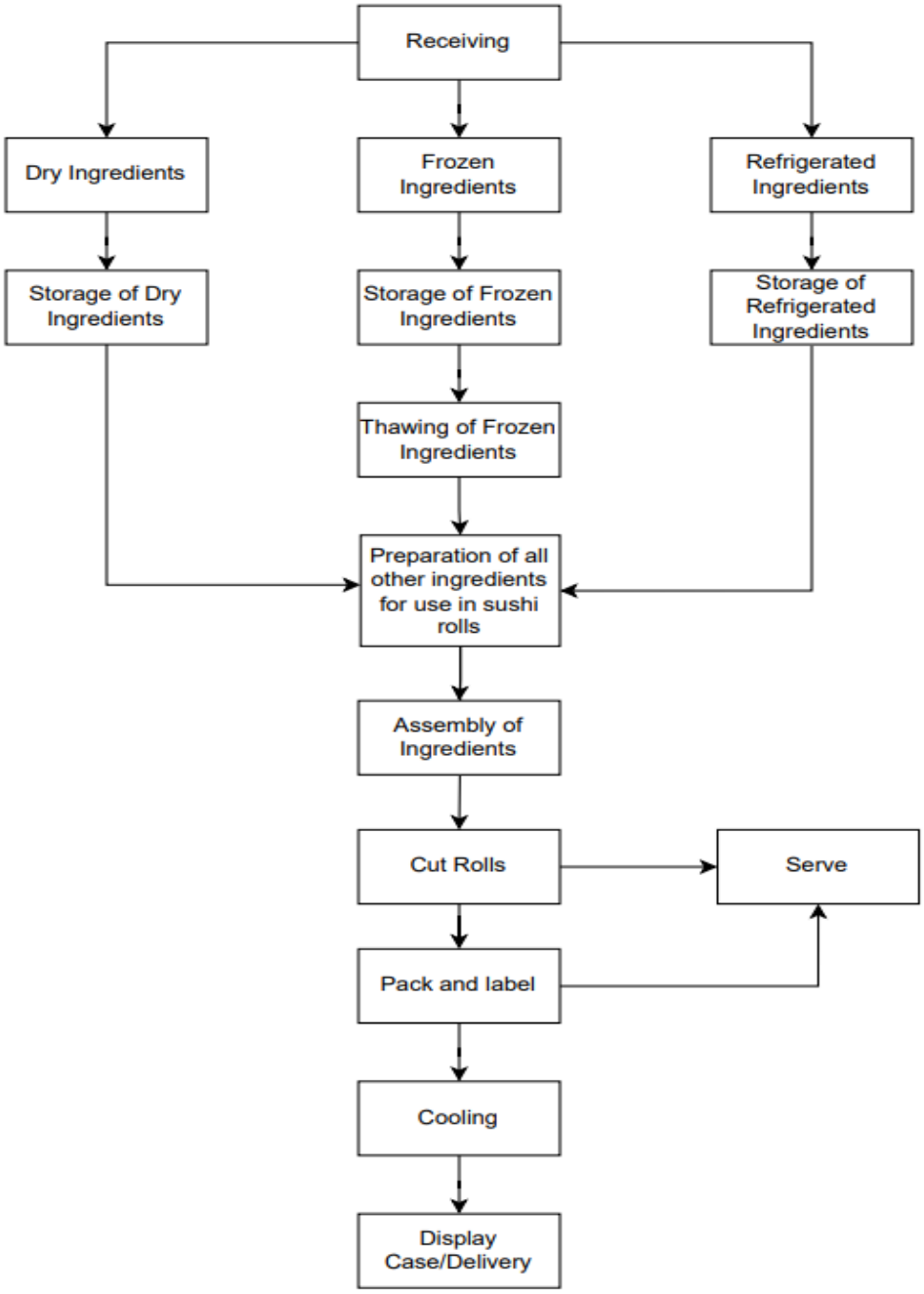
- FDA Consultants: Veronica Moore and Jonathan Tran
- 2021-2022 CFP Executive Board
- Members of Retail Sushi HACCP Standardization Committee

Appendix

A – Food Flow Diagram for Sushi Process
B – Example Permitting Scenarios
C – Decision Tree
D – Food Flow Diagram and Hazard Analysis for Sushi Rice
E – Sample Validation and Verification Checklist

Appendix A: Food Flow Diagram for Sushi Process

This food flow diagram is designed to illustrate the entire process for preparing sushi products and is not intended to be submitted with the HACCP Plan. **This food flow includes many steps that do not need to appear in the food flow diagram for the sushi rice HACCP plan. The only components of this food flow diagram that are required in a HACCP Plan are receiving, storing, preparation, and service.** An example of the food flow diagram that should be submitted with a HACCP plan can be found in Appendix D.



Appendix B: Examples permitting scenarios and how to interpret

Definitions:

I. ***Retail Food Establishments*** are sushi producers that prepare sushi products for direct distribution to the end consumer. The distribution methods may include but are not limited to dine in restaurant, to-go distribution, delivery, mobile food establishments, and vending machines, and can be fixed or temporary facilities or locations. Additional specifics of the retail food establishment definition can be found in FDA Food Code 1-201.10.

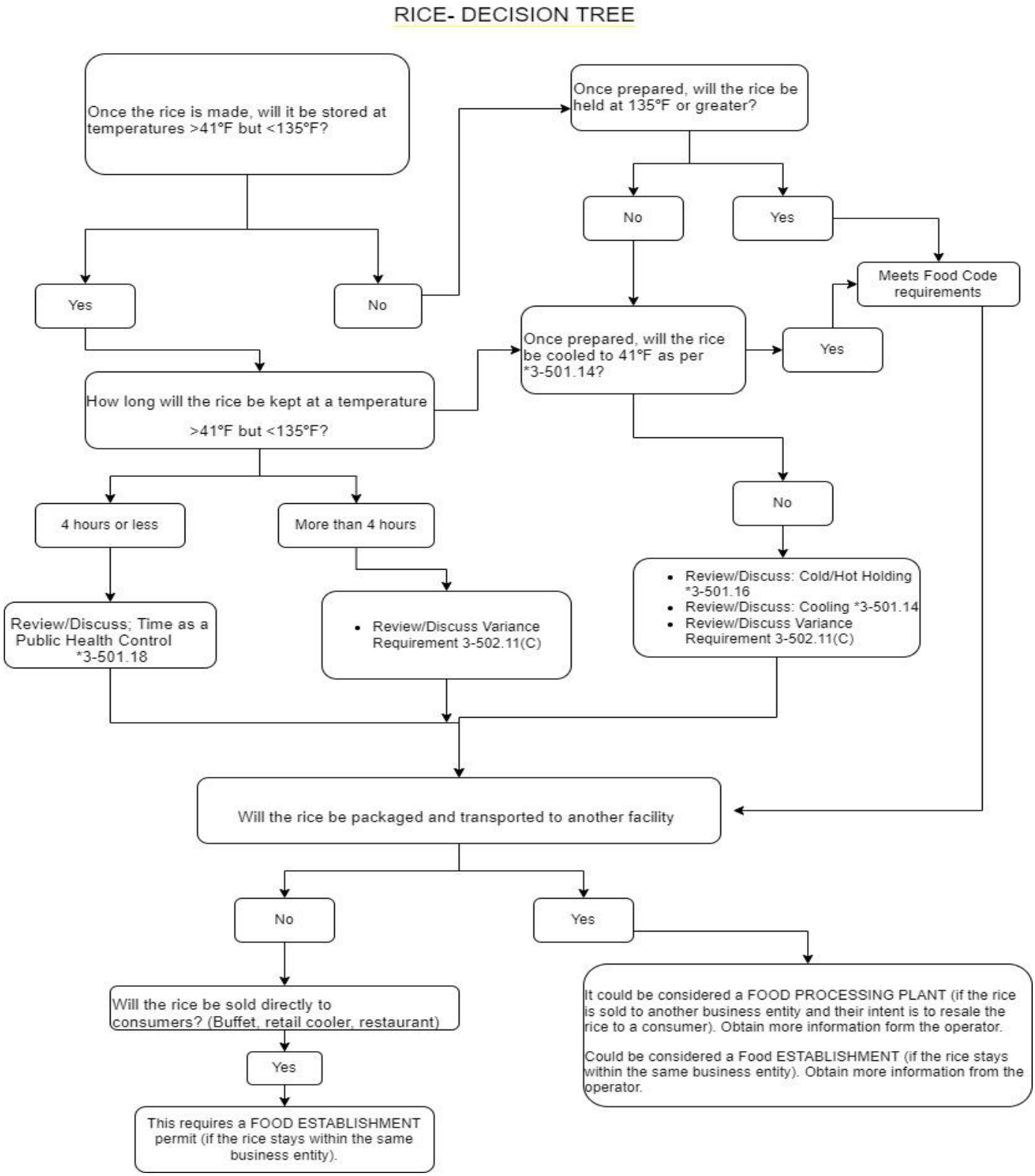
II. ***Food Processing Plants*** are commercial sushi operations that manufacture, package, label, or stores sushi and provides it for sale or distribution to other business entities. These sushi operations are generally offsite from a retail food establishment and sell or distribute to a business (Food Establishment) prior to distribution to the end consumer.

Examples:

1. Sushi is prepared in a restaurant and offered for sale to the consumer either for dine in, take out, or other third-party delivery service. These operations would be **Retail Food Establishments**.
2. Sushi is prepared in retail grocery store by a third-party vendor and the grocery store does not take ownership of the product. The vendor is leasing space, the sushi producer provides finished sushi to the end consumer, and the grocery store takes payment. These operations would be **Retail Food Establishments**.
    - Distribution often includes stocked refrigerators, 3rd party delivery services, and/or vending machines. The sushi establishment does not need to collect money directly for sale of its products.
3. Sushi is prepared at an off-site commissary and delivered to other retail stores or businesses that do not produce onsite. These operations are **Food Processing Plants**.
    - Sushi products made at a food processing plant may be produced at a central commissary location and distributed to other Food Establishments not operated by the company. In this instance, there is a business that receives the products as an intermediary before the final consumer receives the sushi or sushi product.
4. Sushi is produced by a chain operation at a grocery store and distributes it to another kiosk owned by the same operation. These operations would be **Retail Food Establishments**.
    - Sushi products may be prepared or produced at a central commissary location and delivered to other operations owned by the same company. Ownership of the product cannot change, but the product may be made in a different location than where it is offered for sale to the consumer.
5. Sushi is prepared at a preparation site/kitchen/commissary and ends up in university campus/hospital/airport. These operations are **Food Processing Plants**.
    - This would apply to sushi provided to locations such as universities, airports, etc. where the sushi company does not retain ownership of the product. These end locations may have a retail establishment component, but the sushi prepared for service within these locations is considered from a food processing plant, unless the distribution is via vending machine or other direct to consumer Food Establishment criteria.

Appendix C: Decision Tree

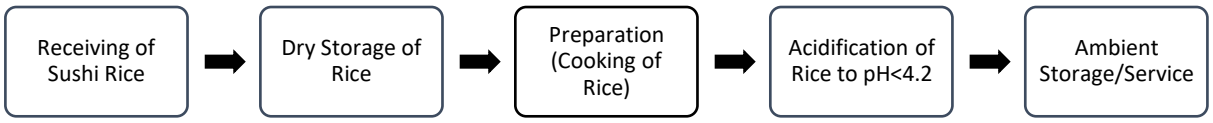
The decision tree is based off the 2017 FDA Model Food Code is intended to provide operators with specific food safety guidance based on the process used by an operator for holding rice. It also includes information about permitting/licensing based on how it will be served/sold.



Appendix D: Food Flow and Hazard Analysis for Sushi Rice

Food Flow Diagram for Sushi Rice

This is an example of a food flow diagram that should be submitted with a sushi rice HACCP Plan. All steps related to the preparation and acidification of rice are included. Please note that food flow diagrams do not have to follow this format, they just must contain the appropriate information.



Hazard Analysis for Sushi Rice

This chart outlines the steps in sushi rice preparation and the hazards associated with them. The CCP has also been identified. This information can be used in assembling the HACCP Plan.

PROCESS	**RECOMMENDATIONS/POLICIES**	**HAZARDS**	**CCP? IF YES, CRITICAL LIMITS**
Receiving	●All food products received from approved suppliers/distributors	●B: Microbial pathogens ●C: Chemical contamination of products ●P: Pest contamination	●No; have prerequisite receiving program Rejection process/segregation of rejected products SOP
Food storage	●Any dry storage foods will be stored away from any chemicals and in a dry, clean, 6" off floor location that is not exposed to other contamination.	●B: Potential growth or survival of pathogens	●No; Food Code parameters met for cold storage and dry storage
Preparation	●Rinse/soak rice to remove any foreign debris ●Cook rice to desired temperature, 135°F for rice that will be hot held	●B: Potential growth of *B. cereus, S. aureus, C. perfringens*	●Follow Food Code parameters for proper cooking and holding of rice.
Acidification	●Acidify rice after cooking, prepare sample for pH measurement and take pH ●Calibrate pH meter according to manufacturer's specs	●B: Potential growth of *B. cereus, S. aureus* and *C. perfringens* if held at room temp	●CCP pH<4.2
Display/Serve	● Display and serve sushi using no bare hand contact with ready-to-eat foods. ● Food should be stored according to time/temperature requirements during display	●B: Potential growth or survival of pathogens	●Follow Food Code parameters for employee health, no bare hand contact, and holding temperatures for TCS ingredients

Appendix E: Checklist HACCP Plan Review and Verification

HACCP Plan Content Requirements	**Observed**
List of all ingredients, equipment, and packaging to be used including recipes and/or formulations	
Food flow diagram (page 15 Appendix D of guidance document)	
Hazard Analysis (*B. cereus, S. aureus* is pathogen of concern)	
Critical control points labeled (acidification step as CCP)	
Critical limit given (pH of rice below 4.2)	
Monitoring procedures (pg. 9-10)	
Corrective actions provided (pg. 7)	
Record keeping procedures (pg. 8)	
Employee training program	
Written prerequisite programs and SOPs	
Notes:	

Verification Activities	**Observed**
Approved equipment used	
Proper ingredients and formulation used	
Identification of employees involved in process	
Proper pH meter calibration observed	
Observation of pH sample preparation and pH meter use	
Corrective actions observed or discussed with trained employees	
Review of pH logs and corrective actions log	
Review and verification of adequate training program	
Observation of prerequisite programs/SOPs	
Notes:	

State	County	Acidified Rice	Variance Required	HACCP plan available	Lab test required for PH	Labelling	Are NIST Calibrated Thermometer required	Is 24 hours continuou monitoring required for Seafood items	Is the temp of the Seafood needs to be 38°F or 40°F or 41°F	Comment	Link
Arizona	Maricopa	4.2 or below	Yes for acidified rice	No	Yes					If the rice is acidified for the purposes of flavor enhancement and not preservation, and it is cooled in accordance with §3-501.14 and maintained at 41°F or below for no longer than 7 days, then neither a HACCP Plan or variance are required	https://conferenceforfoodprotection.sharepoint.com/:f:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/Arizona/Maricopa%20County?csf=1&web=1&e=xa25FC
California	Monterey	4.4 or less	Yes for acidified rice	Yes						If cooked rice is acidified by adding vinegar a HACCP plan is required to be submitted.	https://conferenceforfoodprotection.sharepoint.com/:f:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/California/Monterey%20County?csf=1&web=1&e=tizavD
California	Riverside	target ph <4.4 and must not reach critical limits >4.6	Yes for acidified rice	No	Yes						https://conferenceforfoodprotection.sharepoint.com/:b:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/California/Riverside%20County/Riverside%20-%20Guidelines%20for%20HACCP%20for%20Sushi%20Rice.pdf?csf=1&web=1&e=iLGogd
California	San Bernardino	4.6 or below	Yes for acidified rice	no	Yes					If cooked rice is acidified by adding vinegar a HACCP plan is required to be submitted.	https://conferenceforfoodprotection.sharepoint.com/:f:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/California/San%20Bernardino%20County?csf=1&web=1&e=tri7o7
California	San Francisco	4.1 or below	Yes for acidified rice	Yes							https://conferenceforfoodprotection.sharepoint.com/:f:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/California/San%20Francisco%20County?csf=1&web=1&e=3nLOMr
California	San Luis Obispo	4.6 or below	Yes for acidified rice	Yes	A verification letter from a naccredited laboratory indicating that the fina; pH of the sushi rice is less than 4.6.						https://conferenceforfoodprotection.sharepoint.com/:f:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/California/San%20Luis%20Obispo%20County?csf=1&web=1&e=yZjb3e
California	Sonoma	target ph <4.4 and must not reach critical limits >4.6	Yes for acidified rice	yes	Yes					Yes	https://conferenceforfoodprotection.sharepoint.com/:b:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/California/Sonoma%20County/Sonoma%20-%20Sushi%20Rice%20HACCP%20Plan%20Guidelines.pdf?csf=1&web=1&e=AfUtC3
California	Sutter	target ph <4.4 and must not reach critical limits >4.7	Yes for acidified rice	No	no						https://conferenceforfoodprotection.sharepoint.com/:b:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/California/Sutter%20County/Sutter%20-%20Sushi%20Rice%20HACCP%20Plan%20Guidelines.pdf?csf=1&web=1&e=kVNJ2G
Colorado		4.2 or below	Yes for acidified rice	Yes	Yes, if using the statewide variance option.					Can either obtain their own variance that may need a HACCP plan or can follow the statewide variance criteria (one sample, three different batches or onsite pH testing). Inspectors should be doing field verification for acidified rice.	https://conferenceforfoodprotection.sharepoint.com/sites/ConferenceforFoodProtection/Shared%20Documents/Forms/AllItems.aspx?FolderCTID=0x012000ZE08D3C88C78D24B9F6412D97F4C1B05&id=%2Fsites%2FConferenceforFoodProtection%2FShared%20Documents%2FCouncil%20Committees%2FCouncil%20III%2FRetail%20Sushi%20HACCP%20Committee%2FShared%20Documents%2FColorado%2FRF199%2D24%5FSushi%20Rice%5FApproval%20Letter%5FO40319%5Fmbrandt%2Epdf&parent=%2Fsites%2FConferenceforFoodProtection%2FShared%20Documents%2FCouncil%20Committees%2FCouncil%20III%2FRetail%20Sushi%20HACCP%20Committee%2FShared%20Documents%2FColorado
Delaware		4.1 or below	Yes for acidified rice	Yes							https://conferenceforfoodprotection.sharepoint.com/:b:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/Delaware/HACCP%20and%20Variance%20Template%20for%20Sushi%20Rice%20Acidification.pdf?csf=1&web=1&e=xLImBB
Michigan		4.2 below	Yes for acidified rice	Yes						Only if special process (Acidification of rice)	https://conferenceforfoodprotection.sharepoint.com/:b:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/Michigan/Sushi_Rice_Acidification_Application_715003_7.pdf?csf=1&web=1&e=vv1gJv
Wiconsin		4.3 or below (MN also)	Yes for acidified rice	Yes							https://conferenceforfoodprotection.sharepoint.com/:f:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/WI_DATCP?csf=1&web=1&e=feihqq
South Carolina DHEC		4.1	Yes for acidified rice	No	one-time product assessment from process authority or accredited food lab required to approve variance	For prepackaged "grab and go" foods only	No. Only pH meter and calibration required (sushi rice)	No.	41F	Variance based on approved SOP only if special process (Acidification of rice); Program offers options to use either temperature control or TPHC without control of pH. (SOP required for TPHC)	https://conferenceforfoodprotection.sharepoint.com/:b:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/SC%20DHEC%20Sushi%20Rice.pdf?csf=1&web=1&e=NdRSLL
Nevada	Washoe County	4.2 or below	Yes for acidified rice	Yes	Yes	For prepackage/manufactured foods only	No. Only pH meter and calibration required.	No.	41F	For sushi rice, TPHC or an approved HACCP plan and variance is required by all food establishments in Washoe County. Washoe County also has restrict SOP requirements such as training, employee health, and cleaning/sanitization for all HACCP plans. This often creates a lot of back and forth to get a plan approved from nationwide corp entities.	

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COMMITTEE NAME: **Safe Use of Reusable Containers Committee (SURCC)**

DATE OF FINAL REPORT: *11/22/22*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☐ ***Council II*** ***X*** ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: **Carrie Pohjola (co-chair) and Dagny Tucker (co-chair)**

COMMITTEE CHARGE(S):

- Clarify the scenarios related to reusable containers within the scope of regulation
- Identify and analyze the scientific and other literature related to consumer-owned containers at retail
- Draft recommended guidance around those scenarios and create a definition of reusable container
- Provide recommended code language changes, if necessary, to FDA
- Report progress and report findings and recommendations at Biennial Meeting in 2023

Issue# 2020 I-024 (combined with 2020 I-022 and 2020 I-023)

1. Clarify the scenarios related to reusable containers within the scope of regulation.
2. Identify and analyze the scientific and other literature related to consumer-owned containers at retail.
3. Draft recommended guidance around those scenarios and create a definition of reusable container
4. Provide recommended Code language changes, if necessary, to FDA
5. Report progress back to the next Biennial Meeting in 2023 and the committee findings and recommendations may be presented at the subsequent Biennial Meeting if necessary.

COMMITTEE WORK PLAN AND TIMELINE:

COMMITTEE ACTIVITIES: **Dates of committee meetings or conference calls:** *11/16/2021, 11/30/2021, 12/14/2021, 1/11/2022, 2/8/2022, 2/22/2022, 3/22/2022, 4/5/2022, 4/19/2022, 5/3/2022, 6/14/2022, 7/12/2022, 10/04/2022, 10/28/2022, 11/01/2022, 11/15/2022, 11/22/2022, 11/29/2022*

1. ***Overview of committee activities:***

   The committee determined that subcommittee work would be best to accomplish the charges. The first subcommittee was the Regulatory Foundation Subcommittee that developed a flow chart of what is currently allowed in the Food Code for the safe use of re-usable containers. This will be used to address scenarios that were then addressed by sub-committees. Subcommittees then determined all types of scenarios that could possibly occur at the retail level based on types of sales of foods and finally a sub-committee is working on flows based on the packaging (consumer owned, business owned, third party owned) and when finalized will be used to determine which of the identified scenarios could be safely done with food code language changes. Once this is determined, guidance will be drafted based on identified literature and best practices to safely allow for the re-use of containers.

   The committee continues to work on a guidance document. A sub-committee is working on making the sections within the document more cohesive for review by the full committee on

September 20th, updated to 10/04/2022 due to FDA regional seminar. The final document is to be completed by the end of October for submission in November.

The committee will complete the final guidance document to be submitted to CFP by December 5th. It is currently in the formatting stage of completion.

Food code language and a definition of reuse was drafted based on jurisdictions that have adopted the reuse of containers and literature and documentation that was reviewed by the committee when drafting the guidance document.

2. ***Charges COMPLETED and the rationale for each specific recommendation:***

A.a. Clarify the scenarios related to reusable containers within the scope of regulation. Scenario matrix developed demonstrating reusable/returnable containers currently being utilized in numerous scenarios where current regulatory code does not align with practice.

A.b. Identify and analyze the scientific and other literature related to consumer-owned containers at retail. Current scientific literature specific to consumer-owned containers is limited. Available relevant scientific literature, a precedents overview and other relevant examples and literature was reviewed and is compiled and referenced in the committee's guidance document.

A.c. Draft recommended guidance around those scenarios and create a definition of reusable container. Scenarios and opportunities for safe implementation of reusables/returnables were critically evaluated and a guidance document was drafted. Additionally food code was cross referenced for definitions of reuse, returnable, refillable along with allowable container types in current code and based on those examinations and current scenarios of use, a definition of reusable/refillable container was created.

A.d. Provide recommended code language changes, if necessary, to FDA. Based on the above work as well as current food code precedents at the state level, food code language changes are being recommended.

A.e. Both committee co-chairs plan to attend the Biennial meeting to report progress and report findings and recommendations at Biennial Meeting in 2023.

3. ***Charges INCOMPLETE and to be continued to next biennium:***

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

X ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

1.

2.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. ***Issue #1:*** Report – Safe Use of Reusable Containers Committee Acknowledge the 2021-2023 Safe Use of Reusable Containers Committee final report, thanks the committee members for their work and disband the committee

b. **List of content documents submitted with this Issue:**

Committee Member Roster:

☐ ***See attached revised roster PDF*** x ***No changes to previously approved roster***

"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) ***Committee Member Roster (see attached PDF)***

(2) ***Committee Generated guidance document entitled Guidance Document for Safe Use of Reusable Containers***

(3) ***Meeting Summations***

(4) ***Scenario Matrix***

c. List of supporting attachments: ☐ ***Not applicable***

1. ***Committee Issue #2***: SURCC 2-Approval and Posting of Guidance Document. Recommend acceptance of the Committee generated guidance document entitled "Guidance Document for the Safe Use of Reusable Containers" included in Issue #1: Report- Safe Use of Reusable Containers Committee and; inclusion of the guidance document on the CFP website in a downloadable PDF format.
2. ***Committee Issue #3***: SURCC 3-Amend Food Code Language to Include the Reuse of Containers
3. ***Committee Issue #4***: SURCC 4-Amend Food Code Language to Include a Reuse Definition

Committee Name: Council III-Use of Reusable Containers

Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Tucker	Dagny	Chair	Industry	Vessel	Lyon	CO	3039153079	dagny@threadcountcreative.com
Pohjola	Carrie	Vice- or Co-Chair	Regulatory-State	WI DATCP	Madison	WI	7155799487	carrie.pohjola@wi.gov
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Bonatakis	Kristina	Member	Consumer		Red Bank	NJ	3478914072	kristinabonatakis@icloud.com

Non-Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
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Puente	Eric	Alternate	Industry	Whole Foods Market	Austin	TX	2193918464	eric.puente@wholefoods.com
Pearson	Peri	Alternate	Regulatory-State	Virginia Dept of Health	Richmond	VA	8043047433	peri.pearson@vdh.virginia.gov

Note: *Minimum council committee size is 11 (as noted above): 1-Chair; 1-Vice Chair; 1-State; 1-Local; 2-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise;*
Maximum council committee size is 23 voting members: 1-Chair; 1-Vice Chair; 4-State; 4-Local; 8-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise; 36 -Non-voting alternates.
Membership on standing committees is defined by the Executive Board. On all CFP committees, the committee chair, co-chair(s), and vice chair(s) all count towards constituency balance.

GUIDANCE DOCUMENT
FOR SAFE USE OF REUSABLE CONTAINERS

CONFERENCE FOR FOOD PROTECTION

2020-2023

This page photo courtesy of Conscious Container
Cover photo courtesy of In Good Company

Prepared by the

SAFE USE OF REUSABLE CONTAINERS COMMITTEE 2020-2023 CONFERENCE FOR FOOD PROTECTION

VOTING MEMBERS	AT-LARGE, NON-VOTING MEMBERS
Dagny Tucker, Co-Chair	Tom Arbizu
Carrie Pohjola, Co-Chair	Frank Curto
Kristina Bonatakis	Beth Glynn
Jeffrey Clark	Michael Goscinski
Deborah Crabtree	Jordan Ingle
Abeid Fells	Greg Lux
Bessie Gallanis-Politis	Steve Oswald
Alison Hurysz	Stephanie Teclaw
Sarah Kantrowitz	Peri Pearson
Oren Kariri	Eric Puente
Traci Michelson	
Rayna Oliker	**FEDERAL CONSULTANTS**
Kathryn Olson	Jessica Otto, FDA
Sabrina Salinas	Dan Reddit, FDA
Susan Shelton	Juhi Williams, FDA
Christina Springer	
Kaycee Strewler	**COUNCIL III CHAIR AND VICE CHAIR**
Dilshika Wijesekera	Don Schaffner, Chair
	Chip Manual, Vice Chair

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DEFINITIONS & ABBREVIATIONS

Terms not defined in the Food Code and shortened abbreviations used in this document.

TABLE 1: DEFINITION OF TERMS USED IN THIS GUIDANCE

Term	*Definition*
Contamination-free	A procedure for filling a consumer's container with food or beverage without directly or indirectly contaminating the source container of food or a food-contact surface.
Intermediate Utensil	A utensil used to prevent contamination from refillable containers to food or food-contact surfaces.
Origin	Source of the refillable container, such as the consumer, the food establishment, or a third-party provider.
Reusable Container	A product or primary packaging, to hold food, that is used repeatedly, refilled, or returned for multiple uses and conforms to characteristics of sanitary construction as defined in Chapter 4-1 and 4-2 of the Food Code.
Return Receptacles	Empty containers such as a bin, crate, or cart used to collect reusable containers returned to a food establishment for cleaning prior to refilling with food.
Secondary Reusable Container	Cooler, delivery bag or other container that is returned to a food establishment for reuse but is not a food-contact surface for ready-to-eat foods
Third-Party Providers	Person that provides warewashing services and/or refillable containers cleaned as specified under Parts 4-6 & 4-7 to the food establishment.
Verification	The cleaning, monitoring, or check procedure should be done by a food employee capable of affirming the cleaning process was completed properly.

TABLE 2: TABLE OF ABBREVIATIONS USED IN THIS GUIDANCE

Abbreviation	*Substituted Phrase*
CPG	Consumer Packaged Good
NON-TCS	Non-Time/Temperature Control for Safety Food
RTE	Ready-To-Eat
TCS	Time/Temperature Control for Safety Food
W/R/S	Wash/Rinse/Sanitize
LCA	Life Cycle Assessment
PR3	Partnership to Reuse, Refill, Replace Single-Use Packaging

II–DISCLAIMER

The guidance in this document does not create or confer any rights for, or on, any person and does not operate to bind public health officials or the public. This guide does not have the force and effect of law and thus is not subject to enforcement. This guide encourages food establishments to use the guidance herein to tailor food safety practices appropriate to their operations.

III–PREAMBLE

At the 2021 Conference for Food Protection (CFP) Biennial Meeting, Council III voted and approved the creation of the Safe Use of Reusable Containers Committee. This was in response to Issue #2020 I-024 (combined with 2022 I-022 and 2022 I-023), as presented at the CFP Biennial Meeting.

The following charges were given to the Committee:

1. *Clarify the scenarios related to reusable containers within the scope of regulation.*
2. *Identify and analyze the scientific and other literature related to consumer-owned containers at retail.*
3. *Draft recommended guidance around scenarios identified in the issue and create a definition of reusable container.*
4. *Provide recommended code language changes, if necessary, to the FDA.*

IV–SCOPE

This committee found there are numerous instances where current regulatory code does not align with practice in the field. To address this issue for CFP, the committee created this document around a scenario matrix, which offers an overview of how reusable/refillable/returnable containers are currently being used by the business community.

This document does not include: binding requirements unless adopted by the regulatory authority; nor does it describe W/R/S procedures for containers that are washed by food employees prior to refilling (which is spelled out in the Food Code).

This document will help clarify:

1. *Scenarios for refilling reusable containers in retail food establishments as listed in the 2017 FDA Model Food Code.*
2. *Best practice recommendations for filling reusable containers including those under a variance of the Food Code.*
3. *Reusable containers washed outside of the retail food establishment such as by a third-party provider.*
4. *Literature and local legislation related to refilling reusable containers.*

Photo courtesy of Dispatch Goods

V

INTRODUCTION

There are few pathways available in the 2017 FDA Food Code for refilling consumer-owned or third-party provided containers unless W/R/S in the food establishment or filled by the consumer at a water vending station (see Figure 1).

The CFP convened the 2020 Biennial Meeting using a virtual format in 2021 due to the ongoing coronavirus pandemic. Three issues related to refillable containers submitted to CFP Council I were transferred to Council III at the 2021 meeting. Issue 2020 I-024 Creation of a Committee to Address Reusable Scenarios in Food Retail was combined with 2020 I-022 Amend Food Code to Harmonize the Definition of Reusable Container and 2020 I-023 Amend Food Code to Address New Reusable Scenarios in Food Retail. Council III voted, and subsequently approved, to create the Safe Use of Reusable Containers Committee. The following charges were given to the new Committee:

1. *Clarify the scenarios related to reusable containers within the scope of regulation.*
2. *Identify and analyze the scientific and other literature related to consumer-owned containers at retail.*
3. *Draft recommended guidance around scenarios identified in the issue and create a definition of reusable container.*
4. *Provide recommended code language changes, if necessary, to the FDA.*

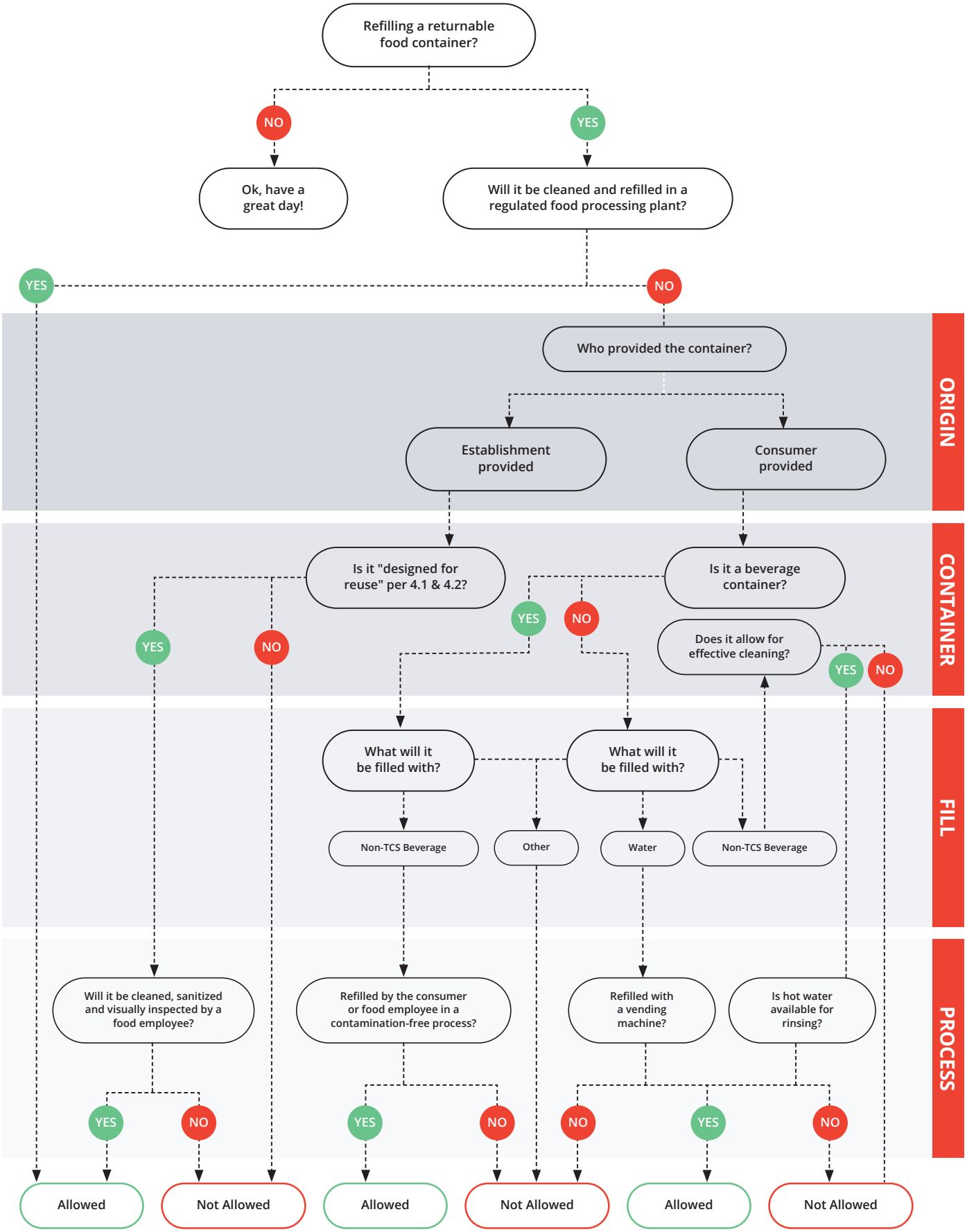
The committee was composed of representatives from academia, the food industry, and local, state, and federal regulatory agencies. Consultants from FDA and academic partners advised the committee throughout the entire process of guidance document preparation. The committee met biweekly with additional subcommittee meetings for approximately 12 months to fulfill its charges, including the completion of this guidance document.
Following a review of state and local codes, waste reduction bills, and the variety of current scenarios with reusable food containers in use, the committee identified several themes:

- *An increase in regulatory emphasis on the reduction of single-use articles to reduce solid waste.*
- *An increasing number of local ordinances that require (specifically for onsite dining) or expressly allow the use of reusable containers.*
- *An increase in the number of businesses that offer services to implement turnkey reusable container solutions for retail food establishments.*
- *The use of reusable containers in retail food establishments is common despite limited allowance in the food code.*
- *There is limited data on disease transmission related to the use of reusable containers.*
- *States recently modifying their food codes to increase the allowance of consumer-owned containers (see Appendix Table 1).*
- *Lack of understanding among industry, consumer, and regulatory partners for the existing allowances for reusable containers, such as those provided by the business for return*

The committee agreed the filling of customer-owned containers and third-party supplied reusable containers in retail food establishments was common despite limited allowance in the food code. The committee also agreed that local, national, and global legislation and movements to reduce solid waste from disposable food containers would increase reuse requirements and the demand for reusable container options from consumers, businesses, and environmental groups. In addition, legislative bodies will likely look toward reusable container options for food service packaging to help address issues of waste, human health, and climate change.

This document is designed to guide the safe use of reusable containers for retail food establishment operators intending to use these types of containers and to provide guidance to regulatory authorities evaluating or approving retail refilling operations. This document addresses scenarios where reusable containers are currently used, was informed by an analysis of literature and best practices related to consumer-owned containers at retail, identifies limitations in the 2017 FDA Food Code related to refilling operations, and highlights recommended guidance for potential food safety controls to help protect consumers, employees, and food if expanded reusable container and refilling operations are approved.

The document includes parameters for reducing potential contamination from direct and indirect contact when filling consumer-owned or third-party provided containers, options for a variety of foods and risk levels, and suggested equipment modifications to reduce risk. It also includes guidance for third-party providers that manage all or a portion of the circular movement of reusable containers for food retailers, such as nationally-distributed CPGs or locally-prepared food items. The committee members encourage regulatory and industry partners to refer to CFP-issued plan review guidance as future reduction of disposable food containers will potentially increase the warewashing and storage considerations for reusable serving containers.


Refilling a returnable food container?
NO
YES
Ok, have a great day!
Will it be cleaned and refilled in a regulated food processing plant?
YES
NO
ORIGIN
Who provided the container?
Establishment provided
Consumer provided
CONTAINER
Is it "designed for reuse" per 4.1 & 4.2?
Is it a beverage container?
YES
NO
YES
NO
Does it allow for effective cleaning?
YES
NO
FILL
What will it be filled with?
What will it be filled with?
Non-TCS Beverage
Other
Water
Non-TCS Beverage
PROCESS
Will it be cleaned, sanitized and visually inspected by a food employee?
Refilled by the consumer or food employee in a contamination-free process?
Refilled with a vending machine?
Is hot water available for rinsing?
YES
NO
YES
NO
NO
YES
NO
Allowed
Not Allowed
Allowed
Not Allowed
Allowed
Not Allowed

VI

CONTAINER CONSTRUCTION & CONDITION

CONTAINER CONSTRUCTION

Containers reused in a food service establishment need to meet the characteristics of sanitary construction as defined in Chapter 4-1 and 4-2 of the Food Code. They should be used as intended and temperature appropriate.

Regulators and retailers may allow for a broader array of refillable containers for raw agricultural commodities such as whole, unwashed fruits and vegetables that are intended to be washed before consumption. For example, a cloth bag may be an acceptable refillable container for produce provided it is clean and in good repair.

Consumers may fill containers such as insulated type vessels or other containers that do not support a reduced oxygen atmosphere with hot foods. Containers, such as lidded jars or heat-sealed bags, supporting a reduced oxygen atmosphere should not be refilled with hot foods. A reduced oxygen atmosphere may be created inside the container as the product cools, allowing pathogenic bacteria such as Clostridium botulinum to potentially grow in the container, presenting a significant hazard to the consumer.

Similarly, containers designed for use with cold foods should not be filled with hot foods. However, foods held at cold or ambient temperatures may be refilled into containers as the corresponding reduced oxygen environment is unlikely to occur.

CONTAINER CONDITION

In addition to multiuse construction, containers presented for reuse in a food service establishment must also be in good repair and condition as defined by Chapter 4 and 3-304.17(4)(c) of the Food Code.

Single-use articles are designed for a single, and often specific, use. Unless the food establishment has a variance of 4-502.13 to ensure damaged, cracked, or unsuitable single-use containers are not refilled, food employees may not refill a single-use container with food. However, the code does not explicitly prohibit a customer from refilling a clean container with their individual food using a contamination-free process. For example, a cleaned yogurt container might be used by a customer to fill with dry grains from a gravity-flow dispenser.

Due to the wide array of containers that may be presented for reuse, food establishments should have clear procedures to evaluate which customer owned refillable containers may be refilled in the food establishment and that single-use containers should not be refilled by a food employee without additional preventive controls as directed by the variance. Peer-reviewed scientific studies show that hazardous chemicals can migrate from plastic food packaging into food[1].

After an initial release of unbound chemicals, some refillable/reusable plastics have also been measured to migrate hazardous chemicals into food following multiple uses[2]. Current safety assessment approaches focus on a specific set of toxic endpoints (e.g. genotoxicity) and are not yet able to fully account for additional sensitive endpoints or for mixture toxicity[3]. Guidelines are therefore needed to ensure the safe reuse of plastic food packaging articles.

1. Yang et al. 2019, Qian et al. 2018
2. Tisler and Christensen 2022
3. Muncke et al. 2020v

VII

CONTAMINATION-FREE FILLING METHODS

Five methods for filling of reusable containers are included for either consumer or employee filling. Some of these methods are already common practice. These methods are examples and are not an exhaustive list of safe filling methods for reusable containers. Processes may vary and food establishments should consult with their regulatory authority to identify approval mechanisms.

METHOD 1

GRAVITY-FED DISPENSERS (SELF SERVICE, BULK GRAVITY FLOW)

Type of Equipment

Dispensers that protect bulk, unpackaged food using a baffle, chute, or other barrier to prevent access to the food. A handle or other mechanism allows the product to flow into the receiving container with no additional utensil needed.

Control Needed

Posted instructions for customer education to ensure proper use and clarity of which products may be refilled to a customer container.

Example

Continuous or portion-controlled flow dispensers used for free-flowing products like cereals, grains, nuts, ice cream and beverages. The customer would fill their refillable container by actuating a lever to allow food to flow. This would need to occur without contact between the refillable container and the dispenser.

METHOD 2

SELF SERVICE, NON-GRAVITY FED

Type of Equipment

Self-service scoop bins, spice containers, and non-TCS bulk foods that need utensils for food transfer.

Single-use articles

Such as a paper liners or utensils such as tray, scoop, or spoon may be used to ensure that customer-provided containers are not brought into food preparation areas, and that unpackaged foods do not come into contact with a contaminated utensil. Receptacles must be provided for both clean and dirty transfer utensils.

Control Needed

Displayed products shall be protected from contamination using packaging, guards, covered display containers or other effective means. Individual utensils must be provided for each bulk food storage bin and or container. Space to hold clean and dirty utensils. Staffing to wash utensils. Posted instructions for customer education to ensure proper use and clarity of which products may be refilled to a customer container.

Example

A customer provided container is filled from a bulk bin or other bulk storage container of non-TCS food. The customer would use a single-use article or transfer utensil to fill the consumer-owned container.

METHOD 3

INTERMEDIARY LINERS (FULL SERVICE, EMPLOYEE REFILLING)

Type of Equipment

Transfer liners such as a wax paper liner may be used to ensure that customer provided containers are not brought into kitchens or service areas, and that work spaces do not come into contact with containers that have not been sanitized according to FDA recommendations. Transfer liners are used on scales and to collect requested food for customers before being placed in the customer-provided container. Adhesive stickers can be provided for customer provided containers.

Control Needed

Intermediary liners shall be protected from contamination using proper storage or other effective means. Food service staff must be educated about proper handwashing procedures in the event of inadvertent hand contact with the customer provided container.

Example

A customer provided container is brought in for refill at a deli, seafood, meat counter, or similar full-service station. The employee would utilize a single-use liner to serve the food. The liner is then transferred to the customer owned container. This method limits waste significantly, while still maintaining existing food safety requirements.

METHOD 4

W/R/S FOR THE CUSTOMER (BEVERAGES & ALTERNATIVE METHOD FOR FULL SERVICE)

The customer presents a container to the food establishment for use, after any approved method for W/R/S service, or approved sanitization method, is completed prior to filling.

Control Needed

Staff must be educated on the defined acceptable condition/criteria of the customer returned container. Staff must be educated on proper cleaning, sanitizing and proper handwashing procedures associated with the handling of the customer returned containers. Intermediary container shall be protected from contamination using proper storage or other effective means.

Example A

Customer brings a container to the food establishment. The container is visually inspected to determine if they will W/R/S the container or use another approved sanitization method. The container is filled and returned to the customer.

Example B

Customer brings a beverage container in for beverages. The container is visually inspected to determine if they will W/R/S the container or use another approved sanitization method. The employee can fill an intermediary container (disposable or washable) with the beverage which is then transferred to their container.

METHOD 5

REUSABLE CONTAINER EXCHANGE — TRADE DIRTY FOR CLEAN, SANITIZED CONTAINERS

The business provides a pre-approved, exchangeable container program. Containers are provided either directly by the establishment, or by a contracted third-party vendor. Receptacles are provided for collection of used containers, and the customer is provided with (by the employee) a verified, sanitized container for use using the food establishment's process.

Control Needed

Staff must be educated about the defined acceptable condition/criteria of the customer returned container. Staff must be educated in proper W/R/S and proper handwashing procedures associated with the handling and cleaning of the customer returned container. Clean, sanitized containers shall be protected from contamination using proper storage or other effective means.

Example A

Customer returns a container provided by the food establishment in exchange for one that has been a W/R/S container. The customer will fill the clean container. The food establishment will W/R/S the returned container for a future exchange. Examples include multiuse to go boxes at a salad bar, beverage containers, lidded containers for bulk foods.

Example B

Customer brings a beverage container in for beverages. The container is visually inspected to determine if they will W/R/S the container or use another approved sanitization method. The employee can fill an intermediary container (disposable or washable) with the beverage which is then transferred to their container.

Photo top left

LOOP Haagen Daz

Photo top left

Tiffens To Go

VIII

THIRD PARTY REUSE PROVIDER

Reusing food contact packaging requires quality control measures that ensure safe and sanitary implementation.

Many food service providers do not have onsite facilities and/or capacity to adequately W/R/S reusable foodware, third party businesses have come to market providing these services as well as forward and reverse logistics services for the containers.

The following section addresses the emergence of third-party reusable foodware service providers beginning with an outline of the types of services provided and followed by considerations for ensuring safe and sanitary implementation of reusables with third-party providers.

Third-party reusables service providers are businesses that engage in any combination of the following activities:

- *Provide reusable food containers and complete circular management between sites (distribution of clean containers and collection of dirty containers);*
- *Clean and sanitize reusable containers at their site before returning to distribution inventory;*
- *Ensure sanitary handling transport for reusable containers between businesses; and*
- *Monitor reusable container condition and manage inventory accordingly.*

While there are many reusable food containers available, there are several critical differentiators between consumer provided reusable packaging, refillable packaging and reusable packaging designed for reuse service systems[4].

Reuse service systems are intentionally designed to incorporate:

- *The existence of infrastructure and reverse logistics for actual take-back, cleaning, refill and redistribution of the packaging (operated by the producers and/or a third party).*
- *A suitable incentive to return the packaging (usually a deposit, but can also be a system in which the consumer pays a fine when the packaging is not returned).*
- *A certain amount of minimum rotations (at least between 10-15 cycles with upwards of 1000+ the ideal[5])*
- *A collection rate of at least 90% of the packaging.*

THIRD-PARTY REUSE SERVICE PROVIDERS: EVALUATION AND CONSIDERATIONS

The rapidly changing third party reuse provider industry has seen exponential growth over the last several years in the number and type of reuse providers coming to market[6]. With any emerging industry it takes time for regulatory and other agencies to evaluate and implement regulations to ensure safe operations.

Currently, the degree of oversight into the reusable service provider space varies significantly across geographies. As such the following guidance offers an outline of considerations retailer's, food service providers and others contracting with a third-party reuse vendor may want to take into account.

REGULATORY OVERSIGHT (PERMIT/LICENSE/ INSPECTION)

It is critical third-party service providers follow state, county and local regulatory agency requirements. While service providers that do not handle food may not be considered a food preparation operation, they may be licensed by some agencies.

CUSTOMER OVERSIGHT (CONTRACTING BUSINESS CONSIDERATIONS)

As with any supplier consider a contract/agreement that ensures second or third-party assessments with onsite facility and/or procedural reviews including clear reporting/communication expectations and processes.

CONTAINER SELECTION

See guidance in VI of this document to evaluate the selection of reusable containers and conduct and/or use current life cycle assessments to ensure the number of reuse cycles provide the intended benefits. Setting individual minimum rotations for each packaging type would cause a very high administrative burden. According to a comparison of 32 LCA studies 10-15 rotations for all packaging materials already brings more benefits compared to single-use packaging.

4. Adopted from "Packaging Reuse vs. Packaging Prevention" Henriette Schneider, Senior Expert Circular Economy, Environmental Action Germany (DUH) Larissa Copello. Production and Consumption Campaigner, Zero Waste Europe. June 2022.2. Tisler and Christensen 2022
5. Reusable vs.Single-use Packaging. A review of environmental impacts. Downloadable at https://zerowasteeurope.eu/wp-content/uploads/2020/12/zwe_reloop_report_reusable-vs-single-use-packaging-a-review-of-environm ental-impact_en.pdf.pdf_v2.pdf

6. www.reuselandscape.org

STANDARD OPERATING PROCEDURES (SOPS)

All third-party service providers must have SOPs in place for the safe and sanitary handling of foodware throughout the container's entire journey. While SOPs for W/R/S are well known and have strong regulatory oversight and guidance, reuse service providers face a unique set of circumstances whereby many of their operations fall outside the normal bounds of regulated space yet still have implications for food safety. In particular, the reverse logistics of collecting dirty containers for transport to a facility for W/R/S, possibly in conjunction with the distribution of clean containers, requires specific attention and the development of SOPs in order to ensure minimal risk of cross-contamination and/or other health and hygiene concerns.

GENERAL CONSIDERATIONS

Well known industry standards exist for the following but we highlight them here so they are not overlooked simply because many of the third-party service providers operate outside of food handling facilities.

- *Employee health & hygiene*
- *Employee illness policy*
- *Hand washing and sinks*
- *Glove usage where appropriate (see example SOPs in appendix)*

WASHING, SANITIZING & HANDLING OF CONTAINERS

Clear guidance and regulations exist for the W/R/S and handling of containers. Please refer to local and federal food safety guidelines with particular attention to ensuring adequate space for stacking reusables after drying and storage of the reusables in secondary containers with lids for protection.

RECORD KEEPING, PROCEDURES AND PROTOCOLS

Third-party contractors and all food service operators must keep and retain adequate records related to their operation including SOP's, hazard control, audit/inspection reports, operational checklists, and if necessary for CPGs, market withdrawal and recall protocols.

REVERSE (COLLECTION) / FORWARD (DISTRIBUTION) LOGISTICS

In the appendix of this document, we offer guidance that addresses the expanded boundaries of food safety considerations required in open-network/offsite reusable foodware systems. This is an excerpt from the PR3 Washing, Sanitization & Handling of Foodware standard[7] which was designed to integrate and support diverse reuse initiatives. Below are some of the key takeaways from that extensive list.

For context it is important to note that several models have emerged for the collection of dirty containers including:

- *Staffed Returns Stations*
- *Automated/Machines*
- *Passive/Unstaffed Return Bins*

Each of these collection models will necessarily have a slightly different set of protocols but all need consistency in safe handling procedures.

All secondary and primary containers must be clearly labeled as clean or dirty. If any of the models being evaluated use the same bin for collection, storage and/or distribution, it is critical the bins and foodware are W/R/S between uses. The containers and bins should have the same level of W/R/S/ to ensure consumer safety and minimize cross contamination.

It is important to also take into account the following considerations:

- *Clean container handling procedures*
- *Storage of the foodware containers while in wash facility, during transportation, and onsite at the food service/restaurant location*

7. Partnership to Reuse, Refill, Replace Single-Use Packaging PR3 standards available for review online: PR3 Standards - RESOLVE

Photo courtesy of Boston Tea Party

IX
CONCLUSION

The above points of consideration and guidance are intended as a starting point for regulatory agencies, businesses, and other parties interested in the safe and sanitary implementation of reusable foodware systems.

While not designed to be comprehensive, this guidance offers key points of consideration when contracting with a third-party reuse provider.

As this new industry continues to mature, we encourage maintaining close contact with regulatory and industry peers on this topic, as well as monitoring for any updated food code and PR3 Reuse Industry Standards to stay abreast of and share emerging best practices.

X

RESOURCES

The following legislative activities, current reuse examples, scientific rationale, and existing guidance resources were evaluated when creating this document.

EXAMPLE MUNICIPALITY AND LEGISLATIVE REQUIREMENTS AFFECTING THE USE OF REUSABLES

California Assembly. (2019, July 12). Assembly Bill No. 619, CHAPTER 93, An Act to AMEND Sections 114121 and 114353 of the Health and Safety Code, relating to retail food facilities. California Legislative Information.

https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200AB619

City of Bainbridge Island, Washington. (2021, November 19). Ordinance NO. 2021-34, AN ORDINANCE of the City of Bainbridge Island, Washington, amending Chapter 8.24 of the Bainbridge Island Municipal Code. City of Bainbridge Island, Document Center.
https://www.bainbridgewa.gov/DocumentCenter/View/15609/Ordinance-No-2021-34-Relating-to-Chapter-824-BIMC-Waste-Reduction_Approved-110921?bidId=

City of Berkeley, California. (2019, February 19). ORDINANCE NO. 7,639-N.S. Adding Chapter 11.64 to the Berkeley Municipal Code to Adopt a Single Use Foodware and Litter Reduction Ordinance. City of Berkeley's Records Online.
https://records.cityofberkeley.info/PublicAccess/paFiles/cqFiles/index.html and searching for "7639"

Nevada Legislature. (n.d.) CHAPTER 446 - FOOD ESTABLISHMENTS. Nevada Administrative Code.
https://www.leg.state.nv.us/NAC/NAC-446.html

PUBLISHED REPORTS ABOUT FOODWARE REUSE

Boomerang Alliance. (2019). Brief on Refillables and Reusables.
https://d3n8a8pro7vhmx.cloudfront.net/boomerangalliance/pages/3903/attachments/original/1576541348/2019_Brief_on_a_Refill_Reusable_Program.pdf?1576541348

Coelho, P. M., Corona, B., Klooster, R. t., & Worrell, E. (2020, May 6). Sustainability of reusable packaging–Current situation and trends. Resources, Conservation & Recycling. Volume 6, 100037.
https://doi.org/10.1016/j.rcrx.2020.100037

Ellen MacArther Foundation. (2019). Reuse - rethinking packaging.

https://ellenmacarthurfoundation.org/reuse-rethinking-packaging

Gordon, M. (n.d.). Reuse wins – The environmental, economic, and business case for transitioning from single-use to reuse in food service. Upstream.
https://upstreamsolutions.org/reuse-wins-report

National Zero Waste Council. (2021, June). Opportunities for Reusables in Retail Settings During the COVID-19 Pandemic in Canada: A Review of Guidance and Evidence.
http://www.nzwc.ca/Documents/NZWC_OpportunitiesforReusablesinRetailReport.pdf

Pinsky, D. (2020, August 25). Reusables are Doable. Greenpeace.
https://www.greenpeace.org/usa/reports/reusables-are-doable

Prindiville, M. (2022). The New Reuse Economy: How reuse systems and services will revolutionize how we consume. Upstream.
https://drive.google.com/file/d/1QD8GufolsA7ZBFnRvt45g_BwCXD1Fea2/view

World Economic Forum. (2021, July). Future of Reusable Consumption.
https://www3.weforum.org/docs/WEF_IR_Future_of_Reusable_Consumption_2021.pdf

SCIENTIFIC ARTICLES RELATED TO REUSABLE CONTAINERS

Matthews, C., Moran, F., & Jaiswal, A. K. (2021, February 10). A review on European Union's strategy for plastics in a circular economy and its impact on food safety. Journal of Cleaner Production. Volume 283.
https://doi.org/10.1016/j.jclepro.2020.125263

Moss, E.,Gerken Kristina, Youngblood Kathryn, Jambeck Jenna R. (2022). Global landscape analysis of reuse and refill solutions. Frontiers in Sustainability. Volume 3.
https://www.frontiersin.org/articles/10.3389/frsus.2022.1006702

Qian, S., Ji, H., Wu, X., Li, N., Yang, Y., Bu, J., Zhang, X., Qiao, L., Yu, H., Xu, N., & Zhang, C. (2018, December 5). Detection and quantification analysis of chemical migrants in plastic food contact products. PLoS ONE. 13(12): e0208467.

https://doi.org/10.1371/journal.pone.0208467

Repp, K.K. and Keene, W. E. (2012, June 1). A Point-Source Norovirus Outbreak Caused by Exposure to Fomites. Journal of Infectious Disease. 205(11): 1639–1641
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3415849

Sinclair, R., Fahnestock, L., Feliz, A., Patel, J., & Perry, C. (2018, June). The Spread of a Norovirus Surrogate via Reusable Grocery Bags in a Grocery Supermarket. Journal of Environmental Health. Vol. 80, No. 10, 8-15.
https://www.jstor.org/stable/26505114

Sundqvist-Andberga, H., & Åkerman, M. (2021, July 15).

Sustainability governance and contested plastic food packaging – An integrative review. Journal of Cleaner Production. Volume 306.
https://doi.org/10.1016/j.jclepro.2021.127111

Sun, X., Kim, J., Behnke, C., Almanza, B., Greene, C., Miller, J. & Schindler, B. (2017, November/December). The Cleanliness of Reusable Water Bottles: How Contamination Levels are Affected by Bottle Usage and Cleaning Behaviors of Bottle Owners. Journal of Food Protection Trends. Vol 37, No. 6, p. 392–402.
https://www.foodprotection.org/files/food-protection-trends/nov-dec-17-sun.pdf

Williams, D. L., Gerba, C. P., Maxwell, S., & Sinclair, R. G. (2011). Assessment of the Potential for Cross-contamination of Food Products by Reusable Shopping Bags. Food Protection Trends. Vol. 31, No. 8, 508–513.
https://www.foodprotection.org/files/food-protection-trends/Aug-11-Gerba.pdf

Yang, J., Song, W., Wang, X., Li, Y., Sun, J., Gong W., & Sun, C. (2019, February 18). Migration of phthalates from plastic packages to convenience foods and its cumulative health risk assessments. Food Additives & Contaminants: Part B. Vol. 12, 151-158.
https://doi.org/10.1080/19393210.2019.1574909

GUIDANCE FOR REUSABLE CONTAINERS

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https://www.cdc.gov/nceh/ehs/ehsnet/plain_language/retail-deli-food-safety-practices.html

Consumers Beyond Waste. (2021, September). Design Guidelines for Reuse: Working Document. World Economic Forum.
https://weforum.ent.box.com/siajeqni5jr8cuocoyouxmlmwi82hegov

Consumers Beyond Waste. (2021, September). Safety Guidelines for Reuse: Working Document. World Economic Forum.

https://weforum.ent.box.com/s/6f5192886e94cq5bluk68ltm8shjgwkn

Oceana. (2022). Taking Food or Drink To Go - Best practice and policy recommendations for a plastic-free future for take-away vendors and large events.
https://europe.oceana.org/wp-content/uploads/sites/26/d_files/factsheet_taking_food_or_drink_to_go.pdf

PR3 Partnership to Reuse, Refill, Replace Single-Use Packaging. (2021, September). Reusable Packaging System Design Standards - Specifications and recommendations. RESOLVE.
https://www.resolve.ngo/site-pr3standards.htm

Reusable Packaging Association. (2016). Guidelines and Best Practices for the Safe Use of Returnable Containers in Food Supply Chains.
https://www.reusables.org/wp-content/uploads/2016/06/RPA-Guidelines-Best-Practices-for-Safe-Use-of-Returnable-Containers-in-Food-Supply-Chain.pdf

HELPFUL REUSE EXAMPLES

Following is a short list of real-life examples of reuse in various scenarios in the U.S. For a comprehensive list of reuse in the U.S. and globally, in various applications see: Reuselandscape.org

U.S. Grocery — Retail and CPG
https://exploreloop.com
https://regrocery.co
Rootszerowastemarket.com
https://nudefoodsmarket.com
Trashless.com

U.S. Restaurants and Third-Party Providers
https://justsalad.com/reusablebowl
https://dispatchgoods.com/partners#restaurants
https://rcup.com
Boldreuse.com/find-bold-reuse-locations
Deliverzero.com
Planetozzi.com

Events
https://rcup.com/
https://turnsystems.co/
https://cupzero.com/

OTHER USEFUL WEBSITES

Refill.org.uk/resources
Reuseportal.org/case-studies

XI

APPENDIX

Filling Methods

Photos courtesy of Oren Kariri

Method 1

GRAVITY FLOW

Liquids/oils/honey/peanut butter

Method 2

SCOOPS / UTENSILS

Traditional bulk foods with scoop

Method 3

TRANSFER SHEETS (EMPLOYEE / DELI COUNTER)

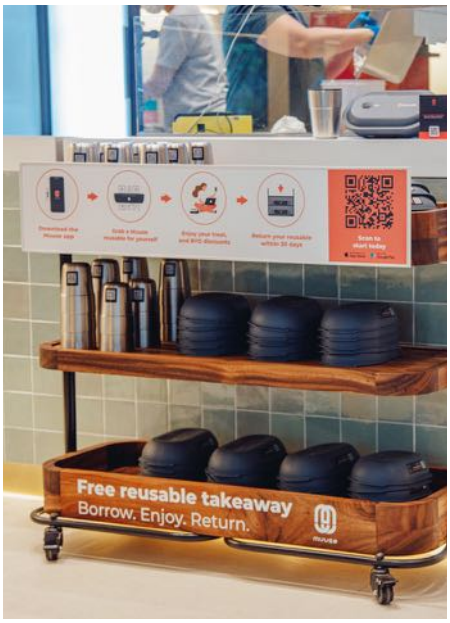
Use of a paper to prevent exposure of the equipment/packaging deli meat

Method 4

CONTAINER WASHED BY FOOD ESTABLISHMENT

Visual inspection/potential refusal of container

Method 5



CONTAINER WASHED BY A THIRD PARTY

Collection stations or transport of dirty containers/delivery of clean containers

CONSUMER OWNED CONTAINERS

WHAT CAN BE USED

Mason jar
Yogurt container
Canvas bag (produce)
Plastic bag
Metal foodware container
Plastic food storage container
Glass food storage container

WHAT CANNOT BE USED

Paper cup
Kitty litter bucket
Tin can
Styrofoam container
Pizza box

SAMPLE BEST PRACTICES FOR **SAFE HANDLING OF FOODWARE DURING REVERSE AND FORWARD LOGISTICS**

EXCERPT FROM PR3's "Washing, Sanitization & Handling of Foodware Standard."*

FOODWARE HANDLING DURING DISTRIBUTION AND COLLECTION

- Third-party employees should have food-handler certificates and receive additional training for safe container handling during collection and distribution.
- Handling procedures should be printed and kept in all vehicles, sorting, storage and washing facilities for reference.
- Distribution vehicles (trucks, vans, pedicabs, bikes, etc.) should have separated and designated dirty and clean areas or be used solely for distribution of clean containers or solely for collection of dirty containers.
- Vehicle operators that switch between collecting used foodware and distributing clean foodware should wash and sanitize vehicle storage areas between uses.
- Vehicle operators should seek further advice from local authorities on local requirements.
- Boxes of clean, food service gloves must be available in vehicles, at or near each collection point, and at the sorting, washing and warehousing facilities where employees drop off used foodware or pick up clean foodware.
- Handwashing should be provided at the receiving facility.
- Employees should use gloves to handle any used foodware or collection bins.
- Employees should wash hands and replace gloves if switching between collection and distribution roles, as detailed below.
- If a glove rips while handling dirty foodware, employee SHALL immediately wash hands and clean and sanitize any surfaces touched on the way to washing hands.
- If any clean foodware comes in contact with a dirty glove, ripped glove, or is dropped, or placed on an unsanitary surface, it SHALL be returned to a washing facility for re-washing and sanitization.

FOODWARE HANDLING DURING DISTRIBUTION

- Clean foodware must be stored and transported in FDA, EPA, NSF and/or other governing body agency approved, sealed storage/distribution containers.
- In the case that collections bins and storage/distribution containers are interchangeable, they SHALL be washed and sanitized between each use and clearly labeled as "clean" or "used.

PICKING UP CLEAN FOODWARE FOR DISTRIBUTION

Employees must follow the below steps in order.

- Employee must wash hands.
- Employee must wear gloves.
- Employee will collect cleaned, sanitized foodware that is packed and sealed in a distribution/storage container(s) from the warewashing provider.
- Employee will place distribution/storage container(s) into the designated clean section of the distribution vehicle(s).

DISTRIBUTING CLEAN FOODWARE

Employees must follow the below steps in order.

- Employee will distribute clean containers in sealed distribution/storage containers to vendors back of house.
- Employee will give storage/distribution container(s) directly to vendor employees or place it in designated areas in the back of house or behind the counter, away from customers and potential contamination until used.

** Partnership to Reuse, Refill, Replace Single-Use Packaging (PR3) standards are in the process of being accredited through the American National Standards Institute (ANSI) and are available for review online: https://www.resolve.ngo/site-pr3standards.htm*

FOODWARE HANDLING DURING COLLECTION

- Collection bins will be cleaned and sanitized with an FDA or other local governing body-approved sanitizing solution for nonfood-contact surface each time it is emptied by an employee.
- Collection bins will be cleaned and sanitized each time before being reused at a collection point.
- Collection bins will be fitted with a lid that seals the bin during collection.

NOTE: Nonfood-contact surfaces of equipment must be kept free of an accumulation of dust, dirt, food residue, and other debris. Timely cleaning and sanitizing prevent the growth of microorganisms on both food-contact surfaces of equipment and non-food contact surfaces. Additionally, proper cleaning frequency prevents the development of slime, mold, or other soil and related microorganisms on food-contact surfaces and equipment.

- Collection bins will be maintained by third-party employees, even if they are located within the vendor's space.

COLLECTING DIRTY BINS FROM COLLECTION POINTS

Employees must follow the below steps in order.

- When directly in front of the collection point, employee will wear gloves
- Employee will open the collection point housing unit and seal collection bin with lid.
- Employee will place the sealed collection bin into the designated dirty section of the collection/distribution vehicle.
- Employee will sanitize the collection point housing.
- Employee will repeat steps if multiple collection point housing units are in the same location.
- Employee will remove gloves and properly dispose of gloves in a nearby trash can and wash hands.

INSERTING CLEAN COLLECTION BINS INTO COLLECTION POINTS

- Employees will follow the below steps in order.
- o Employee will wear a new pair of clean
- o Employee will place sanitized collection bin from collection/distribution vehicle into collection point housing unit.
- o Employee will repeat steps above if multiple additional collection point housing units are in the same location.
- o Employee will remove gloves and properly dispose of gloves in a nearby trash can and wash hands.

RETURNING DIRTY FOODWARE TO SORTING OR WASHING FACILITY

- Employees will follow the below steps in order.
- o Employee will put on new gloves.
- o Employee will unload dirty reusable containers and receptacles for sorting and/or washing/sanitizing.

Photo courtesy of Muuse

SUMMARY OF RECENT FOOD CODE **ACTIVITY RELATED TO CONSUMER-OWNED FOOD CONTAINERS IN THE UNITED STATES**

After reviewing state and local codes, waste reduction bills, and a wide variety of reusable food containers commonly in use, the committee identified several themes:

Lack of awareness or enforcement of existing regulatory restrictions on reusable containers

- *The use of consumer-owned reusable containers, especially for beverages and bulk foods, is considered common practice.*
- *Lack of understanding among industry, consumer, and regulatory partners for the existing allowances for reusable containers, such as those provided by the business for return*

Increase in solid waste regulatory activities encourages consumer-owned reusable containers

- *Restrictions on single-use items are putting pressure on food establishments.*
- *Municipalities are passing regulations expressly allowing reusable food containers.*

Increase in the number businesses that support reusables in retail food services

- *Several businesses already offer services to implement turnkey reusable containers.*
- *Some jurisdictions do not consider these businesses to meet the definition of a "food establishment" and therefore do not provide regulatory oversight.*

Limited data on disease transmission related to the use of reusable containers

- *The existing requirement for filling reusable containers using contamination free process addresses any potential concerns with potential fomite transmission.*
- *Several states recently modified regulations, or are in the progress, to increase the allowance of consumer-owned containers (see Table 1).*

Table 1

Comparison of 2017 FDA Food Code, Recent State Code Modifications, and new CFP Guidance Document Related to Filling Consumer-Provided Reusable Food Containers Using a Contamination-free Procedure.

Allowances for Filling Consumer-Provided Reusable Containers

Shading indicates allowable filling options

	Method 1	***Method 2***	***Method 3***	***Method 4***	***Method 5***
	Bulk foods from protective dispensers	Bulk food using a utensil for transfer	Employee filling using intermediary liners	Employee filing washed or visually inspected container	Reusable container program washed by food establishment or third party
2017 FDA Food Code Section 3-304.17	Only non TCS beverages				No specific guidance for third party
California (2019) Section 114121(b)					Same as FDA Food Code
Illinois (2019) HB3440t					Same as FDA Food Code
Maine (2021) H.P. 641 - L.D. 885					Same as FDA Food Code
Oregon (2022) Proposed Rule for Public Comment					Same as FDA Food Code
Washington (2020) WAC 246-215-03348					Same as FDA Food Code
CFP Committee Guidance (2022)	Provides guidance	Provides guidance	Provides guidance	Provides guidance	Provides guidance for third party

SAFE USE OF REUSABLE CONTAINERS COMMITTEE

2020-2023 Conference for Food Protection

Website
www.foodprotect.org

Photo courtesy of Usefull

SURCC Meeting Summations

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

Date _11/16/2021_____

Recording on: Yes __X___ No____

Reminder of Anti-Trust Statement: Yes_X___ No ____

Roll Call: Dagny Tucker, Frank Cuarto, Eric Puente, Alison Hurysz, Jordan Ingle, Carrie Pohjola, Christina Springer, Kristina Bonatakis, Rayna Oliker, Steph Teclaw, Oren Kariri, Christina Applewhite, Susan Shelton, Gregory Lux, Jeff Clark, Kat Olson, Rayna Oliker, Sarah Kantrowitz, Steph Teclaw, Tom Arbizu, Sabrina Salinas, Traci Michelson

Quorum: Yes_X__ No___

Vote on previous conference call's Roll Call and Summation: APPROVE ____ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes_X___ No____

Summation of call proceedings

Clarifying Scenarios in which Reusable Containers may be used

- **Reusing personal containers for bulk**
- **Personal containers for take out**
- **A grocery might provide containers that are reusable**
- **Third party might be provide container**

Potential Platforms to be used during meetings (Tabled)

- Google Docs
- Food Shield Group
- Teams

Sub Committees to be created per Category

- **Before subcommittees are created per Category the Regulatory Committee will conduct foundation work to determine:**
    - What we want the recommendation to be
    - Proposed framework
    - Understanding where we are and wanting to go

- Review Food Code
    - **Regulatory Committee**
        - Susan Shelton
        - Kristina Bonatakis
        - Rayna Oliker
        - Gregory Lux

Categories to be reviewed:

- Bulk
- Delivery
    - Restaurant
    - Direct to consumer
    - Grocery (i.e. Instacart)
- Grocery
    - Ready to eat
        - TCS vs. Non TCS
    - Not ready to eat
        - TCS vs. Non TCS
- Institutional

    - Self Service Markets & Vending
- Events
    - Temporary & Mobile
    - Trade Shows
- Tabled- CPG (Consumer Product Goods)?

Meeting will be changed to 2:30 pm based on common consensus from group

ACTION ITEMS

Poll to be sent out in reference to Committee interest

- Christina Springer & Oren Kariri(expressed interest in Grocery)

Regulatory Committee will start work for next meeting

Safe Use of Reusable Containers

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

Date _____December 14th, 2021_____

Recording on: Yes __x___ No____

Reminder of Anti-Trust Statement: Yes_x___ No ____

Roll Call: ____Jeff Clark, Jessica Otto, Stephanie Teclaw, Jordan Ingle, Kat Olson, Traci Michelson, Oren Kariri, Susan Shelton, Dan Redditt, Mike Goscinski, Christina Springer, Steve Oswald, Ali Hurysz, Christine Applewhite, Kaycee Strewler, Dagny Tucker, Carrie Pohjola, Eric Puente, Sabrina Salinas, Gregory Lux, Abeid Fells, Rayna Oliker, Sarah Kantrowitz, Don Schnaffer

Quorum: Yes__x_ No___

Vote on previous conference call's Roll Call and Summation:

APPROVE _x___ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes_x___ No____

Summation of call proceedings__

1. Summation/notes are uploaded to TEAMS channel for review

2. Review of draft decision tree per current food code - Jessica Otto would like to take this back to the FDA team to validate it
3. Review of subcommittee meetings and actions
4. Discussion on how we should go about developing reusable container definitions/approvals - look for current definitions, use FDA Food Code definition - add to TEAMS any that the group comes across

(B) A take-home FOOD container returned to a FOOD ESTABLISHMENT may be refilled at a FOOD ESTABLISHMENT with FOOD if the FOOD container is:

(1) Designed and constructed for reuse and in accordance with the requirements specified under Part 4-1 and 4-2; P

5. Discussion on 12/28 meeting - cancel due to holidays - next meeting is 1/11/22

Action Items:

Jessica/FDA to review draft decision tree

Carrie/Dagny to look for reusable container definition - anyone else can upload as well

Subcommittees to continue to work and report out on the 1/11/22 meeting

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CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date __January 11, 2022_____

Recording on: Yes ___X__ No____

Reminder of Anti-Trust Statement: Yes_X__ No ____

Roll Call: In Chat

Jessica Otto, FDA
Traci Michelson - McDonald's
Jordan Ingle - Ecolab
Ali Hurysz - Whole Foods Market
stephanie teclaw- skogens festival foods
Susan Shelton, WaDOH
Bessie Politis Starbucks
Frank Curto, Territory Foods
Dilshika Wijesekera, Instacart

Christina Springer - Oregon Department of Agriculture
Sabrina Salinas- Harris County Public Health
Oren Kariri, New Seasons Market
Tom Arbizu - HEB LP
Debbie Crabtree - Fairfax County HD
Steve Oswald - Wakefern Food Corp.
Peri Pearson - Virginia Department of Health
Kristina Bonatakis - Customer
Sarah Kantrowitz - Perkins&Will
Mike Goscinski, NAMA
Christine Applewhite- future FDA :-)

Quorum: Yes_x__ No___

Vote on previous conference call's Roll Call and Summation: APPROVE ___x_ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes____ No_x___

Summation of call proceedings_____

FDA participant discussed the flow chart: Refilling Returnables 3-304.17. Container – (Food) Code doesn't care who owns the container but how it is used. Contextualize our work - needs to be food contact. Not talking about reusable bags. Filling a container with food. Q. Direct FC v. ?

Scope of diagram. Does the diagram take into account T/T in delivery

world? ___This is a great first step in helping to contextualize what this committee is trying to address. Direct to Consumer Guidance - will share for reference. Final version as a tool - may want to highlight what the rule is v the provision. Non TCS language? Annex 3. Food for thought (from FDA) scenario… can always apply for a variance for a use that is not allowed. _____Q. from committee membe Regarding the asterisk. Separate paragraphs are treated separately. They are distinct. Notes will be shared with the group who developed the diagram.

Subcommittee 1 Discussion:

Discussion around container definition. What's allowed v not allowed - decided to wait to address that. Grocery -identified departments, takeout v delivery, who would be filling a container with what - TCS v non TCS. Direct to consumer and ecommerce - compostable trays, insulation materials - want less packaging or reuse the materials. Suggestion to designate insulation materials as active or passive. Restaurants - same process of identifying who provides, who fills, etc… suggestion to use same terminology as DTC guidance._

Difficult to clean container - growlers, kombucha, etc. Salad food bars - self-service: olives, fruit, etc.

Subcommittee 2 has a bulleted list that will be added to the table that was shared by subcommittee 1. Literature review in process. Added scenarios from other countries (raw meat!) options available some grocery stores are already allowing refilling. Science articles - Norovirus outbreak traced back to reusable canvas bag that was in restroom during a vomiting (?) event.

Documents will be shared (Teams) suggestions for using other methods of sharing as well (in chat). Some subjects that didn't get a lot of interest - institution, mobile/temporary - is anyone interested in taking on those concepts. Sub committee 2 did talk about temp and mobile foods in their subcommittee meeting. _____Suggestion to change "Restaurant" to "Food Service" to incorporate more types of facilities. Let Co-chairs know if there are existing definitions in various state laws (legislated). _____Next meeting scheduled for Jan. 25 - ACTION ITEMS _____No additional action items identified.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

Date : 2/8/22

Recording on: Yes ___X__ No____

Reminder of Anti-Trust Statement: Yes_X_ No ____

In Attendance:

Dagny Tucker

Carrie Pohjola

Jessica Otto

Oren Kariri

Traci Michelson

Don Schaffner

Ali Hursyz

Rayna Oliker

Susan Shelton

Jeffrey Clark

Debbie Crabtree

Abeid Fells

Gregory Lux

Christina Springer

Frank Curto

Kat Olson

Sabrina Salinas

Sarah Kantrowitz

Kristina Bonatakis

Quorum: Yes_X_ No___

Vote on previous conference call's Roll Call and Summation:

APPROVE _X__ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes____ No_X__

Summation of call proceedings

- Dagny reiterated Committee member obligations - attendance etc.
- Approval of 1/11/22 summation
- Regulatory Sub-committee - Confirmed updates made to code visualization based on FDA comments. Will await further approval upon sharing.
- Discussion of shared scenario matrix for integration of sub-committee findings. Records sector, origin, collection, etc.
    - Traci elucidated intent for similar rows and desire to differentiate
    - Dagny explained Grocery/Manufacturer
    - Sarah K. - Raised issue of committee scope in e-commerce or grocery delivery. Does it include secondary packaging used in delivery (ex. dunnage).
    - Discussion of how to capture emerging scenarios, desire to document even if we will not make recommendations.
    - Expect some recent e-commerce, hospital, events/mobile, and "other" scenarios not yet documented
    - Noted call to add additional examples to "Literature Review"

- Reusable Container definition - first review
    - FDA code currently highlighted, but additional content is desired to accommodate other possibilities

- Governance and planning discussion
    - Assignment of small groups raised as a potential next step
    - Full group to decide scenarios for committee focus and recommendations

ACTION ITEMS

- Subcommittee members to contribute any undocumented scenarios to matrix
- Sarah K. to schedule a small-group session to visualize the documented scenarios, overlaps and patterns

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CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date __2/22/2022_____

Recording on: Yes X__ No____

Reminder of Anti-Trust Statement: Yes X__ No ____

Roll Call: In Chat

Oren Kariri, New Seasons Market

Jeff Clark, National Restaurant

Kaycee Strewler - Ecolab

Jessica Otto - FDA

Traci Michelson, McDonald's

Ali Hurysz - Whole Foods Market

Rayna Oliker - Colorado Department of Public Health & the Environment

Debbie Crabtree - Ffx HD

Abeid Fells - Houston Health Dept.

Dagny Tucker Co-chair

Christina Springer, Oregon Department of Agriculture

Sabrina Salinas- Harris County Public Health

Kat Olson - Washoe County Health District

Stephanie Teclaw - Skogen's Festival Foods

Quorum: Yes___ No___

Vote on previous conference call's Roll Call and Summation: APPROVE ___x_ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes _X_ No__

Summation of call proceedings

Note taking asssignment-

Antitrust statement – all accepted

Roll call- attendance discussion

Approval of meeting summation 2.8.2022 - Dagny Tucker 1st Rayna Oliker second approved.

Subcommittee 1 Discussion:

- Reusable refillable chart – discussion for needing revision or update.
    - Are there are FDA edits for this in teams folders
    - There is a version 3 for this chart

- FDA good with the version 3 which is most current in teams
- Used to how to use the decisions for reusables

- Scenarios – Primary Packaging
  - Based on packaging used. Consumer own, retail own, third party owned
  - Types of food (non TCS, TCS, TCS RTE); who fills (employeee, consumer)
  - Might direct fill if consumer to avoid contamination
  - Container uses (wax paper, etc) contact free manner
  - Labeling
  - Life cycle of the container -risk map
    - Moments where there are points of CCP
    - Weights and measures – more bet practices and other one for dirty and handling the clean containers.

Is there an opportunity maybe to align the language in the provision

decision tree and this scenario map? Just so we're using the same language where possible (and it's ok if there are places where it isn't possible/is different).

USDA did not supply a consultant for this committee.

ACTION ITEMS ____no additional action items identified.

Run through the scenrios with this scenario map to match of the language and see where they fall out. Which would work and ones that don't.

Align to clean up language for this scenarios and the decision tree.

1. 4 options in the "Type of Food" line... TCS -RTE (and nonRTE) and nonTCS-RTE (and nonRTE) – Susan Shelton.
2. Definition of reusable – or other definitions that need to be added for this type of setup. Example wash areas, cleaning areas.
3. Example salad, produce about literature on resusables, for deliverables
4. Draft report for committee

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date __3/22/2022_____

Recording on: Yes __X___ No____

Reminder of Anti-Trust Statement: Yes__X__ No ____

Roll Call:

Quorum: Yes___ No___

Vote on previous conference call's Roll Call and Summation: APPROVE

____ DISAPPROVE ____ (document date and results of email vote, if

applicable) APPROVE AS AMENDED ____

Agenda review: Yes____ No____

Summation of call proceedings

- Evaluation of scenarios -do we want to continue with all current

scenarios?

- Does container orientation need to be a point of emphasis?
    - Is this concern more psychological or are issues present?
- Should the cleaning guidelines for coffee mugs be implemented for all reusable food containers?
- Should we abandon the decision tree for a checklist?
- Section 114121 of the California Health & Safety Code

ACTION ITEMS: none

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date: 4/5/2022

Recording on: Yes __X___ No____

Reminder of Anti-Trust Statement: Yes___X_ No ____

Roll Call:

Frank Curto, Dagny Tucker, Jessica Otto, Tom Arbizu, Abeid Fells, Alison

Hurysz, Carrie Pohjola, Christina Springer, Debbie Crabtree, Dilshika Wijesekera, Don Schaffner, Gregory (from Iphone), Jeffery Clark, Jordan Ingle, Kat Olson, Kaycee Strewler, Kristina Bonatakis, Oren Oh-Wren, Payna Oliker, Sabrina Salinas, Susan Shelton, Traci Michelson

Quorum: Yes_X__ No___

Vote on previous conference call's Roll Call and Summation: APPROVE __X__ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes__X__ No____

Summation of call proceedings - Reviewed some of the current state guidance docs (reusable)

docs (reusable)

Discussed Filling Reusable Containers Proposed Regulatory Requirements by scenario - Question was posed by Dagy "do we go with

what we have”?

Don recommended that a “definitions” section be added.

Dagny proposed the formation of groups to focus on specific checklists and topics requiring further defining and scoping - 1. TCS 2. Non-TCS (existing) 3. Contamination-Free Process 4. Definitions (General)

Jessica shared FDA “5 Tips to Consider When Preparing Recommendations for Changes to Retail Policy”

Reviewed Committee Charges and discussed documents that will be needed to fulfill the charges (Draft Recommended Guidance Document) - 1. Categories of scenarios 2. Procedural guidelines & Performance Standards 3. Definitions 4. Recommended Code Changes (low priority)

Conducted working session to flesh out potential definitions needed (Reusable, 3rd Party Operator/washing facility, Intermediate tools, Return Receptacles (hold for further developments/clarity), Immediate

Origin, Sanitized, Validation of Cleaning,

Sanitized, Validation of Cleaning,

Discussed TCS vs. RTE scenarios and clarifying language

Discussed the efficacy of hot water rinsing requirements in respect to beverage food service practices as well as the differences in bulk dry cleaning applications - Tom noted the importance of citing existing FDA code and guidance

ACTION ITEMS:

Sub-committees to form and meeting starting next week - TCS Checklist Development (Oren, Susan, Gregory, Rayna, Debra, Dagny)

Definitions (General) - Traci (Lead), Gregory, Abeida)

Contamination-Free Process - Susan (Lead), Frank, Rayna, Dagny, Gregory, Kristina

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CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date _____May 3, 2022_____

Recording on: Yes __X___ No____

Reminder of Anti-Trust Statement: Yes__X__ No ____

Roll Call:

Carrie Pohjola, WI DATC,

Abeid Fells - Houston Health Dept.

Debbie Crabtree - Fairfax County HD

Oren Kariri, New Seasons Market OR

Dilshika Wijesekera, Instacart

Kat Olson, Washoe County

Steph Teclaw, Skogen's Festival Foods

Ali Hurysz, Whole Foods Market

Eric Puente, Whole Foods Market

Kaycee Strewler, Ecolab

Jeffrey Clark, National Restaurant Association

Greg Lux, Retail Business Services - The Giant Company

Susan Shelton WADOH

Dagny Tucker

Bessie Politis

Rayna Oliker - Colorado department of health and the environment

Tom Arbizu HEB LP - just log in and may have to leave early due to work conflict

Frank Curto, Territory Foods

Sabrina Salinas- Harris County Public Health

Donald Schaffner

Traci Michelson

Quorum: Yes__x_ No___

Vote on previous conference call's Roll Call and Summation: APPROVE

____ DISAPPROVE ____ (document date and results of email vote, if

applicable) APPROVE AS AMENDED ____

Agenda review: Yes__X__ No____

Summation of call proceedings

Carrie will cover the Guidance Doc for Safe Use of Reusable Containers

Dagny- Would we like a precedence in the document;

- Carrie suggested adding it to the Scope or Preamble/Preface;

- Don suggests writing it and determine the layout later

Add an Appendix to the document

Volunteers for the doc creation:

I

II - Susan

III – Abeid, Susan

IV – Steph, Sabrina

V – Susan, Kat

VI - Frank

VII – Rayna, Greg, Debbie, Oren, Eric, Bessie, Ali

VIII - Dagny

Due Date – Outline by next meeting in 2 weeks

Link to Team's Channel -

https://teams.microsoft.com/_#/FileBrowserTabApp/Safe%20Use%20of%20Returnable%20Containers%20Committee?groupId=8328d510-c3d3-

472b-9162-

24d7f910ebda&threadId=19:03a1c96865c945f5bb555f18a65b9834@thread.tacv2&ctx=channel

Jeff Clark Provided - Guidance for Reusable Packaging

https://sustainablepackaging.org/wp-content/uploads/2022/04/Guidance-for-Reusable-Packaging.pdf

ACTION ITEMS

Groups should work on the section they volunteered to write for the guidance doc.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

Date _5/17/2022_____

Recording on: Yes ___X__ No____

Reminder of Anti-Trust Statement: Yes__X__ No ____

Roll Call: __Gregory Lux, Sabrina Salinas, Tom Arbizu, Jessica Otto, Frank Curto, Rayna Oliker, Kat Olson, Abeid Falls, Dagny Tucker, Carrie Pohjola,

Susan Shelton, Eric Puente, Bessie Politis, Steph Teclaw, Christina Springer, Ali Hurysz, Don Schaffner, Christina Springer, Frank Curto, Jordon Ingle, Sarah Kantrowitz, Chip Manual, Beth Glenn

Quorum: Yes_X__ No___

Vote on previous conference call's Roll Call and Summation: APPROVE __X__ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes_X___ No____

Summation of call proceedings

Dagny and Bessie introduced a new member of the committee who is Beth Glenn from Starbucks.

Review of Guidance document work was discussed:

Section III-Susan and Abeid provided work done on the Introduction section which is in the Teams folder. They are relying on further sections to update the draft intro provided.

Section IV-Steph and Sabrina worked on the Definitions section based

on what was already worked on from committee work. They also included abbreviations. Steph requested if we wanted to continue to use returnable or reusable as definitions. Jessica did state the returnable was not defined in the food code. Dagny asked if there strong feelings from the group. Don Schaffner did state that we are not using a term, we don't need to define it. Dagny suggested that we continue with the term reusable.

Section V-Susan reviewed the draft language. Dagny suggested that we include containers not washed onsite what are provided by 3rd party providers.

Section VI-Frank reviewed Container construction and validation and the flow chart was developed and 3 scenarios that could present itself and the first discussed were the counter type scenario. The construction definition was also reviewed and it included some additions of complexity of the equipment. Rayna did suggest we may re-allocate the locations of decision trees and flow charts. Rayna suggested a decision tree for each of the methods provided.

Section VII-Eric reviewed the work on methods of contamination free process and discussed multiple scenarios. They were broken out into A, B, C.

Section VIII-Dagny reviewed the third party reusable containers and a document that was already developed which provided a distribution and collection. Beth did feel that this will provide some guidance for this type of activity. Dagny did review the outline for the Third party and asked if they needed to draft definitions in this section as well. The sub-committee did not come up with who would come up with the oversight of the 3rd party providers.

ACTION ITEMS:

Review the section assignments:

Group 3 no review

Group 4 review Group 5

Group 5 review Group 4

Group 6-no review

Group 7 review by Group 6

Group 8 no review

Next conference call-May 31st will be tentatively a working meeting and we will provide breakouts for the group.

Meeting was adjourned at 3:31 pm by Dagny.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date __6/14/2022_____

Recording on: Yes _____ No_X___

Reminder of Anti-Trust Statement: Yes__X__ No ____

Roll Call:

- Tom Arbizu, H-E-B
- Jeff Clark, National Restaurant Association
- Frank Curto, Territory Foods
- Abeid Fells, Houston Health Department
- Jordan Ingle, Ecolab

- Oren Kariri, New Seasons Market
- Chip Manuel, GOJO
- Rayna Oliker, Colorado Department of Public Health and Environment
- Eric Puente, Whole Foods Market
- Sabrina Salinas, Harris County Public Health
- Susan Shelton, Washington State Department of Health
- Dagny Tucker, Vessel Wrks

Quorum: Yes_X__ No___

Vote on previous conference call's Roll Call and Summation: APPROVE

__X__

Agenda review: Yes_x___ No____

Summation of call proceedings

- Reviewed guidance document and timeline. Each subcommittee chair or vice chair on call reported on status and updates.
- *Definition subcommittee*: edits were made as outlined from last meeting. Few questions remain and will be worked on by the group before the next call. After a discussion, some definitions

were kept in the section, such as “return receptacles,” and will be visited at a later date.

- *Methods of contamination subcommittee* (chapter 7): currently reviewing comments and outlining next steps now chapter. Requesting more feedback from Group 6 and will reach out for additional comments.

- *Container construction and condition subcommittee*: leveraged a lot of the existing code language but needed additional help with additional consumer-facing materials such as bags and non-ridged containers. In addition, needed to review: 1) the back-of-house decision tree when filling containers as well as a verification review; and 2) self-service for consumer product filling. Planning to coordinate with other teams for reviewing chapter.

- *Introduction subcommittee* (Group 3): a draft of the introduction is completed and will is available for review by the other groups.

- *Scope subcommittee* (Group 5): similar to the introduction subcommittee (Group 3), the scope is outlined and is requesting

review from other individuals/groups.

- Other comments/issues? None.

ACTION ITEMS

- Individuals to review other groups' language and suggest edits/changes before the next meeting.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date ____7/26/2022_____

Recording on: Yes _____ No____

Reminder of Anti-Trust Statement: Yes__x__ No ____

Roll Call: __Oren Kariri, Sabrina Salinas, Jessica Otto, Christina Springer, Jeff Clark, Juhi Williams, Kaycee Strewler, Rayna Oliker, Susan Shelton, Traci Michelson, Dagny Tucker, Tom Arbizu, Carrie Pohjola, Beth Glynn, Abeid Falls, Kristina Bonatakis, Bessie Politis, Eric Puente

Quorum: Yes__x_ No___

Vote on previous conference call's Roll Call and Summation:

APPROVE __x__ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes____ No__x__ (agenda not provided)

Summation of proceedings:

Definitions section reviewed-Sabrina had a question regarding return receptacle definition. Dagny did state in the 3rd party section 8 that it become "collection bin" instead of "return receptacle". Sabrina also suggested "origin" be changed to "source". She requested any other suggestions regarding the definitions section.

Carrie and Dagny will put the document together into one cohesive document on August 1st, which means any additions need to happen by July 31st. Please make comments so the groups know what is being asked.

Carrie did request that any reference to W/R/S in the construction

section be removed as it will be covered in the contamination free section.

Rayna asked for a review of the contamination free section and Dagny suggested a regulator review. Susan, Carrie and Christina will take a look from the regulator point. There are some concerns and conversations regarding the consumer self-serve area (buffets,etc.). Rayna did state that they did want to include more than less to put it out there.

Dagny covered the 3rd party section and made a suggestion for a pop out box on best practices and provide something more substantial. Dagny did request that folks go through the section to read through. Traci did ask Jessica for some language/verbiage protocol on recall of the container.

Dagny did acknowledge the Intro and Scope so they can read through the entire document to update the sections.

Provide illustrations, photos, precedence, etc. in you section folder and include where you would like them in the document with brackets or

highlights by August 9th. If this is provided, there will be no meeting on the 9th. Susan did suggest Kristina B.

Jessica did state that the new food code will be complete by the end of 2022. Anything that comes out of the 2023 CFP and approved will make it into the supplement.

Carrie did ask about proposing the charge of language change and asked if it is was ok to just request to align the food code language with the guidance document.

ACTION ITEMS:

- Comments for all sections are due **JULY 31st**
- Illustrations, pictures, etc. are due by **AUGUST 9th**

Next conference call: August 9th, unless the documents are provided by the committee members.

Meeting was adjourned by Dagny at 3:19 PM CT and seconded by Beth.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION

Date ____10/04/2022_____

Recording on: Yes _X____ No____

Reminder of Anti-Trust Statement: Yes_X___ No ____

Roll Call: ___Dagny Tucker, Carrie Pohjola, Jeff Clark, Bessie Politis, Kristina Bonatakis, Tom Arbizu, Abeid Fells, Ali, Hurysz, Jessica Otto, Debbie Crabtree, Greg Lux, Sabrina Salinas, Susan Shelton, Juhi Williams, Oren Kariri, Traci Michelson

Quorum: Yes_x__ No___

Vote on previous conference call's Roll Call and Summation:

APPROVE ____ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes__x__ No____

Summation of call proceedings__

Guidance document was reviewed and provided in the Teams folder. It was suggested to include the scenario matrix spreadsheet as an

appendix. Susan provided some background on the introduction changes for the group. Jessica suggested to circle back around to the charges in the introduction. The group thought it best to reference Figure 1.

Jessica did state some concerns with the number of uses or reclamation rate. But jurisdictions could include number of uses if they see fit. Origin was discussed and it was decided to swap supplier with source___

The FAQs were discussed in the container construction section VI. Jessica also suggested to not reference the food code language but perhaps cross reference to the appendix. There was some discussion on the yogurt reuse FAQ and Jessica will give it some thought. The committee left off at methods of filling.

ACTION ITEMS: Review guidance document for discussion at the next meeting.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM TEMPLATE

Date 10/18/22

Recording on: Yes _X_ No_

Reminder of Anti-Trust Statement: Yes: X No

Roll Call: In Chat

Carrie Pohjola- DATCP

Dagny Tucker-

Debbie Crabtree- Fairfax County Health

Oren Kariri- New Seasons Market

Ali Hurysz- Whole Foods

Frank Curto Alphia

Rayna Oliker- CDPHE

Kaycee Strewler- Ecolab

Traci Michelson (call in)

Susan Shelton- WADOH

Stephanie Teclaw- Festival Foods

Jeff Clark- National Restaurant Association

Greg Lux- RBS

Quorum: Yes_X__ No___

Vote on previous conference call's Roll Call and Summation: APPROVE

____ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes__X__ No____

SUMMATION OF CALL:

Review of FDA Comments:

Science Based Documentation

- Any places where we can make linkages to food safety will assist in strengthening the document
- Washington State may be the best resource for documentation
- Susan S. can provide code references to jurisdictions that allow these practices

3rd Party Delivered & Retail

- 3rd party delivered services are detailed, may need to include more on the retail side and how they handle containers/utensils, specific to collection of containers

- General consensus is that this is a routine concept for most retailers but there should be clarification on this in the document

Food Code Language Cited

- Reference of the language in the document is helpful, but not verbatim- vote determined to use references

Method 2

- Need to add control method. Greg will be adding language to account for the method to address this

FAQ's

- Lacks the safety literature back up, need full analysis for strong source citations, science behind why the recommendations we're making

- Move the FAQ's into the guidance

ACTION ITEMS:

- Put together a paragraph for retailers' collection and sanitation

document – Susan S will reach out to Starbucks Team for any pre established text they have on this

- Literature review from WA that can be placed in the document from Susan

NEXT CALL:

- Interim meeting may occur, Dagny & Carrie will meet prior and send out a note

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CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

Date __11/1/2022_____

Recording on: Yes __X___ No____

Reminder of Anti-Trust Statement: Yes__X__ No ____

Roll Call: Carrie Pohjola, Rayna Oliker, Stephanie Teclaw, Jessica Otto, Tom Arbizu, Kaycee Strewler, Gregory Lux, Jordan Ingle, Dan Redditt, Don Schaeffner, Beth Glynn, Kristina Bonatakis, Christina Springer,

Bessie Politis, Juhi, Williams, Traci Michelson, Susan Sheldon

Quorum: Yes_X__ No___

Vote on previous conference call's Roll Call and Summation:

APPROVE __X__ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes__X__ No____

Summation of call proceedings:

The committee discussed continuing and trying to complete the document for submission, overwhelming consensus was to move forward and provide the finished document to the conference. Meetings will be scheduled every Tuesday in November to complete the guidance document.

ACTION ITEMS:

Carrie will send out meeting invites to the committee for November 8th and the 22nd. In the interim, Carrie and Susan will work on including comments and edits made on the guidance document for the

committee review.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date __11/15/2022_____

Recording on: Yes _____ No____

Reminder of Anti-Trust Statement: Yes__x__ No ____

Roll Call:

Quorum: Yes___ No___

Vote on previous conference call's Roll Call and Summation:

APPROVE __X__ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes_x___ No____

Summation of call proceedings: Susan's changes to the document were reviewed and it was suggested that we also include language for the

scenarios into the introduction. The scenario matrix will be provided as an Issue to CFP. Dagny has a reference for container construction. Greg will work on Controls needed for Methods 3, 4 and 5. Photos provided from Orin will be included in the guidance by the individual formatting the guidance document. The committee will review other jurisdiction code language to provide as part of the charges.

ACTION ITEMS:

-Carrie will provide the current guidance document to Greg for review.

-Carrie will begin developing code language changes

-Greg will draft language for Methods 3.4 and 5.

-We will continue to hold weekly meetings.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date __11/22/2022_____

Recording on: Yes __X___ No____

Reminder of Anti-Trust Statement: Yes__X__ No ____

Roll Call: _Carrie Pohjola, Dagny Tucker, Jeff, Clark, Susan Shelton, Abeid Tucker, Christina Springer, Juhi Williams

Quorum: Yes___ No_X__

Vote on previous conference call's Roll Call and Summation: APPROVE ____ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes__X__ No____

Summation of call proceedings:

Dagny requested that folks who aware of code language for jurisdictions that currently allow for the reuse provide that reference within the document. CA does have language and other municipalities that have added it. It does not need to be at state level. Susan and Christina will provide an opening comment in the Contamination Free Filling Methods.

Jeff will review the guidance document and clean it up (removing comments, track changes, grammar, etc.)

The definition for reusable container definition was discussed and reviewed to replace refillable. Carrie will send out an email for comments for final vote on November 29th.

Code language was reviewed and an email will be sent out for comment for final vote on November 29th.

Actions Items:

-Carrie will send out an email for comments before final vote on the definition and proposed code language.

-Dagny will work with a designer on formatting final guidance document.

-Jeff will review the guidance document and make any needed edits.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

Date _11/29/2022_____

Recording on: Yes __X___ No____

Reminder of Anti-Trust Statement: Yes__X__ No ____

Roll Call: Carrie Pohjola, Dagny Tucker, Traci Michelson, Abeid Fells, Rayna Oliker, Debbie Crabtree, Jeff Clark, Jessica Otto, Oren Kariri, Don Schaffner, Sabrina Salinas, Steph Teclaw, Ali Hurtysz, Susan Shelton, Juhi Williams, Kristina Bonatakis, Beth Glynn

Quorum: Yes_X__ No___

Vote on previous conference call's Roll Call and Summation, November 22nd, 2022:

APPROVE __x__ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes_X__ No____

Summation of call proceedings:

-Guidance document reviewed with Jeff's editing. All edits were

reviewed and accepted.

-discussion regarding refillable v. reusable.

-Susan reviewed her language change regarding the jurisdictions that are currently or in the process of including language to allow for reusable containers. This was included in the introduction of the guidance document. Juhi suggested a table that listed each Method and what jurisdiction allows.

-Susan will work on a chart/table showing what jurisdictions allow reusables to support the food code language changes and Beth will provide background in the guidance document as well. Carrie and Dagny will include all changes in the final document.

-Rayna suggested a vote on the language and definition.

-Food code language was reviewed and approved by the committee.

ACTION ITEMS:

-Final Guidance document completion

-Beth-(1) Condense the language in the guidance document.

-Susan-(2) Add a table as an attachment to the issue OR add the table into the Public Health significance of the issue paper.

Next conference call: None, Committee has come to an end

COUNCIL III SAFE USE OF REUSEABLES COMMITTEE - REUSE SCENARIO MATRIX SAMPLE

The Council III "Safe Use of Reusables Committee" compiled an extensive matrix of scenarios in which reuseable conatiners are currently being utilized.
The following is intended as a representative sample and not an exhaustive list of all reusable container scenarios currently in practice.

GROCERY

Sector	Dept/Area	PKG Origin	PKG Collection	Cleaning Process	Filler	TCS/non-TCS	RTE/non-RTE	PRIMARY FOOD CONTACT PKG Form/Material(s)
Grocery/Delivery	Bulk Dry	Business	Return to Business	W,R,S (business)	Picker	Non-TCS	Both	Bag, box, plastic, glass
Grocery/Delivery	Produce	Business	Return to Business	W,R,S (business)	Picker	Both	Both	bag, box
Grocery/Delivery	Deli	Business	Return to Business	W,R,S (business)	Employee	TCS	RTE	plastic, glass
Grocery/Delivery	Bakery	Business	Return to Business	W,R,S (business)	Picker or Employee	Both	RTE	Bag, box, plastic, glass
Grocery/Delivery	Meat/Seafood Counter	Business	Return to Business	W,R,S (business)	Employee	TCS	Both	plastic, glass
Grocery/Delivery	Beverage/Coffe e Bar	Business	Return to Business	W,R,S (business)	Picker or Employee	TCS	RTE	plastic, glass
Grocery/Delivery	Salad/Food Bar	Business	Return to Business	W,R,S (business)	Picker or Employee	Both	RTE	plastic, glass
Grocery/Consumer	Bulk Dry - Scoop/	Consumer	Consumer	Off site (consumer)	Consumer	Non-TCS	Both	Bag, box, plastic, glass
Grocery/Consumer	Bulk Dry - Gravity	Consumer	Consumer	Off site (consumer)	Consumer	Non-TCS	Both	Bag, box, plastic, glass
Grocery/Consumer	Produce	Consumer	Consumer	Off site (consumer)	Consumer	Both	nonRTE	bag, box
Grocery/Consumer	Deli	Consumer	Consumer	Off site (consumer)	Employee	TCS	RTE	plastic, glass
Grocery/Consumer	Bakery	Consumer	Consumer	Off site (consumer)	Consumer or Employe	Both	RTE	Bag, box, plastic, glass
Grocery/Consumer	Meat/Seafood Counter	Consumer	Consumer	Off site (consumer)	Employee	TCS	Both	plastic, glass
Grocery/Consumer	Beverage/Coffe e Bar	Consumer	Consumer	Off site (consumer)	Consumer or Employe	TCS	RTE	plastic, glass
Grocery/Consumer	Salad/Food Bar	Consumer	Consumer	Off site (consumer)	Consumer or Employe	Both	RTE	plastic, glass
Grocery/Consumer	Honey/Oil/Visc ous Products	Consumer	Consumer	Off site (consumer)	Picker or Consumer	Non-TCS	Both	plastic, glass
Grocery/Manufacturer	Shelf stable retai	Manufacturer	Return to Business/Return Station	W,R,S (third party)	Manufacturer	Both	Both	Glass, aluminum, steel or plastic jars/bottles
Secondary Packaging	All areas	Consumer	Consumer	None	Consumer or Employe	Non-TCS	nonRTE	Canvas bags, single-use plastic bags, linen
Secondary Packaging	All areas	Manu/Distrib	Business/Distributor	None	Manu/Distrib	Both	Both (pack'd and unpackaged)	Generally nonFCS only - Wood, cardboard, metal

Grocery/Delivery - 3rd party would be picking the order for delivery to the consumer **Grocery/Consumer** - consumer would be at the store picking their own order and taking it home

Grocery/Manufacturer- manufacturer packages in reusable container, stocked in store per normal, consumer returns to store, manufacturer or 3rd party washes

RESTAURANT								
Sector	**Dept/Area**	**PKG Origin**	**PKG Collection**	**Cleaning Process**	**Filler**	**TCS/non-TCS**	**RTE/non-RTE**	**PKG Form/Material(s)**
Dine In/Leftovers	N/A	Consumer	Consumer	Cleaned off-site (consun	Consumer	Both	RTE	Plastic/Steel/Aluminum
Dine In/Leftovers	N/A	Business	Business	Cleaned on-site	Consumer or Business	Both	RTE	Plastic/Steel/Aluminum
Dine In/Leftovers	N/A	3rd Party	Business or 3rd Party	Cleaned off-Site (facility)	Consumer or Business	Both	RTE	Plastic/Steel/Aluminum
Consumer Take Out	N/A	Consumer	Consumer	Cleaned off-Site (consun	Consumer	Both	RTE	Plastic/Steel/Aluminum
Consumer Take Out	N/A	Business	Business	Cleaned on-site	Business	Both	RTE	Plastic/Steel/Aluminum
Consumer Take Out	N/A	3rd Party	3rd Party	Cleaned off-Site (facility)	Business	Both	RTE	Plastic/Steel/Aluminum
Delivery Take Out	N/A	Business	Business	Cleaned on-site	Business	Both	RTE	Plastic/Steel/Aluminum
Delivery Take Out	N/A	3rd Party	3rd Party	Cleaned off-Site (facility)	Business	Both	RTE	Plastic/Steel/Aluminum
Institutional: Campuses, Schools, Hospitals, other Large Dining Service Provider Institutions								
Sector	**Dept/Area**	**PKG Origin**	**PKG Collection**	**Cleaning Process**	**Filler**	**TCS/non-TCS**	**RTE/non-RTE**	**PKG Form/Material(s)**
Dine In/Leftovers	Dining Services	Consumer	Not Collected	Cleaned off-Site (consumer)	Consumer	Both	RTE	Plastic/Steel/Aluminum/Glass
Dine In/Leftovers	Dining Services	Business	Business	Cleaned on-site	Consumer or Business	Both	RTE	Plastic/Steel/Aluminum
Dine In/Leftovers	Dining Services	3rd Party	Business	Cleaned off-Site (facility)	Consumer or Business	Both	RTE	Plastic/Steel/Aluminum
Consumer Take Out	Dining Services	Consumer	Not Collected	Cleaned off-Site (consumer)	Consumer	Both	RTE	Plastic/Steel/Aluminum
Consumer Take Out	Dining Services	Business	Business	Cleaned on-site	Business	Both	RTE	Plastic/Steel/Aluminum
Consumer Take Out	Dining Services	3rd Party	Business	Cleaned off-Site (facility)	Business	Both	RTE	Plastic/Steel/Aluminum
Vending Distribution	Dining Services	3rd Party	Business	Cleaned off-Site (facility)	3rd Party	Both	Both	Plastic/Steel/Aluminum
Convenience Store Distribut	Dining Services	Business	Business	Cleaned on-site	Business	Both	Both	Plastic/Steel/Aluminum
Convenience Store Distribut	Dining Services	3rd Party	Business	Cleaned off-Site (facility)	3rd Party	Both	Both	Plastic/Steel/Aluminum
Micro-kitchen	Dining Services	Business	Business	Cleaned on-site	Consumer	Both	Both	Plastic/Steel/Aluminum
Micro-kitchen	Dining Services	3rd Party	3rd Party	Cleaned off-Site (3rd Party facility)	Consumer	Both	Both	Plastic/Steel/Aluminum
K-12 Schools	School nutrition staff	School kitchen staff	Business	stays on site or goes to centralized washing facility	school staff or outside vendor	Both	Both	Plastic/Steel/Aluminum
K-12 Schools	Outside vendor	School kitchen staff or outside vendor	3rd Party Onsite	3rd Party	Reuse service provider	Both	Both	Plastic/Steel/Aluminum
College/ University	School nutrition	School kitchen staff or outside vendor	Business	stays on site or goes to centralized washing facility	school staff or outside vendor	Both	Both	Plastic

EVENTS & MOBILE								
Sector	**Dept/Area**	**PKG Origin**	**PKG Collection**	**Cleaning Process**	**Filler**	**TCS/non-TCS**	**RTE/non-RTE**	**PKG Form/Material(s)**
Food Trucks	N/A	3rd Party	Truck/3rd Party	Cleaned off-Site (facility)	Employee	Both	RTE	
Farmers Markets	N/A	Consumer	N/A	Cleaned off-Site (consumer)	Consumer /Employee	Both	Both	Glass, aluminum, steel or plastic jars/bottles
Farmers Markets	N/A	3rd Party	3rd Party	Cleaned off-Site (facility)	Consumer /Employee	Both	Both	Glass, aluminum, steel or plastic jars/bottles
Farmers Markets	N/A	Vendor/ Farmers	Vendor/ Farmers Mark	Cleaned off-Site (facility)	Consumer /Employee	Both	Both	Glass, aluminum, steel or plastic jars/bottles
Festivals Live Events	N/A	Event Producer/\	Event Producer/Venue	On-site	Employee	Both	RTE	Plastic/Steel/Aluminum
Festivals Live Events	N/A	3rd Party	3rd Party	Cleaned On or off-Site (facility)	Employee	Both	RTE	Plastic/Steel/Aluminum
Festivals Live Events	N/A	Event Producer/\	Event Producer/Venue	On-site	Employee	Both	RTE	Plastic/Steel/Aluminum
Festivals Live Events	N/A	3rd Party	3rd Party	Cleaned On or off-Site (facility)	Employee	Both	RTE	Plastic/Steel/Aluminum
Stadiums	N/A	Venue	Venue	Cleaned off-Site (facility)	Employee	Both	RTE	Plastic/Steel/Aluminum
Stadiums		3rd Party	Venue	Cleaned On or off-Site (facility)	Employee	Both	RTE	Plastic/Steel/Aluminum
E-COMMERCE								
Sector	**Dept/Area**	**PKG Origin**	**PKG Collection**	**Cleaning Process**	**Filler**	**TCS/non-TCS**	**RTE/non-RTE**	**Primary Food Contact Materials/Secondary Packaging**
Home Delivery - Meal Prep	N/A	Producer - Online Sales	3PL Delivery person	3rd party	Producer	TCS	RTE	Bags, Boxes, Jars / Dunnage, Insulated Bags, Ice Packs, Active Refrigeration
Delivery - Corp/Home	N/A	Producer - Online Sales	Producer	3rd Party	Producer	TCS	RTE	Pans/Dunnage, Insulated Bags, Ice Packs, Active Refrigeration
Meal Prep - Storefront/HD	N/A	Producer - Commissary	Driver/Consumer	Internal	Producer	TCS	RTE	Bags, Boxes, Jars/Dunnage, Insulated Bags, Ice Packs, Active Refrigeration
Manufacturer CPGs	N/A	Manufacturer	Driver/Consumer	3rd party	Manufacturer/Producer	Both	Both	Glass, aluminum, steel or plastic jars, bottles/Dunnage, Insulated Bags, Ice Packs, Active Refrigeration
Home Delivery - Meal Prep	N/A	Producer	Driver	Internal	Procucer	Both	Both	Glass, aluminum, steel or plastic jars, bottles/Dunnage, Insulated Bags, Ice Packs, Active Refrigeration
Grocery Home Deliver	N/A	Business	Driver/In-store	Internal/3rd Party	Business	Both	Both	Glass, aluminum, steel or plastic jars, bottles/Dunnage, Insulated Bags, Ice Packs, Active Refrigeration

With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME *Disinfectant committee*

DATE OF FINAL REPORT: *12/26/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☐ ***Council II*** ☒ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Dale A. Grinstead, Anna Starobin

COMMITTEE CHARGE(S):

Issue # _2020 III-035_____

1. Review current regulations related to disinfectant use
2. Develop a guidance document for posting on the CFP website for use by retail food facility operators (chain and independent operators), food safety trainers, and regulators to explain the appropriate use of disinfectants on food-contact surfaces in a retail food facility. Suggested topics include, but are not limited to:
    a. Why to use, including an explanation of the difference between sanitization and disinfection.
    b. When to use to treat a surface exposed to viruses (e.g., vomiting and diarrheal events, foodborne illness outbreaks, COVID-19 illness(es)).
    c. What to use (e.g., EPA-registered products).
    d. How to use (e.g., in accordance with EPA-registered label use instructions).
    e. Recommended protocols for clean-up of vomiting and diarrheal events as specified in FDA Food Code section 2-501.11.
    f. List of existing resources, such as federal agency guidance documents, federal regulations (referencing specific, applicable sections), and other publicly available resources to prevent information duplication or contradiction
3. Consider recommending changes to the FDA Food Code to clarify the use of disinfectants in retail food facilities on food-contact surfaces.
4. Report progress back to the next Biennial Meeting in 2023 and the committee findings and recommendations may be presented at subsequent Biennial Meetings if necessary.

COMMITTEE WORK PLAN AND TIMELINE:

1. Review current regulations on use of disinfectants and engage with EPA to understand any upcoming changes to those regulations
2. Review literature available to inform the guidance document
3. Draft a guidance document based on the best available information
4. Draft suitable language changes for the code to include appropriate use of disinfectants in food facilities and on food contact surfaces.

TIMELINE:

1. First Draft of Guidance to be completed by July 2022
    a. Content of Guidance finalized by August 2022
    b. Guidance document finalized by October 2022
2. First draft of recommended changes to the Code by September 2022
    a. Recommended changes to the Code completed by October 2022
3. First draft of issues from the committee by end of October 2022
    a. Issues finalized by mid December 2022
    b. Issues submitted by first week of January 2023

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

1. ***Overview of committee activities:***

   The committee held by Bi-weekly calls through July 2022 and then changed to weekly calls until mid-November 2020 when the guidance and issue drafts were completed.

2. ***Charges COMPLETED and the rationale for each specific recommendation:***
   a. Review current regulations related to disinfectant use. Completed and no recommendation for this charge. Work was completed to provide information for the guidance.
   b. Develop a guidance document for posting on the CFP website for use by retail food facility operators (chain and independent operators), food safety trainers, and regulators to explain the appropriate use of disinfectants on food-contact surfaces in a retail food facility. Work completed and recommendation to accept and post the guidance is included in Issue 2 from this committee
   c. Consider recommending changes to the FDA Food Code to clarify the use of disinfectants in retail food facilities on food-contact surfaces. Work completed and recommended changes to address the use of disinfectants and to suggest changes to the vomiting and diarrheal language in the code are in Issues 3, 4, and 5.
   d. Report progress back to the next Biennial Meeting in 2023 and the committee findings and recommendations may be presented at subsequent Biennial Meetings if necessary. Work is completed and Issue one recommends disbanding the committee as all charges have been met.

3. ***Charges INCOMPLETE and to be continued to next biennium:***

   None

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☐ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***
☒ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

1. The participation of EPA in this committee was very valuable. CFP should consider that EPA be present as a consultant to Council III deliberations at the biennial meetings.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. ***Issue #1: Report – Disinfectant committee:*** **List of content documents submitted with this Issue:** ***Disinfectant committee final report and Committee member roster.***

b. ***Committee Member Roster:***

☐ ***See attached revised roster PDF*** ☒ ***No changes to previously approved roster***
"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) ***Other content documents:***

c. **List of supporting attachments:** ☐ ***Not applicable***

(1) ***Guidance for the safe and proper use of sanitizers and disinfectants in food establishments***

1. ***Committee Issue #2: Use of Disinfectants in a Food Establishment Guidance.*** **List of content documents submitted with this Issue*: Guidance for the safe and proper use of sanitizers and disinfectants in food establishment.* Supporting documents: *Disinfectant committee final report and Committee member roster.***

2. ***Committee Issue #3: Recommended Food Code Changes to Address Use of Disinfectants in Food Establishments.*** **List of content documents submitted with this Issue*: None.* Supporting documents*: Guidance for the safe and proper use of sanitizers and disinfectants in food establishment***

3. ***Committee Issue #4: Recommended Food Code Changes to correct unclear language in the annex on hand antiseptics.*** **List of content documents submitted with this Issue*: None.* Supporting documents*: Guidance for the safe and proper use of sanitizers and disinfectants in food establishment***

4. ***Committee Issue #5: Updates to the code to address the use of disinfectants during body fluid clean-up.*** **List of content documents submitted with this Issue*: None.* Supporting documents*: Guidance for the safe and proper use of sanitizers and disinfectants in food establishment***

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CONFERENCE FOR FOOD PROTECTION

GUIDANCE FOR THE SAFE AND PROPER USE OF SANITIZERS AND DISINFECTANTS IN FOOD ESTABLISHMENTS

Executive summary

NOTE: The guidance in this document does not create or confer any rights for, or on, any person and does not operate to bind public health officials or the public. This guidance does not have the force and effect of law and thus is not subject to enforcement. EPA, FDA and CDC served as advisors participating in committee discussions as the guidelines were developed. Further, this guidance does not establish regulatory requirements and the recommendations contained herein are not intended to supplant, or otherwise serve as, the rules and regulations applicable to food establishments in a given Federal, State, local, or tribal jurisdiction. The contents of this document are solely the responsibility of the authors and does not necessarily represent the views of their employers.

The Conference for Food Protection (CFP) convened the 2020 Biennial Meeting using a virtual format in August 2021; the meeting was originally scheduled for April 2020 but was delayed due to the COVID-19 pandemic.

Throughout the COVID-19 pandemic, the use of disinfectants significantly increased in food establishments; however, available guidance for safe and proper use of disinfectants at retail was limited and occasionally conflicting. It was not always clear to food industry and regulatory sectors which products were appropriate for use in order to reduce or inactivate microorganisms of concern.

This ongoing confusion resulted in the submission of late-breaking Issue 2020-III-035 pertaining to the use of disinfectants in retail food establishments and the concern that disinfection is not addressed in the 2017 FDA Food Code (Food Code). As a result of Council III deliberation in August 2021, a “Disinfection of Food-Contact Surfaces Committee” was formed with charges including charge 1) propose disinfection language for the Food Code, and charge 2) develop a guidance document for food establishments on when and how to safely apply disinfectants on food contact surfaces as needed to reduce or eliminate disease-causing microorganisms (e.g., bacteria, fungi, and viruses) during the clean-up of bodily fluid events, foodborne illness outbreaks, and the COVID-19 pandemic.

The committee was comprised of representatives from academia, local/state/federal regulatory agencies, and the food industry. Consultants from FDA, EPA and CDC were advising the committee throughout the entire process of guidance document preparation. The committee met weekly for approximately 9 months to fulfill its charges, including the completion of this guidance document.

The committee agreed it was critical to provide guidance on the use of sanitizers and disinfectants, to clarify differences between these categories of products, when and how it is appropriate to use them to control disease-causing pathogens. A review of important regulatory requirements and safeguards, such as EPA registration and product label information, is also provided in this document.

The purpose of this guidance document is to increase knowledge and awareness about the proper use of sanitizers and disinfectants in retail food establishments. When used

properly, sanitizers and disinfectants are powerful and complimentary tools that can keep consumers safe from pathogens that cause infectious disease.

INTRODUCTION

The COVID-19 pandemic heightened attention to the importance of cleaning, sanitizing, and disinfecting of surfaces in food establishments. In response, many governmental agencies governmental agencies, such as the Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), and United States Department of Agriculture (USDA) began emphasizing the need to frequently disinfect high-touch surfaces.[1] In many instances, high-touch surfaces are classified as nonfood-contact surfaces, which according to the US FDA Food Code 2017 must be cleaned. Although the 2017 Food Code does not recommend disinfecting or sanitizing non-food contact surfaces, there are occasions when it is appropriate to use an antimicrobial treatment on those surfaces. Disinfectants are used less frequently in food establishments which has led to some observations of misunderstanding and misuse of these antimicrobials.

In addition to disinfectant use during unusual circumstances such as outbreaks and pandemics, there are other occasions when disinfectant use is appropriate in the retail food and food service industry (hereafter referred to as food establishments). Disinfectants should be used during clean-up of bodily fluid spills as well as during foodborne outbreaks. Other occasions when disinfectant use is appropriate in food establishments is when the organism to be controlled is not controlled by available sanitizers or when a higher level of microbial control is desired.

Clearly, there are a number of occasions, some of them quite common, when disinfectant use is appropriate in food establishments. Although sanitization is a routine, common

practice defined in the U.S. Food and Drug Administration (FDA) Food Code, disinfection is not addressed in the Food Code. Sanitizers and disinfectants may both be present in food establishments, but sanitizers are more frequently used in those environments. It is important to emphasize that sanitizers and disinfectants are **not** interchangeable products and care must be taken to ensure they are not inadvertently misused. Consequently, end users need to understand the differences between sanitizers and disinfectants as well as when, why, and how both can be used in food establishments. The aim of this guidance is to increase knowledge about proper use of sanitizers and disinfectants in food establishments to facilitate proper use. When used properly, sanitizers and disinfectants are powerful and complementary tools that can keep food establishments safe from pathogens that cause infectious disease.[1]

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DEFINITIONS

Note: These definitions are intended for use only in this guidance document. They are not exact references of U.S. Environmental Protection Agency (EPA) or US Food and Drug Administration (FDA) definitions and are included here solely to aid the reader of this guidance document.

ACTIVE INGREDIENT: chemicals in a pesticide product (e.g., surface sanitizer or disinfectant) that act to control the pests.[1]

ANTIMICROBIALS: substances or mixtures of substances used to destroy or suppress the growth of pathogens (e.g., bacteria, viruses, or fungi) on inanimate objects and surfaces. While hot water and steam can be used to treat surfaces, they are not legally defined as antimicrobials.

BACK OF THE HOUSE: any place that the customers cannot go within a FOOD ESTABLISHMENT, such as kitchens, food preparation areas and storage areas.

DETERGENT-SANITIZER: surface sanitizer that can also be used as a cleaner

DISINFECTANT: substance, or mixture of substances that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment.[3]

EPA ESTABLISHMENT NUMBER: the EPA assigns a unique number to each establishment that produces any pesticide, active ingredient, or pesticide device. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that each producing establishment must place its EPA ESTABLISHMENT NUMBER on the label or immediate container of each pesticide, active ingredient or device produced.[4]

EPA REGISTRATION NUMBER: all EPA-registered DISINFECTANT and SANITIZERS must have an EPA REGISTRATION NUMBER (EPA Reg. No.). The EPA Reg. No. of a product can be more useful than its brand name for identifying the EPA-registered product. Alternative brand names have the same EPA Reg. No.

FOOD-CONTACT SURFACE: a surface of equipment or a utensil with which food normally comes into contact or a surface of equipment or a utensil from which food may drain, drip or splash into a food, or onto a surface normally in contact with food.[5] Term is abbreviated as FCS in this document.

FOOD-CONTACT SURFACE SANITIZER: substance, or mixture of substances, that reduces the microbial population in the inanimate environment by significant numbers but does not destroy or eliminate all microorganisms.[3]

Note: *The FDA defines the process of sanitization but does not provide a definition for SANITIZER. The EPA, however, does define a surface sanitizer. The abbreviated version of EPA definition (above) will be used in the context of this guidance document.*

FOOD ESTABLISHMENT**:** operation that stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption.[5]

FRONT OF THE HOUSE: any place where customers can go within a FOOD ESTABLISHMENT, such as the dining room, bar, patio, areas open to shoppers, checkout counters and bathrooms.

INERT INGREDIENT: substances in addition to the ACTIVE INGREDIENT(s) referred to as “inert ingredients” or sometimes as “other ingredients.” An INERT INGREDIENT generally is any substance (or group of similar substances) other than an ACTIVE INGREDIENT intentionally included in a pesticide product. Examples include emulsifiers, solvents, carriers, aerosol propellants, fragrances, and dyes.[3]

MASTER LABEL: contains claims and directions for all approved uses for a given product and all associated required labeling. All other labeling for a given product must not contain any text beyond that which is approved in the master label. This label goes on file with the EPA once it is stamped “accepted.”

NONFOOD-CONTACT SURFACE: surfaces that typically do not come in contact with food. Term is abbreviated as NFCS in this document.

NONFOOD-CONTACT SURFACE SANITIZER: substance, or mixture of substances that when evaluated for efficacy by the EPA, is sufficient to yield a reduction of 3 logs within 5 minutes on a NONFOOD-CONTACT SURFACE, which is equal to a 99.9% reduction.

PRODUCT LABEL: written, printed, or graphic matter on, or attached to, the pesticide container or device or any of its wrappers.[4]

PESTICIDE: any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.

DIFFERENCES BETWEEN DISINFECTANTS, FOOD-CONTACT SURFACE (FCS) SANITIZER, AND NON-FOOD-CONTACT SURFACE (NFCS) SANITIZERS

DISINFECTANTS, FCS and NFCS SANITIZERS are different classifications of ANTIMICROBIALS used for different purposes. Understanding those differences is important when selecting the correct antimicrobial product to achieve the desired outcome.

Contact Time

One common difference between surface SANITIZERS and DISINFECTANTS is contact time. Most FCS SANITIZERS are tested at 30- and 60- seconds contact time, but a 1-minute contact time is listed on the PRODUCT LABEL, whereas contact times for NFCS SANITIZERS are 5 minutes or less. DISINFECTANTS have a wider range of contact times – from less than 60 seconds up to 10 minutes. Moreover, some DISINFECTANTS have different contact times for different microorganisms and product use concentrations. For example, a DISINFECTANT may have one contact time against human norovirus, a different contact time when used against coronaviruses, and a third contact time when used against *E. coli.* The contact times can also vary depending on use concentrations as some DISINFECTANTS can be used at more than one concentration. DISINFECTANT manufacturers can assist in selecting the correct DISINFECTANT to ensure microorganisms of concern are controlled and the DISINFECTANT is properly used. It is important to review the PRODUCT LABEL to verify that the correct contact time and DISINFECTANT concentration are used to control microorganisms of concern.

Chemical Concentration

Another common difference between SANITIZERS and DISINFECTANTS is the ACTIVE INGREDIENT concentration which is often higher and sometimes different in DISINFECTANTS than in most surface SANITIZERS. This higher concentration is one of the reasons DISINFECTANTS can achieve a higher level of ANTIMICROBIAL efficacy compared

to surface SANITIZERS. In most cases this higher level of ACTIVE INGREDIENT exceeds the level that can be safely applied to a FCS without a follow-up rinse. Furthermore, some INERT INGREDIENTS that do **not** meet the statutory limit outlined in 40 CFR 180 might be used in a DISINFECTANT, making the DISINFECTANT inappropriate for a no-rinse FCS application.[6] Therefore, **it is critical to carefully review PRODUCT LABELS for all registered surface SANITIZERS and DISINFECTANTS to ensure their safe and proper use.**

Cleaner-Disinfectants and Detergent-Sanitizers

Some DISINFECTANTS are designed to be used on surfaces without prior cleaning. These products are referred to as "cleaner- DISINFECTANTS" or "one-step DISINFECTANTS." They contain ingredients that enhance product's ability to remove soil from surfaces, often in a single cleaning and disinfection step. To ensure an additional soil load does not interfere with the DISINFECTANT'S antimicrobial performance, efficacy testing is done with 5% soil added to the test solutions.[7]

FCS SANITIZERS are designed to be used on a clean surface. When using DETERGENT-SANITIZERS, often called cleaner-SANITIZERS, that can also be used as a cleaner, it is important to ensure the product is first used for cleaning, followed by a repeat application on the precleaned surface. FCS sanitization is always a multi-step procedure. The Food Code states that if a DETERGENT-SANITIZER is used to clean a FCS and the same DETERGENT-SANITIZER is used to SANITIZE the surface, then no rinse is required between cleaning and sanitizing that FCS (Food Code 4-501.115).[5] However, it is important to remove soil during the cleaning process. Carefully review PRODUCT LABELS for all registered surface SANITIZERS and DISINFECTANTS to ensure safe and proper use.

Surface DISINFECTANT/ Surface SANITIZER Combination Products

Some products can be used as both a surface SANITIZER and a DISINFECTANT. These ANTIMICROBIALS come in two broad categories.

Those with different concentrations and/or contact times for disinfection and sanitizing

Many surface SANITIZER products have DISINFECTANT claims on the EPA-registered PRODUCT LABEL. Surface SANITIZERS and DISINFECTANTS may have different contact times and concentrations. For example, a quaternary ammonium-based product may be used at 200 PPM with a 60 second contact time and be an effective FCS SANITIZER. That same product, however, may be used at 600 PPM with the same or different contact time and be registered as a DISINFECTANT. While FCS SANITIZERS are meant to be used on FCS without a follow-up rinse, that is not always the case for DISINFECTANTS. Some DISINFECTANTS require a rinse step following application. Check the PRODUCT LABEL and consult with the chemical manufacturer to verify correct use of the chemical.

Those with the same concentration and contact time for disinfection and sanitizing

In recent years, a handful of DISINFECTANTS known as no-rinse DISINFECTANTS have been introduced to the market. These DISINFECTANTS have passed EPA Product Performance Test Guidelines as a DISINFECTANT and are designed within the limits outlined in 40 CFR 180, which permits them to be used on FCS without a follow-up rinse.[6] These products may also have FCS SANITIZERS claims. Specific claims vary for these products and so do their contact times. Refer to the PRODUCT LABEL to ensure these products are used correctly. Manufacturers of these chemicals can provide guidance on appropriate use of these no-rinse DISINFECTANT products.

Products with biofilm claims

Biofilm kill claims are primarily allowed for DISINFECTANTS. Because these claims were only recently allowed, only a few DISINFECTANTS have that claim. A limited number of surface SANITIZERS have biofilm claims, some of which were granted prior to current, more strict requirements.

Pesticidal (antimicrobial) devices

Sometimes a device is used to sanitize or disinfect surfaces. In some cases, the device may generate sufficient chemical to kill microorganisms on a surface. In other cases, the device may inactivate microorganisms via a physical process. EPA refers to these devices as pesticide devices. Examples of generated chemical antimicrobial agents include hypochlorous acid, ozone and ozonated water, and chlorine dioxide. Devices that inactivate microorganisms via non-chemical means include UV light and high temperature. The EPA does not require registration of pesticide devices. However, these devices must be produced in EPA-registered establishments and some states do require registration of pesticide devices, and a few require efficacy data for submission.

The data plate on the device must list the establishment number. ***"***Because there is no EPA registration of solutions generated and used on-site, the user of the equipment should look to the equipment manufacturer for data to validate the efficacy of the solution that is generated by the device as well as the conditions for use of the solution" (Food Code Annex 3 7.204-11 Sanitizers, Criteria).[5] There are several companies which choose to register end use solution, following EPA required efficacy test protocols.

Maintaining and cleaning devices used for on-site generation of sanitizing solutions in accordance with manufacturer specifications help ensure SANITIZERS are generated in the form and concentration for which their efficacy was assessed.

WHICH SURFACE SANITIZERS OR DISINFECTANTS TO USE?

The U.S. EPA is the regulatory authority for ANTIMICROBIALS like surface SANITIZERS and DISINFECTANTS used in FOOD ESTABLISHMENTS. Therefore, **only** EPA-registered surface SANITIZERS and DISINFECTANTS can be used in FOOD ESTABLISHMENTS.

Considerations for choosing to use a surface SANITIZER or DISINFECTANT:

When choosing a surface SANITIZER or DISINFECTANT multiple factors should be considered, such as:

- Microorganisms against which the surface SANITIZER or DISINFECTANT are effective against
- Contact time required for surface SANITIZER or DISINFECTANT to be effective
- Compatibility of surface SANITIZER or DISINFECTANT with surfaces being treated
- Safety
- Cost
- Tolerance to hard water
- Stability/shelf life
- Effectiveness in presence of soil

Table 1. Attributes of common SANITIZER and DISINFECTANT ACTIVE INGREDIENTS[1]

ACTIVE INGREDIENT	SPECTRUM OF ACTIVITY[A]	ADVANTAGES	DISADVANTAGES
Free available chlorine, hypochlorous acid, sodium hypochlorite	Vegetative bacteria and enveloped and nonenveloped viruses	• Broad spectrum of activity • Good hard water tolerance	• May be incompatible with some soft metals • Rapidly inactivated by soil • Limited shelf life that varies with pH • Can generate chlorine gas if mixed with acid or ammonia
Quaternary ammonium compounds (QAC)	Vegetative bacteria and enveloped and nonenveloped viruses	• Broad spectrum of activity • Compatible with most surfaces • Very stable with	• Can be inactivated by hard water • Can be inactivated by some surfactants used in cleaners • May bind to cleaning cloths,

ACTIVE INGREDIENT	SPECTRUM OF ACTIVITY[A]	ADVANTAGES	DISADVANTAGES
		long shelf lives • Less reactive with soil	reducing active levels in a solution • Food Code requires use above 24°C (75°F)
Peroxides	Vegetative bacteria and enveloped and nonenveloped viruses	• Minimal residue • Formulated for hard water tolerance	• May require elevated levels to be effective against catalase-positive organisms. • May be incompatible with some soft metals
Peracids	Vegetative bacteria and enveloped and nonenveloped viruses	• Broad spectrum of activity (note that antifungal activity may require a mixture of peracid) • Compatible with most surfaces • Minimal residue	• Pungent odor • Limited shelf life • Inactivated by some types of soil • May be incompatible with some metals
Acid anionics	Vegetative bacteria and enveloped and nonenveloped viruses	• Compatible with residual cleaners if rinsing is incomplete • Good cleaning performance • Good material compatibility • Good hard water tolerance	• May be incompatible with some soft metals and some plastic surfaces • Can generate chlorine gas if mixed with chlorine products
Alcohol	Vegetative	• Can be used in	• High flammability

ACTIVE INGREDIENT	SPECTRUM OF ACTIVITY[A]	ADVANTAGES	DISADVANTAGES
	bacteria and enveloped viruses	environments where aqueous SANITIZERS or DISINFECTANTS are undesirable • No residue • Limited impact on organic matter	• Some alcohols display poor compatibility with certain plastic materials • RTU format only

Chlorine and quaternary ammonium compound-based (QAC) SANITIZERS are the most commonly used on FCS in FOOD ESTABLISHMENTS. The EPA-registered PRODUCT LABEL will include critical information (e.g., kill claims and contact times) for various use concentrations of the product.

Material Compatibility

Material compatibility profiles for SANITIZERS and DISINFECTANTS are important to consider when selecting a product. The material compatibility profile is highly dependent on not only the product's ACTIVE INGREDIENT, but also the total formulation, as well as an application method for the SANITIZERS and DISINFECTANTS. Over time, surfaces can become damaged if exposed to repeated use of a surface SANITIZER or DISINFECTANT incompatible with the surface. Repeated use of incompatible surface SANITIZERS or DISINFECTANTS can lead to micro-abrasions, cracks, and pitting that can make cleaning, sanitizing, and disinfecting more difficult to accomplish as microorganisms can "hide" in these imperfections and eventually form biofilms.[8]

While every FOOD ESTABLISHMENT is unique, some generalizations can be made. Stainless steel, a common material used, is usually resistant to a variety of chemicals. However, repeated use of strong oxidizers (e.g., chlorine-based), may cause pitting to occur over time. Soft metals (e.g., aluminum, brass, bronze, copper) are highly sensitive

to pH extremes. Surface SANITIZERS and DISINFECTANTS with alkaline or acidic formulations may accelerate oxidation of these soft metals. Plastic materials found in FOOD ESTABLISHMENTS vary widely in their chemical composition and construction. Some solvents used in surface SANITIZER and DISINFECTANT formulations may be incompatible with various plastic materials. The chemical manufacturer is an excellent resource for determining the material compatibility profile of a surface SANITIZER or DISINFECTANT. Often, the material compatibility profile is listed on the PRODUCT LABEL.

Dispensing Considerations

DISINFECTANTS and surface SANITIZERS can be dispensed using three different dispensing platforms. The goal of the dispensing platform is to safely deliver the product in its registered use concentration.

Automatic dilution of concentrates. The most frequently dispensed solutions in FOOD ESTABLISHMENTS are concentrates. Concentrates are diluted at the point of use via automatic dispensers. These concentrates have a variety of advantages. Minimal packaging size provides cost savings during shipping to the FOOD ESTABLISHMENT and products are often less expensive when diluted at the point of use (versus ready-to-use products). It is extremely important that automated dosing and dispensing systems are set up and installed appropriately to consistently deliver an accurate chemical dose. Poor dosing control can lead to a variety of challenges, such as increased risk of health hazards related to exposure by employees, use of an ineffective product, and regulatory concerns (potentially even fines). Because these systems can degrade over time, periodic checks and/or servicing by a chemical provider are recommended.

Manual dilution of concentrates. Manual dosing systems are rarely used due to issues with under- and over-dosing. These systems are more prone to human error and typically used in unique situations, such as tight spaces and boil water advisories.

Ready-to-Use. Ready-to-use (RTU) surface SANITIZERS and DISINFECTANTS do not require dilution prior to use. Advantages of RTU products include ease of use, since they do not require mixing, and limited/reduced risk related to under- or overdosing of the

product. The main disadvantage of RTU products is cost - usually they are more expensive.

WHEN TO USE A SURFACE DISINFECTANT VS. A FCS SANITIZER?

When is use of a disinfectant the right choice?

Given the differences between surface SANITIZERS and DISINFECTANTS, it is reasonable to ask when use of a DISINFECTANT is the right choice for a FOOD ESTABLISHMENT.

There are several situations when a DISINFECTANT as opposed to a surface SANITIZER should be used:

Product user suspects surfaces are contaminated with a virus or fungus

As mentioned above, a key difference between surface SANITIZERS and DISINFECTANTS is that SANITIZERS are generally not approved for use against spores, mycobacteria, viruses and fungi, such as mold or mildew. Currently with few exceptions, the EPA does not allow these claims for surface SANITIZERS, which compels the user to control these types of microorganisms with a DISINFECTANT. The PRODUCT LABEL lists microorganisms and conditions of use (concentration, contact times, application methods, etc.) under which surface SANITIZERS and DISINFECTANTS are effective.

Note: the EPA is reviewing its policy, and, in the future, more SANITIZERS may have virucidal claims.

To achieve a higher level of antimicrobial efficacy

Another scenario when a DISINFECTANT may be used instead of a surface SANITIZER is when a higher level of efficacy is desired. Cleaning up bodily fluids is a common example of such situation. Many microorganisms of concern are viruses (e.g., HIV, norovirus, hepatitis, etc.) so a DISINFECTANT is likely to be a better choice than a surface SANITIZER. Use of a DISINFECTANT may be appropriate when cleaning restrooms due to the potential presence of high levels of human pathogens, such as viruses. Another

situation when DISINFECTANTS may be a better option is when cleaning high-touch surfaces, such as door handles, touch screens for credit card readers, push buttons for dispensers, chairs, light switches, etc.

When a surface SANITIZER effective against the microorganism(s) of concern is not available.

In addition to efficacy against viruses and fungi, there may be bacteria that need to be controlled that surface SANITIZERS are not commonly tested or effective against. Examples include *Pseudomonas* spp. or *Mycobacterium* spp*.* Many DISINFECTANTS are effective against a broad range of bacteria. Similarly, when biofilm control is a priority, a DISINFECTANT (with few exceptions) is likely the correct choice. Check the PRODUCT LABEL for the complete list of organisms against which a DISINFECTANT is effective to verify correct product selection. Chemical manufacturers can assist with product selection.

Another instance when DISINFECTANTS should be used is when required by a regulatory authority. It is important to make sure the required use is in compliance with the EPA-registered PRODUCT LABEL.

When is use of a surface SANITIZER the right choice?

A FOOD-CONTACT SURFACE SANITIZER is recommended for use by the Food Code.[5] A surface SANITIZER is the default option for most applications in FOOD ESTABLISHMENTS. Use a surface SANITIZER if (1) it is effective against the microorganisms of concern and listed on the EPA-registered label, and (2) it is required by a regulatory authority. Ensure product used is in compliance with the EPA-registered label. Select an FCS SANITIZER or NFCS SANITIZER depending on the nature of the surface being sanitized.

Other considerations:

Several other factors can impact whether to use a DISINFECTANT or a SANITIZER:

- DISINFECTANTS tend to be more expensive than surface SANITIZERS because they are often used at higher concentrations than surface SANITIZERS and may

have more complex formulations. They typically have more microorganisms on the label, which are costly to test.

- Most DISINFECTANTS have a relatively complicated process for use on FCS. After DISINFECTANT application on an FCS, the surface must be rinsed if required by a PRODUCT LABEL. Surfaces must remain wet with SANITIZERS or DISINFECTANTS for the required contact time specified on the PRODUCT LABEL. Many DISINFECTANTS have longer contact times than surface SANITIZERS. Because of the long contact time during which the surface must remain wet with DISINFECTANT, multiple applications of DISINFECTANT to the surface may be needed.
- Most DISINFECTANTS and surface SANITIZERS are not interchangeable. Use patterns highlighted above create challenges regarding proper use of a product. When both surface SANITIZERS and surface DISINFECTANTS are available in a FOOD ESTABLISHMENT, it is easy to misuse them. This could result in an unintentional contamination or adverse health effects for the user or public. Therefore, employee training on proper use of SANITIZERS and DISINFECTANTS is important.
- The relatively high concentration of ACTIVE INGREDIENTS found in many DISINFECTANTS as well as other ingredients can present a safety profile different from FCS SANITIZERS. Proper Personal Protective Equipment (PPE) should be worn if required on the product Safety Data Sheet or the PRODUCT LABEL. For guidance on PPE requirements, contact the chemical manufacturer and provide training for employees as needed.

HOW TO USE DISINFECTANTS IN FOOD ESTABLISHMENTS

When using an EPA-registered DISINFECTANT, read the PRODUCT LABEL and follow the directions, including the application method.

The EPA regulatory process requires that all registered DISINFECTANTS legally sold in the United States include directions for use to ensure efficacy without resulting in adverse effects on the environment.[9]

DISINFECTANT procedures and application types can vary based on the purpose of the procedure implementation, which is why it is important to read and follow the instructions on the PRODUCT LABEL. Deviating from the PRODUCT LABEL use instructions, including application methods, is illegal and could be unsafe.

Reading EPA-registered product labels

PRODUCT LABELS display the most relevant and useful information for the end user. It is important to note that a product can be sold under a different name than the one that appears on the MASTER LABEL. Key parts of the PRODUCT LABEL include:

EPA registration number

On the PRODUCT LABEL, the registration number is displayed as “EPA Reg. No.” followed by two or sometimes three sets of numbers. Because products may be marketed and sold under different brand names, they might have the same EPA REGISTRATION NUMBER. Products made by a supplier or distributor (i.e., not a manufacturer) have three sets of numbers. The last set of numbers identifies the supplier, who is not the same as the manufacturer. If the first two sets of numbers match a registration number that is on EPA lists (e.g., List G or List N), the product is equivalent to the listed product. For example, if “EPA Reg. No. 12345-12” is on List N, then all products labeled EPA Reg. No. 12345-12-#### are an equivalent product, because the last set of numbers identifies the supplier or distributor.

Format

The PRODUCT LABEL specifies if the product is RTU (i.e., does not require any dilutions) or if it is a concentrate (i.e., liquid or powder requiring dilution as specified by the label before use).

Directions for use

Use instructions present valuable information on dilution, contact time (see below), and whether the product can be sprayed, wiped, mopped and so on. They also list cleaning steps and whether a potable-water rinse is required.

Dilution

A concentrated product will have precise instructions for use, listing ounces per gallon and parts per million (ppm) to help the end user achieve the correct concentration. The efficacy of some antimicrobial products, such as SANITIZERS and DISINFECTANTS, may be affected by the water hardness used to prepare diluted product. Because of this, which is why manufacturers test efficacy of the product in hard water. The label will indicate the water hardness level at which efficacy testing was done, indicating the highest water hardness to be used when the product is diluted. Water hardness varies throughout the United States. For information about a specific location, contact the local health agency or local water utility.

Contact time

The contact time indicates how long the surface must be in contact with a surface SANITIZER or DISINFECTANT. Similarly, to an FCS SANITIZER, for a DISINFECTANT to be effective, the surface must be wet with the product for the entire contact time. Importantly, some DISINFECTANTS with longer contact times may need to be applied more than once to achieve the full required contact time.

Contact times can vary based on product type, target microorganism, or specific use/application. Required contact time for FCS SANITIZERS is typically one minute, apart from sanitizing in a dish machine[5]; required contact time for NFC surface SANITIZERS can be up to 5 minutes. DISINFECTANTS can have various contact times for different bacteria, viruses, or fungi but generally do not exceed 10 minutes. If a PRODUCT LABEL lists multiple contact times for the same application, it is recommended to use the longest contact time and the strongest dilution noted. When a specific microorganism is targeted, the contact time for that microorganism listed on the label must be used.

Claims

A claim is an EPA-approved statement about a product supported by data that has been approved by the EPA. Claims can range from simply naming a product as a surface SANITIZER or DISINFECTANT to specifics about its ability to kill a particular virus or bacterium or claims it will SANITIZE a particular surface type.

Efficacy claims are specific to the intended use as a surface SANITIZER or DISINFECTANT, and they are also specific to the concentration and contact time. Product marketing materials or associated literature are regarded as “labeling” by the EPA.[10] Therefore, claims listed in these materials are subject to the same rules as claims on product packaging and physical labels. An emerging viral pathogen claim is another type of claim, such as one used during a COVID-19 pandemic. This type of claim will appear on a MASTER LABEL and can be used on marketing materials during an active outbreak, such as during the COVID-19 pandemic.

Surface type and compatibility

Some products may have information about surfaces for which the product is intended (e.g., stainless steel, glazed tile, cabinets, or floors). PRODUCT LABELS may also mention surfaces that could become damaged through use of the product. For example, peracid products should not be used on soft metals like copper and highly acidic or highly alkaline chemicals may damage aluminum.

Shelf life

The EPA requires shelf life (expiration date) to be listed on the PRODUCT LABEL only when the shelf life is less than one year. Shelf life is determined for an unopened container by the product manufacturer. For products that are in use (e.g., wiping cloth solution), the concentration must be checked according to in the FDA Food Code (Section 4-302.14).

Storage and disposal

Any specific instructions regarding storage or disposal are listed on the EPA-registered PRODUCT LABEL.

Statutory precautionary statements

These statements alert the user to hazards associated with misuse of the product and first aid procedures should injury occur.

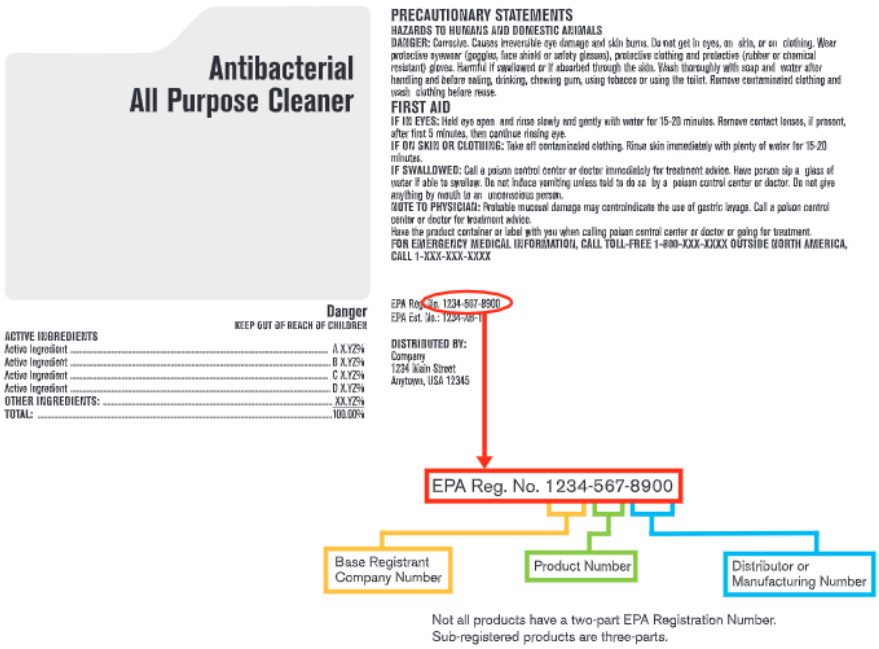
Phone number

A phone number must be listed for the user to access additional information or file a complaint about the product as well as an emergency phone number in case of exposure.

An example of a PRODUCT LABEL is in

Figure 1.

Figure 1. Example of a Product Label.[1]



Frequency of surface SANITIZER and DISINFECTANT use.

Section 4-702.11 of the Food Code states FOOD-CONTACT SURFACES shall be sanitized before use and after cleaning. Therefore, frequency of sanitizing is dependent on frequency of cleaning. Cleaning frequency for FOOD-CONTACT SURFACES is presented in section 4-602 and summarized below:

- When changing between types of food, such as fish, beef, chicken, pork
- When changing between raw and ready-to-eat foods
- Any time FCS and utensils may be contaminated
- Every 4 hours unless the equipment is held below room temperatures

The following table is provided in the Food Code to determine cleaning frequency at temperatures below room temperature:

Table 2. Food Code recommended FOOD-CONTACT SURFACE cleaning frequency[5]

Temperature	Cleaning frequency
5.0°C (41°F) or less	24 hours
>5.0°C -7.2°C (>41°F -45°F)	20 hours
>7.2°C -10.0°C (>45°F -50°F)	16 hours
>10.0°C -12.8°C (>50°F -55°F)	10 hours

While the 2017 Food Code provides guidance for frequency of sanitizing, it does **not** address disinfection.

Frequency of disinfection varies depending on circumstances at the time of disinfection. During normal, routine conditions, surfaces should be disinfected at least daily. High-touch surfaces (e.g., door handles, dispensers, restroom surfaces) should be disinfected at least daily when the facility is open. During outbreaks surfaces should be disinfected at the frequency recommended by public health officials. Surfaces should also be disinfected immediately after a bodily fluid event.

Application methods for surface SANITIZERS and DISINFECTANTS:

- **Coarse Spray Application**
    - Coarse spray is the most common application method where relatively large droplets are generated. Large droplets are not suspended in the air for very long and typically do not spread very far from the sprayer. According to the American Society of Agricultural and Biological Engineers, the volume median diameter (VMD) of a coarse spray is >325 µm. Examples of coarse sprays include trigger sprayers, most hose-end sprayers, and wall-mounted dispensing systems with dispensing hoses. Unless otherwise specified on a label, if surface SANITIZER or DISINFECTANT use instructions say to "spray" the surface SANITIZER or DISINFECTANT, it is a coarse spray. Many dispensing systems can give somewhat inaccurate dosing if a very small amount of surface SANITIZER or DISINFECTANT is dispensed. For this reason, it is better to fill small containers from a larger volume. A good practice for surface SANITIZERS is to dispense a surface SANITIZER into the surface SANITIZER compartment of a sink **then** fill spray bottles from that compartment. A container used to dispense DISINFECTANT or surface SANITIZER must be clean and should never be used to hold any other chemical such as a cleaner. Residual cleaners may inactivate a DISINFECTANT or surface SANITIZER added to that container.
- **Wipe Applications**
    - Cloth Immersed in surface SANITIZER
        - Surface SANITIZERS can be prepared in a bucket and a wiping cloth immersed into the solution, which can then be used to clean surfaces. However, as indicated in the Food Code, while wiping a surface with a surface SANITIZER-soaked cloth may be adequate for cleaning purposes, it does not constitute sanitizing the surface. "Soiled wiping cloths, especially when moist, can become breeding grounds for pathogens that could be transferred to food. Wiping cloths that are

not dry (except those used once then laundered) must be stored in a surface SANITIZER solution of adequate concentration between uses. Wiping cloths soiled with organic material can overcome the effectiveness of, and neutralize, the surface SANITIZER. The sanitizing solution must be changed as needed to minimize the accumulation of organic material and sustain proper concentration. Proper surface SANITIZER concentration should be verified by monitoring the solution periodically with an appropriate chemical test kit. The sanitizing solution must stay on the surface for a specific contact time in accordance with the manufacturer's EPA-registered label (Food Code Annex 3-304.14 Wiping Cloths, Use Limitation).[5] Surface SANITIZER concentration should be checked at least every 4 hours and whenever a fresh solution is dispensed into the container. The PRODUCT LABEL includes instructions of this use application. The manufacturer can also provide guidance on product use.

- Cloth Immersed in DISINFECTANT
  - DISINFECTANT can be prepared in a bucket with a cloth immersed in the solution, which can then be used to disinfect surfaces. Ensure DISINFECTANT solution in the bucket is at the correct concentration. Soil can build up in buckets, inactivating the DISINFECTANT and reducing its concentration. Both dirty and clean cloths may inactivate DISINFECTANT solution, therefore the concentration in such containers must be verified at least every 4 hours. A surface being disinfected must remain wet with DISINFECTANT for the duration of the registered contact time. The PRODUCT LABEL includes instructions for this use application. The manufacturer can also provide guidance on product use.
- Disposable SANITIZER wipes
  - Disposable wipes, single use wiping cloths or towelettes are popular application methods. Typically, they are pre-moistened with surface

SANITIZER in a container with a surface SANITIZER. These wipes are intended to be single use, then discarded. Wiping a surface with a disposable wet sanitizing cloth is an acceptable practice for wiping food spills and equipment surfaces. However, this practice does not constitute cleaning and sanitizing of FCS to satisfy the methods and frequency requirements in parts 4-6 and 4-7 of the Food Code. The sanitizing solution must stay on the surface for a specific contact time in accordance with the manufacturer's EPA-registered label.[5] It should also be noted that the EPA does not currently allow wipes to be used on items that could be immersed in SANITIZER, e.g., utensils, cutting boards, glasses, etc. Wipes should be used on immobile surfaces or those that cannot be immersed in SANITIZER.

- It is important to make sure at least two wipes are used for an EPA-registered cleaner/surface SANITIZER wipe. The first wipe is used for a cleaning step, the second for a sanitizing step. If the wipes are not registered as a cleaner/surface SANITIZER, a three-step process should be followed (wash, rinse, sanitize), using at least one wipe for each step.
- Disposable wipes may hold less solution than other wipes, therefore, make certain surfaces remain wet for the entire contact time listed on the PRODUCT LABEL.

- <u>Disposable DISINFECTANT wipes.</u>
  - Disposable DISINFECTANT wipes, single use wiping cloths or towelettes have become popular in recent years. They are pre-moistened with DISINFECTANT at the correct concentration. These wipes are meant to be used once, then discarded. If FCS are wiped with a DISINFECTANT wipe, a rinse step may be required. The PRODUCT LABEL will provide use instructions and specify if rinse step is required.

        - Disposable DISINFECTANT wipes may hold a limited amount of a product solution; therefore, make certain surfaces remain wet for the entire contact time listed on the PRODUCT LABEL.
    - Mopping
        - This application method is always used on NFCS. The soil level in the mop bucket tends to be very high, therefore, the concentration of surface SANITIZER or DISINFECTANT in the bucket must be closely monitored to ensure its effectiveness.
- **Immersion**
    - In this application, items being treated are completely immersed in surface SANITIZER or DISINFECTANT for the required contact time. They may be immersed in a sink, bucket, specialized tank or other equipment containing surface SANITIZER or DISINFECTANT. Some equipment or utensils must be disassembled prior to immersion to ensure all treated surfaces have contact with a surface SANITIZER or DISINFECTANT. After items are sanitized or disinfected, care must be taken to prevent recontamination during reassembly. It may be necessary to disinfect or sanitize any tools used to reassemble the equipment or utensils. Chemical and equipment manufacturers can provide guidance on proper procedures for sanitizing or disinfecting equipment.
- **Clean In Place (CIP)**
    - CIP involves circulating cleaning, rinsing and sanitizing solutions through piping and flushing interior surfaces of equipment. The CIP process is specific to a piece of equipment. Equipment and chemical manufacturers can provide guidance on how to conduct the CIP process along with recommendations for selecting the best surface SANITIZER for CIP equipment. CIP processes can have some unique requirements for surface SANITIZER, such as low foam or a high-temperature tolerance.

- **Misting/Fogging**

  Application of surface SANITIZERS or DISINFECTANTS via fogging or misting should be approved by the EPA and must be specified on the PRODUCT LABEL along with use instructions and safety requirements. In these applications the surface SANITIZER or DISINFECTANT is dispensed via a device that delivers the liquid surface SANITIZER or DISINFECTANT via very small droplets. Fogging typically generates droplets with <50 µm VMD, whereas misting generates slightly larger droplets with a 50 to 100 µm VMD. The purpose of this application is to increase a treated surface coverage. The very small droplet size in mists and fogs compared to coarse spray application droplet size can significantly impact the safety of the surface SANITIZER or DISINFECTANT because small droplets are more easily inhaled deeply into lung tissue. When surface SANITIZERS or DISINFECTANTS are applied as a mist or fog, employees should vacate the area or wear respirators if their presence is required. In addition, for DISINFECTANTS which are registered for misting or fogging, PRODUCT LABELS are required to state that foods must be removed from the area of treatment or be covered up. Small droplets stay suspended in the air much longer than those applied using a coarse spray and may remain in the treated area for hours. Restricted access to the treated area may be required for entire application time as well as several hours after treatment.

  - **ElectroStatic Spray (ESS)**

    ESS is different from misting and fogging, even though it might seem to be similar. The primary difference is the device used for dispensing the surface SANITIZER or DISINFECTANT generates and applies a very small electrical charge to the products' droplets. The intent of this charge is to attract droplets to the surface being treated to ensure the surface SANITIZER or DISINFECTANT covers all treated surface areas. Mists and

fogs applied with ESS systems do not remain in the air for a long time, but due to the small droplet size, the use of respirators may be required in the areas being treated. Most ESS systems dispense small volumes of surface SANITIZER or DISINFECTANT; therefore, it is important to ensure enough product is dispensed to cover surfaces for the entire contact time specified on the PRODUCT LABEL. When surface SANITIZER or DISINFECTANT is registered for application via ESS, directions and safety precautions are provided on the PRODUCT LABEL.

- **Gaseous/Vaporized**

  This application is similar to fogged or misted surface SANITIZER or DISINFECTANT except in this case the surface SANITIZER or DISINFECTANT is applied as a gas form, not in small droplets. PPE is required and employees or other personnel should vacate the area because many gaseous or vaporized surface SANITIZERS or DISINFECTANTS are highly toxic when inhaled. When a surface SANITIZER or DISINFECTANT is registered for this type of application, directions and safety precautions can be found on the PRODUCT LABEL and SDS.

Surface SANITIZER and DISINFECTANT Concentration Verification

Section 4-302.14 of the Food Code states, “A test kit or other device that accurately measures the concentration in MG/L of SANITIZING solutions shall be provided”, and section 4-501.116 states, “Concentration of the SANITIZING solution shall be accurately determined by using a test kit or other device.” A surface SANITIZER concentration needs to be measured to ensure it meets minimum concentration requirements for proper sanitization and does not exceed appropriate use levels.[5]

Test strips are the most common test kits used in FOOD ESTABLISHMENTS. Acceptable test strips are usually specified by chemical manufacturers and are different for various surface SANITIZER and DISINFECTANT actives. Although some chemistries have similar actives, they may require different test strips.

It is important to read directions for each type of test strip or other measuring device. Accuracy of results may depend on the tested solution temperature, time required for the strip immersion in the solution, and time needed before comparing the color of the strip and the chart.

Test strips will change color in response to certain levels of the active chemical being measured and will cover a range of concentrations typical to the DISINFECTANTS or surface SANITIZERS the test strips are intended to measure. When using test strips, it is important to choose a test strip with a measurement range that brackets the expected active concentration. For example, if measuring an active concentration of 600 ppm, select a test strip with a range that is both above and below the target level, with the smallest increments possible.[11]

Usually, surface SANITIZER concentrations are measured in three-compartment sinks, towel buckets, spray bottles, and warewash machines. Surface SANITIZER concentrations are measured immediately after dispensing surface SANITIZER and during use. It is customary to check the surface SANITIZER concentration at least every four hours, or more often if necessary. Frequency for measuring concentration could vary and depends on multiple factors, such as:

- Chemistry used
- Soil levels in the solution
- SANITIZER solution temperature
- Towels/surface SANITIZER ratio
- Type of towels used

Some wiping cloths when placed in quaternary ammonium chloride (QAC) surface SANITIZER solutions for storage, may bind the active to the wiping cloth material, leading to a quick drop of the ACTIVE INGREDIENT in the solution. QACs are known for this but other ACTIVE INGREDIENTS are also susceptible to binding of the active.

Residual cleaning chemical, soil or other materials in surface SANITIZER or DISINFECTANT solution containers can also inactivate the surface SANITIZER or DISINFECTANT. It is critical that any container that will be used to hold the surface SANITIZER or DISINFECTANT is clean and is never used to hold any other chemical.

For accurate measurement, test strips must be used correctly by following the directions on the strip dispenser. An example of a common error is measuring concentration of a surface SANITIZER solution that is too warm or too cold. Most test strips are designed for use at ambient temperature (approximately 75˚F). Temperatures above 10˚F or below 75°F can lead to inaccurate readings. Another source of an error when measuring detergent-based SANITIZERS, such as QAC is presence of a foam in the sample tested. It is important to ensure a sample tested has no foam on it. Many dosing systems can be slightly inaccurate if a small amount of surface SANITIZER is dispensed for concentration verification. If a small amount of surface SANITIZER (one quart or less) is needed, it is best to dispense a larger volume (one gallon or more) into a container such as a three-compartment sink and test that solution. Smaller containers can then be filled from the larger volume.

Test trips are calibrated for room temperature use and may provide inaccurate results if the surface SANITIZER solution is tested above or below that temperature. It may be necessary to take a smaller portion of surface SANITIZER from a larger volume and allow it to come to room temperature before it is tested. It is important to use test strips before their expiration date.

Other more complicated techniques can be used for measuring concentrations, such as titration kits, but they are seldom used in FOOD ESTABLISHMENTS. Chemical manufacturers may use them to calibrate dispensing equipment.

The FDA Food Code 2017 does not address the use of DISINFECTANTS (only mentioned in Annex 3), therefore, there are no Food Code recommendations for measuring their concentrations. Because all DISINFECTANTS are EPA-registered products, concentration of dilutable products should be tested. Measuring techniques discussed above can be used to verify DISINFECTANT concentration.

DISINFECTION of FOOD-CONTACT SURFACES

Review the PRODUCT LABEL to determine appropriate use as directions can vary. Determine disinfection needs within the FOOD ESTABLISHMENT, then follow the PRODUCT LABEL instructions for specific use(s) of the chemical.

DISINFECTANTS can be used on an FCS; however, most DISINFECTANTS require rinsing after being applied to an FCS. Regular food preparation and cooking would follow the rinse step (if required) after a DISINFECTION step.

The procedure to clean and disinfect an FCS with a DISINFECTANT requiring rinsing after application is as follows:

- Clean the FCS using a cleaning product, or cleaner- DISINFECTANT.
- Rinse cleaner and soil from the FCS.
- Apply DISINFECTANT and allow FCS to remain wet for the required contact time of DISINFECTANT.
- Rinse off DISINFECTANT.

The procedure to clean and disinfect FCS with a no-rinse DISINFECTANT (i.e., one that does not require a rinse step after use) on an FCS is as follows:

- Clean the FCS using a cleaning product, or cleaner- DISINFECTANT.
- Rinse cleaner and soil from the FCS.
- Apply the DISINFECTANT according to use instructions making sure the FCS remains wet for the required contact time of the DISINFECTANT.

Note the following details on the PRODUCT LABEL:

- **Warning statements:**

  Without proper precautions in place, exposure to many cleaning, SANITIZING, or DISINFECTING products can be risky to your health. The Occupational Safety and Health Administration (OSHA) requires any hazards associated with product use be clearly stated on the PRODUCT LABEL. Labels highlight required PPE, first aid procedures in case of a spill or other exposure, and disposal precautions (if necessary). The EPA categorizes products from I (highly toxic) to IV (very low toxicity). If possible, select products rated as category IV to reduce risk of harm.

- **Dilution/refilling and testing of chemical containers:**

  The PRODUCT LABEL indicates if the product is in a ready-to-use (RTU) form (i.e., does not require any dilutions) or if it is a concentrate, such as liquid or powder. If the product is in a concentrated form, it will need to be diluted per label instructions before use. A concentrated product has precise instructions for use, listing ounces per gallon and final concentration of a use solution (ppm) to help the end user achieve the correct concentration. The efficacy of some diluted products may be affected by the hardness of the water used to prepare the product. For this reason, manufacturers commonly test product efficacy in hard water. The LABEL may indicate the water hardness level at which efficacy testing was done. Product efficacy may be negatively impacted if the product is diluted in water above the hardness stated on the PRODUCT LABEL. Water hardness varies throughout the United States. For information about a specific location, users should contact the local water utility.

  Personal Protective Equipment (PPE):

  - To determine PPE requirements, refer to the PRODUCT LABEL and the Safety Data Sheet (SDS), paying attention to how the product will be used. Once a surface SANITIZER or DISINFECTANT is diluted to use concentration,

PPE may not be required. SDS will sometimes recommend two sets of PPE, one for the concentrate and one for the use solution.

- PPE is designed to protect an individual from chemical exposures. Adequate PPE should address exposure risks to skin, eyes, lungs, face, hands, feet, and other parts of the body. Examples of PPE include safety glasses, goggles or eye shields to reduce eye damage resulting from splashing, chemical resistant gloves, long-sleeved garments (e.g., uniforms, closed-toe shoes, and respirators) to prevent accidental inhalation.

- **Contact time**

Contact times can vary based on product type, target organism, or specific use.

- The required contact time for food-contact hard surface SANITIZERS is typically 1 minute, with the exception of contact time for sanitizing in a dish machine.[5]
- Contact time for nonfood-contact SANITIZERS can be up to 5 minutes.
- DISINFECTANTS can have various contact times which depend on the type of bacteria, viruses, or fungi but do not exceed 10 minutes.

If a product has multiple contact times for the same application, it is recommended to use the longest contact time **and** highest concentration. For additional guidance consult your local health department or the product manufacturer. In cases when a specific organism is targeted, the contact time for that organism listed on the PRODUCT LABEL should be used. For a DISINFECTANT to be effective, the surface must be wet with DISINFECTANT for the full duration of the contact time. Some DISINFECTANTS with longer contact times might need to be applied more than once to achieve the full required contact time.

Safety

Mixing:

Never mix multiple products! Mixing will not only negatively impact performance, but it is an extremely dangerous practice that could result in serious injury or death from the formation of toxic fumes. For example, mixing bleach-based solutions with vinegar or ammonia can generate chlorine and chloramine gases that could result in severe lung tissue damage if inhaled. In a recent CDC survey of chemical end users and consumers, a large percentage of people were unaware of the dangers of mixing chemicals, with only 35% of responders understanding that mixing bleach with vinegar is dangerous.[12] This knowledge gap highlights the need to educate end-users on the potential dangers of mixing chemicals.

Directions for use on different surfaces:

The use instruction section of a PRODUCT LABEL provides information on use concentration, contact time (see below) and the product application type (product can be sprayed, fogged, misted, electrostatically sprayed, wiped, immersed or mopped). The instructions will also indicate if a pre-cleaning step or a potable water rinse is required. It is important to always adhere to product use instructions on LABEL instructions. Use of surface cleaner, surface SANITIZERS or DISINFECTANTS for tasks they are not designed for could result in damaged equipment or surfaces and lead to employee and/or guest exposure.

Storage and Disposal:

Always refer to the PRODUCT LABEL to determine chemical storage and disposal requirements. Store all products together by chemical type and hazard class code (if applicable). Do not store products together that could cause reactions if mixed. Follow PRODUCT LABEL instruction for ambient temperature storage requirements and do not expose to direct heat. Never store products on the floor and do not store higher than eye level. Storing products on top shelves is a dangerous practice and increases risk of a chemical spill. Be sure all products are properly LABELED so that all handlers are aware of instructions, risks, and safety precautions. Only store products in original packaging or

appropriate containers with correct labels. Re-using empty containers to store other products or chemicals is a risky practice and could result in accidental mixing or exposure as well as violations during safety inspections and is a violation of the Food Code.[5]

WHERE TO USE DISINFECTANTS IN A FOOD ESTABLISHMENT

Most DISINFECTANTS used in FOOD ESTABLISHMENTS are intended for targeted interventions or specific areas. Typically, they are reserved for restrooms, high touch points, blood and bodily fluid clean up, pathogen remediation, outbreak control, or biofilm control. It is important to use DISINFECTANTS only when needed and **not** as a substitute for a surface SANITIZER.

The following are examples of when it is appropriate to use DISINFECTANTS:

- When the user is concerned about surfaces contaminated with a virus or fungus
- When a surface SANITIZER effective against the organism(s) of concern is not available.
- When required by a regulatory authority

If needed for bodily fluid clean up or pathogen remediation, DISINFECTANTS can be used on most surfaces within FOOD ESTABLISHMENTS, such as food equipment surfaces (food-contact and nonfood-contact), dining tables and chairs, counter tops, food display cases, mop sinks and cleaning tools, restrooms and other customer service areas. To ensure efficacy and safety of DISINFECTANTS, it is critical to use EPA-registered DISINFECTANTS and follow LABEL instructions. Post-rinsing may be required after a DISINFECTANT is used on FOOD-CONTACT SURFACES (this requirement is listed on the EPA-registered label).

DISINFECTANTS can be used on all surfaces listed on the EPA registered PRODUCT LABEL. Currently, there is a limited number of products with EPA registered claims for soft surface disinfection with virucidal claims.

BODILY FLUID CLEAN-UP PROCEDURE

In Section 2-501.11 Clean-up of Vomiting and Diarrheal Events states of Food Code 2017 "*A* FOOD ESTABLISHMENT shall have written procedures for EMPLOYEES to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the FOOD ESTABLISHMENT. The procedures shall address the specific actions EMPLOYEES must take to minimize the spread of contamination and the exposure of EMPLOYEES, consumers, FOOD, and surfaces to vomitus or fecal matter. *Pf."* Guidelines for implementation of this regulatory provision are in Annex 3 Public Health Reasons/Administrative Guidelines for Section 2-501.11 Clean-up of Vomiting and Diarrheal Events[5], which identifies what components need to be included in a written plan for clean-up of vomitus and fecal matter in FOOD ESTABLISHMENTS.

Based on these recommendations the following plan should include, but is not limited to:

- Contents of clean-up kit
    - Cleaning agent(s) and effective DISINFECTANT(S)
        - DISINFECTANTS should be an EPA-registered product with a stated claim against norovirus. Consult with your chemical provider to address the questions on product registration if not listed on the PRODUCT LABEL.
    - PPE
    - Cleaning tools
- Procedure for:
    - Preparing contaminated area(s) before clean-up which include:
        - Removing food (packaged and unpackaged), and all items that might have been contaminated (e.g., tablecloth, condiments, flatware, etc.). ***Note:*** *Do not disinfect packaged food as currently there are no EPA-registered DISINFECTANTS approved for this application.*
    - Identifying and isolating areas that will be cleaned
    - Cleaning and disinfecting contaminated area(s)
    - Containing and removing vomit/diarrheal waste
    - Disinfecting pre-cleaned surfaces

- Instructions for post clean-up procedure, which include:
    - Handling PPE and tools used to clean-up vomitus or fecal matter (discarding or cleaning/disinfecting)
    - Discarding open food items which may have been contaminated
    - Cleaning and disinfecting cleaning equipment and tools which may have been contaminated
- Training program for workers on implementation of procedures
    - Training is highly recommended for all new and current employees at least once per year.

Who performs clean-up?

Ideally, nonfood workers should be responsible for cleaning-up vomit/diarrheal waste to prevent cross-contamination. (*This might not be feasible for FOOD ESTABLISHMENTS with limited staff*). Regardless, all workers tasked with clean up should be trained. Professional cleaning services can also be used.

Clean-up kit and other supplies needed for clean-up

Having a clean-up kit readily available ensures all tools needed to properly clean contaminated areas are readily available. Clean-up kits can be purchased or self-assembled.

<u>At a minimum</u> all clean-up kits must include:

- Personal protective equipment – PPE to be worn during cleaning.
    - Follow use directions and PPE requirements listed on a PRODUCT LABEL and SDS.
    - Provide a list of the PPE that must be worn when using the chemicals specified in the FOOD ESTABLISHMENT'S clean-up procedure.
    - At a minimum, anyone cleaning-up vomit/diarrheal waste should wear durable, single-use gloves, disposable eye protection and a disposable apron. Other PPE items may be required for the chemical used. PPE should protect an individual from the chemical used for disinfection as well as from pathogens that may be present in the bodily spill being cleaned and disinfected.

- Cleaning/disinfecting chemicals
    - EPA-registered SANITIZER or DISINFECTANT effective against norovirus.
    - Detergents if used in the clean-up procedure.
- Cleaning tools
    - Absorbent powder/solidifier (e.g., kitty litter or product provided by your kit supplier)
    - Disposable paper towels. Do not use cloth towels as they could be a source of cross-contamination.
    - Mop head if vomit/diarrheal waste are on the floor. If a mop is used, it must be thoroughly disinfected or discarded after use.
    - Bucket, if preparing DISINFECTANT solution.
- **Waste removal**
    - 1 disposable scoop/scraper
    - 2 plastic bags with 2 twist ties
- **Tools to mark area to be cleaned, such as cones, tape, placard, among others.**

Clean-up procedures

- Before cleaning begins:
    - Direct everyone (i.e., employees and patrons) to vacate the area where the event occurred.
    - Block off the affected area.
    - Put on PPE.
        - At a minimum, personnel assigned to clean should wear, durable, single-use gloves and a disposal apron. Refer to the SDS to determine if additional PPE needs to be worn.
- Cleaning Hard Surfaces
    - Place sufficient absorbent powder/solidifier to completely cover the body fluid waste.
    - Completely cover solidified waste with disposable paper towels.
    - Apply DISINFECTANT (i.e., spray, pour over) so paper towels are saturated.

- Remove the covered waste, which includes solidified matter and paper towels, using a scoop or a scraper. Place covered waste and the scoop/scraper into the first trash bag.
- Spray DISINFECTANT over the area from which the waste was removed.
- Make sure all treated surfaces are wet for the entire contact time listed on the PRODUCT LABEL. Use the contact time for norovirus listed on the PRODUCT LABEL, if the cause of body fluid contamination is unknown.
- Wipe or rinse off the disinfected area with clean paper towel(s).
- Put paper towels and disposable cleaning tools into the first trash bag and tie with a twist tie, then place into second trash bag. Secure the second trash bag with a second twist tie.
    - If non-disposable cleaning tools are used (e.g., mops, buckets), disinfect them after clean-up is complete, before returning them to storage area.
- Remove PPE and place it into the second trash bag tying with the second twist tie.
- Discard the double-bagged waste into a dumpster.
    - Never place contaminated waste in a regular trash receptacle located inside the establishment.
- Wash hands and forearms with soap and warm water for 20 seconds[5]
    - Wipe hands with a paper towel and turn off the faucet using this paper towel

- Cleaning soft surfaces, such as upholstered furniture, and draperies.
    - Place sufficient absorbent powder/solidifier to completely cover the body fluid waste.
    - Completely cover solidified waste with disposable paper towels.
    - Remove the covered waste, which includes solidified matter and paper towels, using a scoop or a scraper. Put into the trash bag, along with the scoop/scraper used in to the first trash bag.
    - Use DISINFECTANTS with claims against norovirus designed to be used on soft surfaces.
    - Apply (i.e., spray, pour over) so paper towels are saturated.

A. Spray DISINFECTANT over the area from which the waste was removed.
    - *Make sure that the DISINFECTANT used is registered for use on soft surfaces.*
    - *Make sure all treated surfaces are wet for the entire contact time listed on the PRODUCT LABEL*.

Use steaming for disinfection if EPA registered DISINFECTANTS are not available for the soft surface of interest, such as carpet.

B. "Steam clean (heat inactivation) at 158°F for 5 minutes or 212°F for 1 minute for complete inactivation. Disinfecting with bleach may discolor carpets and/or upholstered furniture"

- Wipe or rinse off the disinfected area with clean paper towel(s).
- Put paper towels and disposable cleaning tools into the first trash bag and tie with a twist tie then place into the second trash bag. If non-disposable cleaning tools are used, disinfect them after clean-up is complete.
- Remove PPE and place it into the second trash bag tying with the second twist tie.
- Discard the trash bag into a dumpster.
- Never place it in a regular trash receptacle located inside the establishment. If non-disposable cleaning tools are used, disinfect them after clean-up is complete and before returning them to a storage area.

- Wash hands and forearms with soap and warm water.
    - Wash the faucets along with washing hands.
    - Wipe hands with a paper towel and turn off the faucet using the same paper towel.

Cleaning Launderable items

Wash laundry thoroughly

If possible, remove and wash clothes or linens that may be contaminated with vomit/diarrheal waste as soon as possible.

- Handle soiled items carefully without agitating (shaking) them.
- Wear rubber or disposable gloves while handling soiled items.

- Wash the items with detergent (cleaning agent) and hot water at the maximum available cycle length and then machine dry them at the highest heat setting.
- Wash hands and forearms with soap and warm water for at least 20 seconds.[5]
    - Wipe hands with a paper towel and turn off the faucet using the same paper towel.

ANNEX:

REGULATIONS ON DISINFECTANT AND SURFACE SANITIZER USE IN FOOD SERVICE ESTABLISHMENTS

Oversight and registration of DISINFECTANTS and surface SANITIZERS in the USA

The EPA is the primary regulatory authority for environmental surface SANITIZERS and DISINFECTANTS used in FOOD ESTABLISHMENTS (i.e., retail and foodservice operations). Surface SANITIZERS and DISINFECTANTS are identified as ANTIMICROBIAL PESTICIDES by the EPA, as they fit the statutory definition of products intended to reduce or eliminate microorganisms.[1] The FIFRA gives the EPA the authority to regulate the distribution, sale, and use surface SANITIZERS and DISINFECTANTS.

The EPA requires laboratory testing to verify manufacturers' antimicrobial activity claims for their surface SANITIZERS and DISINFECTANTS. In addition, the EPA requires extensive data on the potential health and environmental effects of all these products, before granting a registration, which is a license to market a product in the United States.

Regulatory process, testing, review, and approval

The EPA has developed criteria to substantiate acceptable levels of microbial kill or "efficacy" for a product to be registered as a surface SANITIZER or DISINFECTANT. Minimum testing requirements mandate efficacy against specific bacterial strains. Additional microorganisms can be added to the registration if the manufacturer of the DISINFECTANT or surface SANITIZER submits additional lab testing for these microorganisms. Based on data provided by the manufacturer, the EPA determines the human and ecological risks from exposure to products reviewed. Based on this review, precautionary language such as "Caution", "Warning", or "Danger" as well as PPE and first aid labelling. Scientific experts at the EPA analyze the data submitted and make decisions on whether proposed marketing language from the manufacturer is truthful and not "false and misleading." Once data have been evaluated and deemed

acceptable, the EPA approves a product MASTER LABEL and assigns an EPA REGISTRATION NUMBER.

A MASTER LABEL includes all approved uses for a surface SANITIZER or DISINFECTANT, use directions, safety information and an approved marketing language. The PRODUCT LABEL is the label attached or associated with the product as it is distributed and sold. Note the following differences between the two labels:

- PRODUCT LABEL
    - May only contain a subset of the information provided on the MASTER LABEL
    - Is not required to include all information from the MASTER LABEL
    - Cannot contain information not included on the MASTER LABEL
    - Users must comply with this label
- MASTER LABEL
    - Contains all claims approved for use on a registered product
    - Contains all claims approved for use on a registered product for multiple settings, such as household, food service, hospitals, etc.
    - multiple settings such as household, food service, hospitals, etc.

The Occupational Safety and Health Administration (OSHA) has direct authority over Safety Data Sheets (SDS), formerly called Material Safety Data Sheets (MSDS) for surface SANITIZERS and DISINFECTANTS. When an SDS is distributed with a product, it becomes a part of its labeling because it is accompanying the product (FIFRA 2(p)(2)(A)). Therefore, if an SDS includes warnings, precautions or any other information that conflict with the FIFRA-approved label, it could be misleading to end users, resulting in the product to be considered misbranded and unlawful for sale or distribution. For example, in 2012 OSHA adopted a revised Hazard Communication Rule for SDSs which utilizes the criteria for signal words, (e.g., Danger or Warning) adopted by multiple countries under the Globally Harmonized System (GHS) for hazard

communication language and symbols. The EPA has not adopted the GHS criteria; thus, an OSHA SDS may have a signal word that differs from the one the EPA requires for a surface SANITIZER or DISINFECTANT PRODUCT LABEL. PR Notice 2012-1 explains how a company can explain and justify such a difference if it occurs in order to prevent users from being misled by the inconsistencies. If there is a conflict that prevents compliance with both, the chemical manufacturer should be contacted to clarify the conflict.

The data package submitted to the EPA to register surface SANITIZERS and DISINFECTANTS must include:

- Microbiological data (i.e., efficacy data)
- Chemistry data (ingredients and their concentration)
- Stability (or shelf life) data
- Toxicology data (to help determine precautions and recommendations for PPE)
- Food-contact tolerances for each ingredient (FOOD-CONTACT SURFACE SANITIZERS and DISINFECTANTS)

The submission must also include a detailed MASTER LABEL containing:

- First aid statements
- Precautionary language
- Directions for use
- Efficacy claims (often a list of microorganisms and the contact times and product concentrations)
- Approved marketing language

Antimicrobial chemical efficacy testing

DISINFECTANTS, FCS and NFCS SANITIZERS can be tested for antimicrobial efficacy in various ways. The methods are standardized, and some have been validated through multi-lab collaboration.

Although the test methods vary, most of the performance standards show a reduction of test microorganisms. Test methods vary, for example in some test methods test culture is added to the antimicrobial product's use solution (suspension method) or to a test surface (carrier test).

FCS SANITIZERS are generally tested using a 30-second contact time, but the shortest contact time that can be claimed on the PRODUCT LABEL is 60 seconds. Note that FCS SANITIZERS for use in dish machines could claim shorter contact times if the data submitted to the EPA supports that claim. NFCS SANITIZERS and DISINFECTANTS have multiple contact times which could vary for different microorganisms.

Label, labeling and antimicrobial claims

Companies selling or distributing EPA-registered surface SANITIZERS and DISINFECTANTS may not make ANTIMICROBIAL efficacy claims on PRODUCT LABELS or any other written or graphic material, including literature, marketing materials and websites, unless the data supporting the claims were reviewed and approved by the EPA. Surface SANITIZER and DISINFECTANT LABELS provide critical information about how to safely and legally handle and use these products.

EPA-registered MASTER and PRODUCT LABELS are legally enforceable, and all include the statement, *"It is a violation of Federal law to use this product in a manner inconsistent with its LABELING."* **In other words, the LABEL is the law.**

If the intended users of a product are in FOOD ESTABLISHMENTS, companies manufacturing surface SANITIZERS and DISINFECTANTS typically develop data and claims that are most relevant for the product's intended use (e.g., norovirus, *Listeria monocytogenes*, *Salmonella* spp., *Shigella* spp., *E. coli* O157:H7 control, etc.). Many products have proven efficacy as FCS and NFCS SANITIZERS, as well as DISINFECTANTS. It is common for these product categories to be used at different concentrations and contact times.

PRODUCT LABELS generally contain a subset of the claims and use instructions that appear on the MASTER LABEL. A PRODUCT LABEL will often only contain those claims and use instructions appropriate for a specific use setting, such as FOOD ESTABLISHMENTS, health care or other settings. As a result, a product might have a long list of efficacy claims on its MASTER LABEL, but a much shorter list on a PRODUCT LABEL. The user of any surface SANITIZER or DISINFECTANT is required to comply with the PRODUCT LABEL and use the chemical as instructed on that label.

MASTER LABELS of all EPA-registered surface SANITIZERS and DISINFECTANTS are listed in a searchable database available in the EPA PPLS[13] and in the National Pesticide Retrieval Information System (NPRIS).[14] To help users select an appropriate surface SANITIZER or DISINFECTANT to control microorganisms of interest, the EPA maintains multiple specialized lists of ANTIMICROBIAL products registered by the EPA.[15] Examples include List G, the EPA's Registered ANTIMICROBIAL Products Effective Against norovirus, and List N, DISINFECTANTS for Use against SARS-CoV-2 (COVID-19). The EPA's newest lists include searchable tables for ease of use. Lists may not be updated regularly therefore; it is important to follow the PRODUCT LABEL use instruction to ensure that the proper surface SANITIZER or DISINFECTANT is used correctly.

Enforcement

The EPA enforces requirements under FIFRA, which governs the distribution, sale and use of surface SANITIZERS and DISINFECTANTS. The EPA is authorized to take enforcement action under the following circumstances:

- Distribution or sale of unregistered surface SANITIZERS and DISINFECTANTS
- Composition of registered surface SANITIZERS and DISINFECTANTS that differ from the formulation submitted at registration

- Registered surface SANITIZERS and DISINFECTANTS that are misbranded or adulterated
- Registered surface SANITIZERS and DISINFECTANTS that are applied using an unapproved method (e.g., fogging)

Enforcement can include fines, stop sale orders, and/or seizure of products not meeting EPA requirements. Additionally, EPA's enforcement program aims to ensure surface SANITIZERS and DISINFECTANTS entering the United States meet EPA requirements.

End users can report suspicious products or individual surface SANITIZER and DISINFECTANT incidents by contacting pesticidequestions@epa.gov. Efficacy of registered products is occasionally confirmed by regulators or manufacturers. Manufacturers are required to review reports of adverse effects or efficacy issues for their registered products and comply with the EPA incident reporting requirements.[16]

The role of state and local authorities in registration and lawful use of DISINFECTANTS and surface SANITIZERS

Surface SANITIZERS and DISINFECTANTS that are sold, distributed, or used must be registered by each state. States have a variety of requirements for registration which can include all or a subset of the information submitted to EPA and in the case of some states can include additional data requirements. Refer any additional questions to your chemical supplier.

FDA oversight of Food Code and connection to EPA/CDC

The FDA Center for Food Safety and Applied Nutrition, Retail Food Protection Staff, Retail Food Police Team (CFSAN/RFPS/RFPT) produces the model FDA Food Code. It represents the FDA's recommendations for a uniform system of regulation to ensure food at retail is safe for consumers. The Food Code is offered for adoption by local, state and federal governmental jurisdictions for administration by various health agencies with delegated compliance responsibilities for FOOD ESTABLISHMENTS.

FDA partners with federal internal and external agencies who have a stake in food safety (CDC, USDA/FSIS, EPA, FDA-Office of Food Additive Safety, FDA-Office of Food Safety/Division of Seafood Safety and Division of Milk/Dairy Products, etc.) and work together to harmonize regulatory provisions and recommendations where applicable.

The federal government is committed to enhanced coordination of food safety efforts with state, local, and tribal agencies, and the food industry to protect the food supply. Establishing uniform and enforceable standards of food safety in FOOD ESTABLISHMENTS is an important part of strengthening the U.S. food protection system. The FDA, EPA, and USDA partner with food safety stakeholders and are committed to reducing the incidence of foodborne illness in the United States.

Key sections of FDA FOOD CODE addressing surface SANITIZERS and DISINFECTANTS

The use of surface SANITIZERS is addressed in the Food Code in several places. The Food Code states in part 1-2, Definitions, that “sanitization” means the application of cumulative heat or chemicals on cleaned FOOD-CONTACT SURFACES that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, equal to a 99.999% reduction of representative disease microorganisms of public health importance. Part 4-7 specifies the frequency and methods for sanitizing FOOD-CONTACT SURFACES, the final step prior to reuse of a FOOD-CONTACT SURFACE. It includes two options for sanitizing cleaned and rinsed surfaces (i.e., use of hot water or chemical surface SANITIZERS). Important criteria for using chemical surface SANITIZERS, along with examples of commonly used chemicals, are in Food Code Section 4-501.114, 4-703.11(C), 7-204.11.[5] All surface SANITIZERS must be used in accordance with the EPA-registered label use instructions.

DETERGENT-SANITIZERS are addressed in FDA Food Code Section 4-501.115.[5] These combination products can be used for both cleaning and sanitizing steps and do

not require a rinse between the two steps. Apply to clean the surface, which may include wiping if needed to remove soil, then apply again with the same product to sanitize. Refer to the PRODUCT LABEL for use pattern information. Contact your chemical manufacturer to answer any questions.

NFCS SANITIZERS are not directly addressed in the Food Code. The Code recommends only cleaning these NFCS as needed. However, operators often use surface SANITIZERS and/or DISINFECTANTS on NFCS SANITIZERS to minimize the possible risk of cross-contamination.

DISINFECTANTS are not defined in the 2017 Food Code, but their use is referenced in Annex 3 Section 2-501.11, “Clean-up of Vomiting and Diarrheal Events.” The Food Code specifically states that procedures to clean up after a vomiting or diarrheal event should involve a more stringent process than routine sanitization: “It is therefore important that FOOD ESTABLISHMENTS have procedures for the cleaning and disinfection of vomitus and/or diarrheal contamination events that address, among other items, the use of proper DISINFECTANTS at the proper concentration.”[5] As stated above, disinfection is currently not a regulatory requirement in FOOD ESTABLISHMENTS. However, when a DISINFECTANT is used on a FOOD-CONTACT SURFACE, special attention must be paid to the EPA-registered label use instructions (i.e., concentration, contact time, and application method and requirement for post-disinfection rinse).

The Food Code addresses surface SANITIZER use concentration verification. In Section 4-302.14, the code specifies that “a test kit or other device that accurately measures the concentration in mg/L [ppm] of sanitizing solutions shall be provided.”
The code further goes on to say in section 4-501.116 that the “Concentration of the SANITIZING solution shall be accurately determined by using a test kit or other device”.[5]

Development of disinfection guidance for the public by Centers for Disease Control and Prevention (CDC)

The CDC is the nation's leading science-based, data-driven, service organization that protects the public's health. The CDC is one of the government agencies where recommendations during a public health crisis could be found. In tandem with government agencies, including the FDA and EPA, the CDC makes evidence-based recommendations to the public on the control of pathogens that pose a public health concern. These recommendations often come in the form of guidance documents, such as those released during the COVID-19 pandemic. The CDC takes into consideration the risk factors related to transmission of disease-causing microorganisms as well as the availability of EPA registered products effective against the target microorganism. The CDC provides guidance documents to assist manufacturers or distributors of DISINFECTANTS and surface SANITIZERS in their communication with end users on suitability of products for control of the target pathogen.

During outbreaks caused by a new emerging pathogen, for which effective antimicrobial products might not be registered with the EPA, the CDC can provide recommendations for surface SANITIZER or DISINFECTANT use. In anticipation of such situations, the EPA has published a guideline which helps to register products against new emerging viral pathogens.[17]

Sustainability considerations when selecting DISINFECTANTS and surface SANITIZERS

In recent years, consumer demand for more sustainable and environmentally friendly products and processes has increased. This demand for more "eco-friendly" and/or "green" products has also carried over to both cleaning and ANTIMICROBIAL products.

The US EPA has programs to help consumers make informed purchases for environmentally friendly products. The EPA's Safer Choice program[18] helps

consumers, businesses, and purchasers find products that perform and contain ingredients that are safer for human health and the environment. ANTIMICROBIAL products are not within the scope of the EPA Safer Choice program. Instead, EPA maintains a program called Design for the Environment (DfE).[19] Similar to the Safer Choice program, the DfE program helps purchasers make informed decisions when selecting environmentally friendly ANTIMICROBIAL products, such as surface SANITIZERS and DISINFECTANTS.

The DfE program is optional and there is no regulatory requirement that any surface SANITIZER or DISINFECTANT be certified under this or any other sustainability program. Products approved under the DfE program have been certified by EPA and are ones that:

- minimize any possible risks to human health by excluding ingredients that might have the potential to negatively impact young children, cause cancer, or have other negative effects
- further protect fish and other aquatic life
- minimize pollution of air or waterways and prevent harmful chemicals from being added to the land
- ensure products have no unresolved compliance, enforcement, or efficacy issues

Importantly, the EPA does not consider the DfE logo to be a product endorsement. The DfE logo indicates the product has been certified by the EPA, but these products do not meet the Safer Choice Standards.

Although DfE provides a certification for sustainability of certain attributes of ANTIMICROBIALS, many other products, particularly some concentrates do not meet the DfE certification criteria. However, concentrated ANTIMICROBIALS products have additional sustainability benefits, utilizing less packaging and less carbon associated with transportation, and have the same efficacy and hazard profile as products that are sold as ready to use, when diluted as directed. When choosing a SANITIZER or

DISINFECTANT, it is important to understand the full picture of sustainability of the product and which sustainability attributes matter to you, rather than looking for a certification or seal as this may not be aligned with you/your companies' goals for sustainability.

It should also be noted there are other sustainability programs such as Greenseal and EcoLogo, which offer certifications for cleaning products as well as guidelines for sustainable disinfection. These programs are independent of the EPA DfE and Safer Choice certification but are intended to achieve a similar purpose, i.e., allow users of chemicals to better understand the sustainability and environmental impact of those chemicals. However, it is critical to note that DfE is the only on label certification allowed by the EPA for SANITIZERS and DISINFECTANT. It is also important to understand that all of these programs are completely optional and that a FOOD ESTABLISHMENT is not required to use surface SANITIZERS or DISINFECTANTS that have been certified in any sustainability program, and that sustainable sanitizing and disinfection can be achieved by selecting products with key sustainability attributes in alignment with company goals, independently and regardless of third-party certification.

Supplemental Labeling

Supplemental labeling contains modifications to the pesticide label since the last MASTER LABEL approval (e.g., new use, change application timing). Supplemental labels must be submitted for EPA and state approval, stamped "ACCEPTED" and placed in the official record. Supplemental labels are partial labels distributed with the product by the registrant or distributors in addition to the complete PRODUCT LABEL. Because these are partial labels, they must bear a statement referring the user to the PRODUCT LABEL for complete directions, precautions, and a statement that both the PRODUCT LABEL and supplemental labeling must be in the possession of the user. Compliance with both the PRODUCT LABEL and supplemental labeling is required to safely and effectively use the product.

Supplemental labeling must include the following:

- Product Name
- EPA REGISTRATION NUMBER
- Restricted use classification statement (if applicable)
- “It is a violation of Federal law to use this product in a manner inconsistent with its labeling.”
- “This labeling must be in possession of the user at the time of application.”
- “Read the label affixed to the container for [product name] before applying.”
- “Use of [product name] according to this labeling is subject to the use precautions and limitations imposed by the label affixed to the container for [product name].”

Typically, supplemental labeling will be incorporated into the MASTER LABEL at the next printing of the PRODUCT LABEL (final printed label) or within 18 months, whichever comes first. There are circumstances when these updates may not be completed. For example, if directions for use on the supplemental labeling are subject to continual, frequent change (e.g., California aerial application county restrictions can change every six months). Supplemental labeling must be approved prior to distribution. Supplemental labeling also includes state registration of special local need (SLN) under FIFRA 24(c).

Distributor label

A distributor label is used when a product is registered to one company but is distributed or sold (known as “supplemental distribution”) by another company (known as the “distributor” or “sub-registrant”). (40 CFR 152.132). Distributor labels are not submitted for approval, but a Notice of Supplemental Distribution must be submitted to EPA and states before supplemental distribution of the product.

The registrant is responsible for the contents of both the distributor product and the distributor label.

A distributor label must be the same as the registered PRODUCT LABEL except for:

- Product name
- Distributor name and address
- EPA ESTABLISHMENT NUMBER
- EPA REGISTRATION NUMBER (a third set of numbers is added at the end denoting the distributor's company number, e.g., EPA Reg. No. 1234-56-7890)
- Product claims (specific claims may be deleted as long as no other changes are necessary, but new claims cannot be added)
- Warranty statements (if allowed by contract between the registrant and the distributor and such change is not false or misleading)

The term "supplemental distributor labeling" is sometimes used but is not proper EPA terminology and is often confused with the term "supplemental labeling." The correct term is "distributor label." A supplemental label is used to add new uses or directions for a product, while a distributor label cannot include any uses or directions that differ from the registered product's labeling.

WHAT IS A RADIUS OF THE AREA TO BE CLEANED AND DISINFECTED?

Introduction

Vomiting is a hallmark symptom of a norovirus infection. Infectious norovirus particles can spread in the environment via droplets or aerosol formed during vomiting episodes. Hence, proper environmental disinfection is critical to disrupt its spread. At present, no conclusive evidence is available to support a cleaning radius for vomitus because the extent of contamination and quantity of aerosol formed during vomitus emission and cleanup is still unknown. In fact, most cleanup procedures rarely include a cleaning radius, leaving this to the discretion of the cleaner.

A pattern of viral particles spread is influenced by an array of factors (i.e., viscosity and volume of vomitus, air flow in the room, height of vomiter and type of vomit and establishment layout among others). Given the complexity of each individual factor and

their interaction, it is very difficult to recommend a single radius for clean-up of vomitus. A brief summary of the state of the science regarding norovirus spread in vomitus is below. Multiple studies showed different results regarding the radius of vomit clean-up. This summary is intended to help individual FOOD ESTABLISHMENTS to make a decision on the clean-up radius to be used after a vomiting episode.

Laboratory-Based Studies in Chronological Order

Few laboratory-based studies aim to investigate norovirus spread induced by vomiting. In 2013, U.S. researchers investigated droplet spread during vomiting by conducting a "tipping bucket" experiment.[20] In these experiments, various volumes of artificial vomit (either artificial saliva or oatmeal) were dropped from a height of 3.5 ft and the amount of splatter across the room was evaluated. The maximum travelling distance of the droplets was 14.5 ft, leading to recommendation for this distance to be a minimum radius for vomit clean-up procedures. Airborne particles may spread further than 14.5 ft.

In a 2014 study, researchers created "vomiting Larry" a vomiting machine designed to replicate realistic vomiting episodes so the droplet spread could be studied.[21] In this study, water with a fluorescent dye was used to track spread of droplets during vomiting episodes. In a conclusion of this study an area of approximately 84 ft^2 was recommended to be decontaminated after a vomiting episode. It was emphasized that this area does not take into consideration airborne particles, since they could not be visualized in the experiments.

In 2015, these same researchers published results from aerosolization experiments using a "vomiting machine" which anatomically mimicked a scaled down version of a vomiting episode.[22] In this study, simulated vomitus and MS2 bacteriophage, a surrogate virus for human norovirus were used. Less than 0.03%. of total virus was aerosolized in all experiments, which corresponds to >13,000 norovirus particles aerosolized during a typical vomitus event. This study did not assess total particle spread.

Select Outbreak Case Studies

There are many outbreak investigations where environmental spread of norovirus was documented. In 1998, 58 out of 129 dinner guests became ill at a hotel after a guest

vomited on the wooden floor of the restaurant.[23] Analysis of attack rates by dining table showed an inverse relationship with the distance from the person who vomited, providing strong evidence for norovirus spread by aerosolization during the vomiting incident. The authors also noted the presence of ceiling fans near the incident, which likely promoted norovirus particle spread throughout the restaurant. No distances between tables were given in the research article, although every table in the restaurant had guests who later became ill from the incident.

In 1999, more than 300 people became sick over a five-day period after a concert attendee vomited multiple times during the concert.[24] Many of the individuals sickened did not sit in the same section as the index case. This study resulted in the widespread use of 25 feet as a recommended radius for cleaning up suspected norovirus incidents, since there were cases within a 25-foot radius of the index case who became ill.

Conclusions

In summary, there is convincing evidence that vomiting can spread norovirus particles through droplets as well as aerosols. While a facility will need to determine the appropriate practical clean-up radius for their own establishment, there are several best practices that should always be used. Any surface with visible vomitus or diarrhea needs to be cleaned and disinfected during the clean-up procedure. EPA-registered DISINFECTANTS with norovirus claims must be used in these procedures. Since EPA DISINFECTANTS are not registered for decontaminate inanimate packaging materials, packaged foods suspected to be impacted by the norovirus incident should be discarded not disinfected. Airflow should be considered when determining the appropriate area for clean-up. For example, an indoor environment with multiple ceiling fans will likely spread virus further than an environment without fans.[23] The establishment should consider all affected areas besides the floors such as table legs, table surfaces, shelves, display cases, etc. during cleanup as norovirus particles can spread in all directions during an incident. Consider cleaning other areas which sick individual may have touched.

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Additional Resources

Additional information for control of specific pathogens.

COVID-19

- Cleaning and Disinfecting Your Facility Every Day and When Someone Is Sick https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html
- Cleaning, Disinfecting, and Ventilation Plan, Prepare, and Respond https://www.cdc.gov/coronavirus/2019-ncov/community/clean-disinfect/index.html https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/disinfecting-your-home.html
- Healthcare https://www.cdc.gov/hai/pdfs/resource-limited/environmental-cleaning-RLS-H.pdf https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf

Norovirus

- https://www.cdc.gov/norovirus/about/prevention.html
- Guidelines for Norovirus cleaning – Michigan DOH and Dept of Ag
- Norovirus: step-by-step clean up of vomit and diarrhea | UMN Extension
- Norovirus Response and Cleanup (U.S. National Park Service) (nps.gov)
- Microsoft Word - Steritech White Paper - Guidelines for Response to Vomiting and Diarrheal Incidents in Foodservice Establishments-Revisions.docx
- Preventing Norovirus | CDC
- https://www.osha.gov/sites/default/files/publications/norovirus-factsheet.pdf
- General Information about Norovirus | HAI | CDC
- Food Safety Resources | EHS Activities | EHS | CDC; CDC helped this partner: NorovirusIncident_8.5x11_Eng_Clr_Concentrated_v4 (waterandhealth.org).
- Norovirus Response and Cleanup (U.S. National Park Service) (nps.gov)

Hepatitis A

https://www.cdc.gov/hepatitis/hav/index.htm

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Daily Breeze Article

SpaceX’s Inspiration4 update: Cold pizza, zero-gravity flips and a ukulele solo

Hawthorne-based SpaceX's crew of amateur astronauts will return to Earth on Saturday evening

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This photo provided by SpaceX shows the passengers of Inspiration4 in the Dragon capsule on Friday, Sept. 17. They are, from left, Chris Sembroski, Jared Isaacman, Sian Proctor and Hayley Arceneaux. SpaceX got them into a 363-mile (585-kilometer) orbit following Wednesday night’s launch from NASA’s Kennedy Space Center. That’s 100 miles (160 kilometers) higher than the International Space Station. (SpaceX)

By **TYLER SHAUN EVAINS** | tevains@scng.com |

PUBLISHED: September 17, 2021 at 4:34 p.m. | UPDATED: September 17, 2021 at 4:35 p.m.

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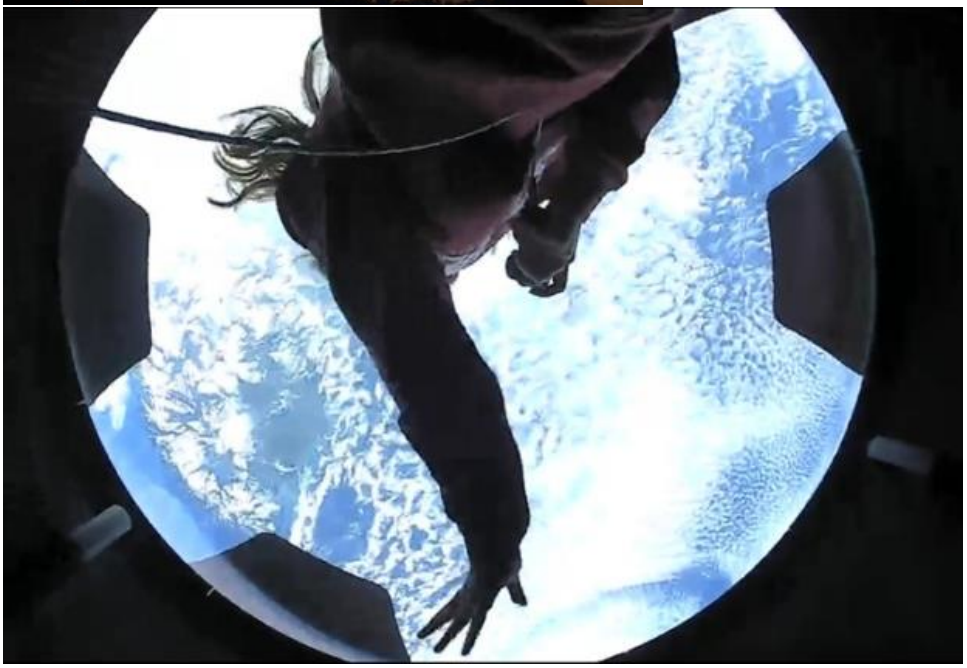
- 

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1 of 4

This photo provided by SpaceX shows Hayley Arceneaux, one of the passengers of Inspiration4 in the Dragon capsuleon Friday, Sept. 17. (SpaceX)

Two days into Hawthorne-based SpaceX's Inspiration4 mission, the Earth-orbiting crew of amateur astronauts provided a lively livecast update on its journey on Friday, Sept. 17, 24 hours before they're due to splash down off the Florida coast.

The event included zero-gravity tumbles, lots of high spirits, displays of artwork created in space and an interstellar ukulele solo.

During the livestream, the crew announced that the quartet was scheduled to return to Earth at 4:06 p.m. PDT Saturday, splashing down into the Atlantic Ocean off the coast of Florida.

SpaceX's Dragon capsule was scheduled to perform two burns Friday night to reduce the spacecraft's altitude to 365 kilometers, SpaceX tweeted Friday, to align the craft with its landing site.

Dragon reached as high as 590 kilometers, or 367 miles, above earth's surface before the astronauts took off their space suits, said Andy Tran, quality engineer at SpaceX, during the update.

Dragon lifted off Wednesday at NASA's Kennedy Space Center in Florida.

Aboard the history-making, fund-raising flight are the four amateur astronauts: mission commander Jared Isaacman, billionaire CEO of payment processing company Shift4 Payments, who funded the trip; mission pilot Sian Proctor, a geoscientist and community college professor in Arizona; mission medical officer Hayley Arceneaux, a physician's assistant at St. Jude Children's Research Center in Memphis, TN; and mission specialist Chris Sembroski, an aerospace data engineer.

Their first meal in space was cold pizza, which the crew said, Tran relayed. And it was extraordinary, he added.

On Friday, Proctor turned the camera to the Dragon's cupola window, trying to share a view the stars and an aurora around Earth amid the dark atmosphere.

"We've been spending so much time in this cupola, the largest window flown into space," Arceneaux said. "We could see the entire perimeter of the Earth, which gives such incredible perspective; the views, I have to say, are out of this world."

Well, they literally are just that.

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The crew floated above Europe during the update, Proctor said, as Proctor showed her marker illustration of the Dragon being carried by an actual dragon off of Earth, Sembroski played his ukulele and Arceneaux turned flips in the zero-gravity environment.

The crew only had 10 minutes of connectivity to Earth on Friday, Tran said, as SpaceX can only communicate with a spacecraft travelling 17,500 mph when it is flying over a designated ground station.

They've been taking swabs of different body parts to evaluate the microbiome and how that changes in those three days in space, Arceneaux said. The crew has also been taking blood samples for research teams back on Earth to study, as well as cognitive tests.

Aside from scientific research, the mission's biggest goal is to raise $200 million for St. Jude Children's Research Hospital. Isaacman looks to the greater community to match the $100 million he's pledging to the hospital.

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Axiom Article

4 days in, Axiom Space's crew makes history for private space flight at ISS

Axiom-1 is the first all-private mission to the International Space Station.

*BY***DORIS ELÍN URRUTIA**

APRIL 12, 2022

SpaceX/Axiom

Over the weekend, the Axiom-1 mission carried four rich guys and philanthropists, a celebrity-chef menu, and biomedical experiments to the International Space Station (ISS).

On Friday (April 8) at 11:17 a.m. Eastern, Axiom-1 launched atop a reused SpaceX Falcon 9 rocket from NASA's Kennedy Space Center in Cape Canaveral, Florida. This flight began the 10-day mission for the first all-private mission for Axiom Space, a company based in Houston near NASA's Johnson Space Center that seeks to place the first commercial space station into low-Earth orbit sometime this decade.

Everything leading up to the flight went smoothly for the most part. Personnel noticed a slight loss of pressure after the hatch was first sealed, so a ground crew reopened and resealed it about two hours prior to takeoff.

Two minutes and 45 seconds after launch, the pre-flown first stage — the bottom two-thirds of the rocket — separated from the upper stage and successfully navigated back to Earth's surface, landing on a SpaceX drone ship floating in the Atlantic Ocean.

A SpaceX Falcon 9 rocket launched on Friday (April 8) shortly before noon local time with the four crewmembers of the Axiom-1 mission.

ANADOLU AGENCY/ANADOLU AGENCY/GETTY IMAGES

Axiom-1's crew were meanwhile "hooting and hollering" during the ride, Axiom-1 pilot and American real-estate investor Larry Connor said during a video message to SpaceX headquarters the following day. Commander and former NASA Space Shuttle astronaut Michael López-Alegría remained "diplomatic" during the cheers, Connor added.

They rode within a SpaceX Dragon Endeavour crew capsule, which is now on its third mission to the ISS. Once this robotic cocoon reached its targeted orbit about 12 minutes after launch, the crew got comfortable and had their first meals for the mission. The Axiom-1 mission menu includes Iberian ham and chicken paella, according to a video segment that SpaceX aired during its pre-launch broadcast. The food was prepared by the non-profit organization World Central Kitchen, helmed by celebrity chef José Andrés.

A "Caramel the Dog" stuffed animal traveled to space with Axiom-1. This is the mascot for the Montreal Children's Hospital in Canada.

AXIOM SPACE

Caramel the Dog, the mascot for the Montreal Children's Hospital Foundation, made an appearance after launch. Astronauts typically use stuffed animals as zero-G indicators, which lets them see whether or not weightlessness has kicked in while remaining safely strapped into their seats. A camera inside Endeavour aired the first microgravity flight of Axiom-1's zero-G indicator. The toy was selected because Mission Specialist and Canadian entrepreneur Mark Pathy collaborates with Canadian health centers as part of his philanthropic work.

The 21-hour trip to the space station suffered a snag at the end. When Endeavor reached the ISS and attempted to dock, the astronauts on the space station couldn't see the feed from an Endeavour camera that was necessary for the docking procedure. Docking was delayed about 45 minutes as teams figured out a solution, which was eventually reached through support from SpaceX Headquarters and NASA.

The SpaceX Dragon Endeavour carrying the Axiom-1 astronauts approaches the International Space Station on April 9, 2022.

NASA/FLICKR

At 10:13 a.m. on Saturday (April 9), the Axiom-1 crew successfully docked to the ISS, bringing the orbiting laboratory's population up to 11. The space station was already housing Expedition 67, a mission made up of three NASA astronauts, one European astronaut, and three Roscosmos cosmonauts.

A NASA blog post published on Monday (April 11) details the science work they will be assisting during their eight days on the space station. The experiments will tackle questions about genetic markers in cellular aging, changes to brain activity in microgravity, and a DNA editing system.

Monday marked Flight Day 4 of Axiom-1.

2-million-dollar bacon sando Article

Heston Blumenthal's Canned Bacon Sandwich Cost $2.8 Million

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Is it the priciest sandwich in the galaxy?

by Dana Hatic@DanaHatic Mar 15, 2016, 4:30pm EDT

Via TV chef Heston Blumenthal creates bacon sandwich costing 'a couple of million pounds' [The Mirror], Heston, we have a problem... the top chef cooks for Tim Peake [The Guardian], and All Heston Blumenthal Coverage [E]

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Stuart C. Wilson/Getty Images

British chef, TV personality, and proprietor of the many-starred Fat Duck in Bray, England, Heston Blumenthal is known for innovative and elaborate cooking styles, but his latest production takes the cake. Blumenthal designed a canned bacon

sandwich for Major Tim Peake, a British astronaut stationed at the International Space Station, and transport of the expensive sandwich cost "a couple million pounds," according to *The Mirror*. That's over $2.8 million.

The chef, who often makes use of molecular gastronomy techniques in his kitchens, curated a handful of meals for Peake, all of which were was designed to hold up under zero-gravity situations. The meal also had to abide by the strict regulations of the world's space agencies which had to approve the meal. Heston spent two years working on the sandwich, eventually landing on canning as the best method of preservation. Though canning cut the risks, it still left Blumenthal in of fear of giving Peake food poisoning, *The Guardian* reported.

In addition to the bacon sandwich, Blumenthal created a red Thai curry, beef stew with truffles, Alaskan salmon, and apple crumble, among other items. These dishes were sent to the International Space Station on a rocket from Cape Canaveral and were waiting for Peake when he arrived in December. Back then we didn't know Blumenthal was the chef, though we did know Peake was excited about having a bacon sandwich in space.

Most expensive bacon sandwich ever? Probably. Worth it? Peake will be the judge, and the world will find out in a TV special called, "Dinner in Space," featuring a video-chat dinner with Peake and Blumenthal, which airs on March 20.

Kimchi Article New York Times

Kimchi goes to space, along with first Korean astronaut

- Give this article

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By [Choe Sang-Hun]

- Feb. 22, 2008

SEOUL — Koreans say they must eat kimchi wherever they are. When South Korea dispatched troops to the Vietnam War in the 1960s, tearful mothers sent off their sons with clay pots containing homemade kimchi. Soon troopships were filled with the pungent smell of the fermenting cabbage slathered with pepper and garlic.

So it was only natural for Koreans to think that their first astronaut must have the beloved national dish when he goes on his historic space mission in April. Three top government research institutes went to work. Their mission: to create "space kimchi."

"If a Korean goes to space, kimchi must go there, too," said Kim Sung Soo, a Korea Food Research Institute scientist. "Without kimchi, Koreans feel flabby. Kimchi first came to our mind when we began discussing what Korean food should go into space."

Ko San, a 30-year-old computer science engineer who beat 36,000 contestants to become the first South Korean space traveler, will blast off April 8 on board a Russian-made Soyuz rocket, together with two Russian cosmonauts. He will stay in the International Space Station for 10 days conducting scientific experiments.

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Ko's trip will be an occasion for national celebration. Since 1961, 34 countries, including Vietnam, Mongolia and Afghanistan, have sent more than 470 astronauts into space, but none of them was Korean - something South Koreans have found humiliating, given their country's economic stature. So when their government finally decided to finance Ko's trip, they wanted him well prepared for his momentous journey. Which means he must take kimchi with him.

After millions of dollars and years of research, South Korean scientists successfully engineered kimchi and nine other Korean recipes fit for space travel. When the Russian space authorities this month approved them for Ko's trip, the South Korean food companies that participated in the research took out full-page newspaper ads.

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The other space food Koreans created include the national instant noodle called ramyeon, hot pepper paste, fermented soybean soup and sticky rice.

But kimchi - a must-have side dish at every Korean meal - was the toughest to turn into space food.

"The key was how to make a bacteria-free kimchi while retaining its unique taste, color and texture," said Lee Ju Woon at the Korean Atomic Energy Research Institute, who began working on the newfangled kimchi in 2003 with samples provided by his mother.

Ordinary kimchi is teeming with microbes, like lactic acid bacteria, which help fermentation. On Earth they are harmless, but scientists fear they could turn dangerous in space if cosmic rays cause them to mutate. Another problem is that kimchi has a short shelf life, especially when temperatures fluctuate rapidly, as they do in space.

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"Imagine if a bag of kimchi starts fermenting and bubbling out of control and bursts all over the sensitive equipment of the spaceship," Lee said.

Lee's team found a way to kill the bacteria with radiation while retaining 90 percent of the original taste. Lee's space kimchi comes in cans, whereas the Korea Food Research Institute's version, developed by Kim's team using a different technology to control the fermentation process, comes in a plastic package.

"This will greatly help my mission. When you're working in space-like conditions and aren't feeling too well, you miss Korean food," Ko, who is training in Russia, said in a statement transmitted through the Korea Aerospace Research Institute, which is overseeing his mission. "Since I am taking kimchi with me, this will help cultural exchanges in space."

Ko plans to be host of a Korean dinner in the space station on April 12 to celebrate the 47th anniversary of the day the Soviet cosmonaut Yuri Gagarin became the first human in space. The dinner will conclude with Korean ginseng and green tea.

What about kimchi's strong aroma, which often keeps non-Koreans from trying it?

"We managed to reduce the smell by one-third or by half," Kim said. "So the other astronauts will feel comfortable trying our space kimchi."

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Sea moss has recently seen increasing popularity for use in “healthy” smoothie beverages, with some products formulated with sea moss appearing to be a major ingredient. Despite the unpermitted vendors selling in various local venues, there are several safety concerns associated with sea moss (*Chondrus crispus*) that require specific controls to ensure the safety of consumers. The production process requires regulatory approval, and the producer must operate from a commercial kitchen under a Retail Food Establishment permit.

Here are the safety concerns:

1. The spores of *Clostridium botulinum* are present in the marine environment and may be present on the product. These bacteria, often referred to as “**C. bot**.”, produce the toxin that causes botulism poisoning. In producing the sea moss gel, growth and toxin formation by C. bot. must be controlled by one of two methods:
    a. Use of a scientifically backed cooking process to destroy the spores and bacteria, or
    b. Acidification of the product to a pH of 4.6 or lower to prevent growth and toxin formation by any C. bot that may be present.

    A written procedure must be submitted to the regulatory authority for approval of the production process using one of the two options above as the safety control. The “Fish and Fishery Products Hazards and Controls Guidance,” March 2020 includes validated guidance on cooking processes for destruction of the spores of C. bot. If the product will be acidified, an initial product assessment for pH must be obtained from a recognized Process Authority. That report must be provided to the regulatory authority as one requirement for approval of the production process. The retail producer will be required to do their own pH testing of each process batch, and must maintain batch production records that include the pH test results for each batch.
2. The supplier of raw sea moss must harvest from an area free from contaminants such as heavy metals, agricultural or industrial chemicals and microorganisms associated with septic waste, which are commonly associated with runoff water from populated and industrial areas. An approved harvester/producer of the sea moss must be able to provide a letter to the retail establishment attesting that their harvesting practices meet this requirement. This letter must be made available to retail food inspectors, and a copy of the letter must be supplied to the regulatory authority as another requirement for approval of the production process.
3. Sea moss and seaweed are natural sources of iodine. Maximum serving sizes must consider the maximum daily allowance of dietary iodine. The concentration of iodine in the sea moss gel will depend on factors such as the local source of the raw material as well as the processing of the gel. The National Institutes of Health (NIH) have published a study of various seaweed products showing, anecdotally, that sea moss had the lowest concentration of iodine of all types of seaweed in the study (see Table 4 of the study). For the sample tested, an 8 gram serving of sea moss would provide 85% of the NIH recommended 150 micrograms daily intake of iodine. NIH recommended a tolerable upper limit of 650 micrograms of daily iodine intake, corresponding to approximately 40 grams of sea moss. NIH further reports that iodine toxicity can occur with more than 1100 micrograms iodine intake per day, resulting in a variety of thyroid health problems. The best guidance is to maintain a balanced diet and moderate consumption of sea moss products.

4. Sea moss is the natural source from which the thickener/emulsifier carrageenan is refined. Use of carrageenan is regulated as a food additive under 21 CFR 172.620. Additional information on allowed use is found at 21 CFR 172.623. The FDA Food Additive Status List provides maximum allowed concentrations of food additives in food.

The above requested documentation should be submitted to foodvariances@dhec.sc.gov for review and approval.

Be aware that if the sea moss gel will be processed using the acidification option, you will need a pH meter with which to test each production batch to be sure the critical pH value is met.

The topic of health claims is one that requires specific FDA guidance to navigate the fine details of what is allowed or not allowed. No health claims can be approved by local agencies such as SC DHEC, and the use of health claims renders the associated product as a dietary supplement, and not a food. As such, the product would be regulated by FDA, not by any local regulatory agency. Here are resources to assist you:
FDA Customer Service Hotline: 1-888-463-6332
FDA Office of Nutritional Products, Labeling and Dietary Supplements 240-402-2375
CFSAN Industry Assistance Information

Additional Resources:
FDA Warning Letter – Everything Health LLC 05-24-2021
FDA Warning Letter – Red's Kitchen Sink 03-02-2021
Consumer Advisory – Michigan Dept. of Agriculture and Rural Development
Sea Moss Fact Sheet – Ohio Department of Agriculture
Iodine Intake from Sea Moss – National Institutes of Health

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Share Bulletin

Consumer Advisory: MDARD Urges Consumers to Dispose of Royalty Sea Moss Lemonade and Gel Products Because of Possible Health Risk

Michigan Dept of Agriculture & Rural Development sent this bulletin at 10/17/2022 10:30 AM EDT

For immediate release: October 17, 2022
MDARD Program Contact: Tom Tederington, 517-749-5849
MDARD Media Contact: Jennifer Holton, 517-284-5724

Consumer Advisory: MDARD Urges Consumers to Dispose of Royalty Sea Moss Lemonade and Gel Products Because of Possible Health Risk

LANSING - The Michigan Department of Agriculture and Rural Development (MDARD) is advising consumers not to eat, drink, or consume any sea moss lemonade or gel products produced by Royalty Sea Moss of Mt. Pleasant, MI.

MDARD initiated the investigation after receiving a complaint from the Maryland Department of Health, Office of Food Protection. During the investigation, MDARD identified the firm produced these products with inadequate processing controls required to stop the growth of deadly foodborne pathogens including botulism. In addition to inadequate process controls the firm does not hold a license to manufacture, hold, or sell food products, which is a violation of the Michigan Food Law of 2000, P.A. 92, MCL 289.5101(1).

Improperly processed beverages and food products may have the potential to be contaminated with Clostridium botulinum, a tasteless and odorless bacterium which can cause life-threatening illness or death.

Botulism, a potentially fatal form of food poisoning, can cause the following symptoms: general weakness, dizziness, double-vision and trouble with speaking or swallowing. Difficulty in breathing, weakness of other muscles, abdominal distension and constipation may also be common symptoms. People experiencing these problems should seek immediate medical attention.

No illnesses have been reported at this time. Consumers are warned not to use the product even if it does not look or smell spoiled.

Products were primarily distributed across the U.S. through the firm's website, and social media platforms. Products advertised on their website lack adequate and consistent labeling including but not limited to ingredient statements, lot codes, and sell by dates.

- Regular Sea Moss Gel
- Fruit Flavored Sea Moss Gel:
  - Mixed Berry with Blueberry Strawberry Raspberry
  - Pineapple Cherry Strawberry
  - Peach Strawberry Flavor
  - Strawberry Dragon fruit
  - Mango Pineapple
  - Strawberry Banana
- Sea Moss Lemonade:
  - Blue Raspberry

- Mango
- Lemonade
- Watermelon
- Strawberry Peach
- Green Apple
- Pink Strawberry
- Strawberry Lemonade
- Grape
- Pineapple
- Strawberry Kiwi
- Cherry
- Fruit Punch

If consumers have additional questions or concerns, they may contact MDARD at 800-292-3939, Monday through Friday between 8 am and 5 pm.

###

Michigan Department of AGRICULTURE & Rural Development
QUESTIONS?
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[Picture of seaweed removed due to file size constraints]

The identification of potential food safety hazards in seaweed

Words by Clare Winkel

The consumption of seaweed has many health and nutritional benefits and Australia currently imports a significant amount of seaweed for human consumption.

Between 2017-2018, seaweed imports were worth $40 million and 85% of that was for human consumption. Every year there are at least 36 recalls or import alerts worldwide for seaweed-based foods. In 2019, Australia instigated at least 50% of these recalls or rejections.

There are currently only a small number of domestic harvesters, growers and processors producing and selling seaweed for human consumption, but given the food safety concerns with imported seaweed, how does the local product compare?

AgriFutures

To assist this small industry, AgriFutures has funded Integrity Compliance Solutions (ICS) to undertake a project to identify potential food safety hazards and develop HACCP Plans (Hazard Analysis Critical Control Point) for two seaweed case studies. These documents will provide the basis of a readily adaptable program for seaweed processors and guidance for regulators in terms of minimising risks in the processing of seaweed for human consumption.

The project is focused on two seaweed species: one grown and one wild harvested. The first case study is *Phyco Health & Venus Shell Systems,* run by Dr Pia Weinberg. This business grows sea lettuce in large 'swimming pools' which is then heat dried and processed. The second case study is *Sea Health Products,* run by Jo Lane. This business harvests kelp from the beach which it then sun dries and processes.

The end-products from both businesses in the case studies are similar dried flaked products that can then be further processed into almost any type of processed foods including pasta, seasonings, chips, cheese, chocolate and coated snacks such as roasted nuts.

To start the hazard identification process, a literature review was undertaken. One study by the European Union Rapid Alert System[1] identified 22 food safety hazards in European seaweed - four were considered major, five moderate and thirteen minor.

The four major hazards identified were: arsenic, cadmium, iodine and Salmonella. Some of the minor hazards included pesticide residues, dioxins, polychlorinated biphenyls, brominated flame retardants, polycyclic aromatic hydrocarbons, pharmaceuticals, marine bio toxins, allergens, nano plastics, pathogenic bacteria and viruses. The pathogenic bacteria include Salmonella and viruses include norovirus and hepatitis B.

These minor hazards are organisms or chemicals that are found within the European environment. Some are naturally occurring, such as marine biotoxins, and some are clearly a result of human activities such as nano plastics, pesticides, dioxins and flame retardants. There are safety concerns related to adverse events associated with seaweed consumption, particularly the variable and potentially dangerously high concentrations of iodine and heavy metals (including inorganic arsenic) in certain seaweeds.[2,3]

Only one publication by the University of Connecticut[4] focused on seaweed sold to the consumer (including raw and chilled), whether in restaurants or as a processed product. The food safety hazards identified

[Picture of person collecting seaweed removed due to file size constraints]

Jo Lane collecting Golden Kelp (Ecklonia radiata) at dawn from case study 2. Photo taken by Honey Atkinson and supplied by Jo Lane.

were pathogens from the harvest area, which were potentially significant because the seaweed may be consumed as a raw product, without any additional processing kill step.

Pathogens of concern include *Vibrio, Salmonella, E.coli* O157:H7, *Shigella, Norovirus* and Hepatitis. Environmental chemical contaminants were considered potentially significant as certain species of seaweeds exhibit a high affinity for accumulating heavy metals and other contaminants in their tissues. Natural toxins from the harvest area including outbreaks related to the consumption of several *Gracilaria* species. These toxins are often heat-stable and even if seaweed is cooked before consumption, the toxin will remain in the final product.

The spores of *Clostridium botulinum,* that form botulinum toxin, are naturally occurring in the marine and estuarine environment. It could be considered for seaweed products that are raw or blanched and then packaged in a modified/reduced atmosphere package (e.g. vacuum packed). Almost all papers reviewed were based on Northern hemisphere seaweed species and environments.

In addition to the literature review, the project reviewed 20 years of worldwide recall notices and border rejections using the Horizon Scan database.[5] This process identified the following food safety hazards:

- Iodine: 262 incidents between 2000 – 2022
- Inorganic arsenic: 64 incidents between 2000 – 2022
- USA Import refusals: 35 incidents between 2002 – 2021 including labelling failure, processing failure, 'filth' and unauthorised colours
- Cadmium: 13 incidents between 2005 – 2020
- Salmonella: 11 incidents between 2011 – 2018
- E. coli O7:H4: 3,000 school students and staff in Japan in 2020 (red seaweed salad)
- Chemical hazards: Nitrofurans, sulphites, benzopyrene and aluminium
- Unauthorised colours
- Unauthorised irradiation
- Microbiological organisms: Listeria, mould and coliforms
- Allergens: soy, gluten and sesame
- Fraud: documentation (labelled as organic from Nth Korea in 2020) and species substitution (Vietnam 2021).

The process steps undertaken in the case studies were reviewed for actual food safety hazards, control measures and critical control points (CCP). The hazards identified were quite different to those identified in most of the publications. These were:

- Allergens: crustaceans and molluscs - controlled by washing in fresh water
- Physical contamination: sand and marine debris - controlled by washing in fresh water
- Micro contamination: Salmonella - controlled by the drying process resulting in a final product of Aw below 0.83 and salt content
- Chemical contamination: iodine – possibly controlled by blanching of raw material
- Almost all hazards were controlled or eliminated by growing seaweed in controlled tank conditions.

Variables that need to be considered to identify further controls for the identified food safety hazards include:

- Species specific hazards in local seaweed species
- Seaweed plant age and which parts of the plants are used
- Local harvest environmental conditions
- Rainfall levels in the local harvest area and harvest water temperature
- Blanching process.

Project partners:

1. Sea Health Products: https://www.seahealthproducts.com.au/
2. Phyco Health & Venus Shell Systems: https://www.venusshell-systems.com.au/

References

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Clare Winkel is the Executive Manager – Technical Solutions for Integrity Compliance Solutions (ICS).

[Picture of seaweed removed due to file size constraints]

Photo supplied by Pia Winberg: finished product (dried farmed seaweed- Ulvophyceae) from case study 1.

NATIONAL COFFEE ASSOCIATION USA EST. 1911

January 23, 2023

Dr. David McSwane, REHS, CP-FS
Executive Director
Conference for Food Protection
30 Elliott Court
Martinsville, IN 46151-1331
Dmcswane.cfp@gmail.com

Cc: Sharon Farrell, MS, RD,
Indiana Department of Health

Dear Dr. McSwane:

The NCA appreciates the opportunity to comment and submit an Issue to the Conference for Food Protection on retail cold brew coffee to consider for recommendation to the Food Code. We provide this supporting document to summarily describe justification, current enforcement practices, and a comprehensive challenge study currently underway, to help inform the creation of a standard on retail cold brew coffee for the Food Code.

The National Coffee Association (NCA), established in 1911, is the nation's leading coffee trade organization, representing more than 200 member organizations across all segments of the U.S. coffee industry, including growers, importers, traders, roasters, retailers, and allied organizations. Coffee plays a key role in the U.S. economy, supporting more than 1.6 million jobs and contributing more than $225 billion to the economy annually. Most Americans (66% of those over 18) drink coffee each day, more than any other beverage, including water[1].

While "traditional" coffee is recognized as a safe food, cold brew coffee involves a different preparation method, one that exchanges a heat-based extraction method for one that takes place over a longer period of time at ambient or cooler temperature, and results in a beverage that tastes less acidic and is smoother than traditionally prepared coffee. Given a lack of consistent and clear regulations regarding safe preparation, storage, and dispensing of cold brew coffee, coupled with its rapidly growing popularity, state and local health departments as well as coffee retailers (such as coffee shops) are in need of guidance in the form of regulations that provide clarity for food safety enforcement and compliance, as well as consumer safety.

As a result, there is a pressing need for the creation of a Food Code standard on cold brew coffee prepared for retail sale to help provide uniformity of food safety enforcement and compliance across the many enforcement agencies across the country.

[1] National Coffee Data Trends Report Fall 2022, National Coffee Association USA, Inc. https://www.ncausa.org/Portals/56/PDFs/Communication/Fall-2022-media-highlights.pdf

Outlined below is a summary of some safety concerns and enforcement considerations that have been brought to our attention via prominent health departments and businesses. In addition, we have summarized the objectives, outcomes and timing for a comprehensive cold brew challenge study that the NCA has commissioned with a leading national third-party accredited laboratory, currently underway, intended to result in empirical data to support the creation of safety standards.

Summary of Justification, Enforcement, and Challenge Study Research Objectives

Safety concerns in retail cold brew coffee, existing food code enforcement, and research objectives for a cold brew coffee challenge study designed to resolve regulators' concerns and inform the Food Code.

Safety concerns for retail cold brew coffee:

1. Temperature abuse or ambient brewing allowing for increased microbial growth.
2. Extended shelf-life increases risk of microbial growth
3. Sanitation concerns
4. Reduced oxygen packaging (ROP)

Health inspector enforcement of existing food code:

Health inspector enforcement of existing food code standards on retail cold brew has varied significantly across state and local jurisdictions. Some of the most rigorous and prominent enforcement has included (excerpted from Maricopa County Environmental Services Department):

1. Cold brew coffee has been regarded by various jurisdictions as a time/temperature control for safety (TCS) food unless evidence has been provided to health departments to indicate it is a non-TCS food.
    a. A food that because of its pH or a_w (water activity) value, or interaction of a_w and pH values, is designated as a non-TCS food.
    b. If the interaction of the product's pH and a_w indicates a product assessment is required, then a challenge study will need to be conducted in accordance with National Advisory Committee on Microbiological Criteria for Foods (NACMCF) standards and provided to departments of health for consideration.
2. HACCP plans and variances are not required if cold brew coffee is handled in accordance with all applicable parameters of the food code:
    a. Brew, hold, and dispense at 41°F or below.
    b. Date marked for no more than 7 days from the date of production.
3. Kegging cold brew coffee, or using a similar packaging method, such as bottling, is a reduced oxygen packaging (ROP) process. With the exceptions identified below, a HACCP plan and a variance may be required.
4. HACCP plans and variances are NOT required for non-TCS food.
5. HACCP plans and variances are NOT required if sealing the product using ROP methods and holding the product in package for less than 48 hours (after 48 hours product must be discarded, removed from package or unsealed) in accordance with §3-502.12 (F) and if handled in accordance with all other applicable parameters of the food code.

6. When packaging (packaged at 41°F or below) is conducted in accordance with §3-502.12, only a HACCP plan will be required. If processes deviate from §3-502.12, a variance will also be required.

Research Objectives:

1. NCA has commissioned a nationally accredited third-party laboratory to determine the ability of proteolytic and non-proteolytic *Clostridium botulinum* (*C. bot.*) and non-*C. bot.* pathogens (*Bacillus cereus* spores, *Escherichia coli* O157:H7, *Listeria monocytogenes*, *Salmonella*, and *Staphylococcus aureus*) to grow in cold brew coffee concentrate prepared by the bucket method (4-6° Brix) at ambient temperature for 12-18 hours and single-strength cold brew (1.5-2° Brix) packaged into bag-in-box (BIB) and stored at 85°F for up to 11 days of storage.

Outcomes & Timing:

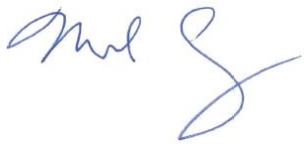
The NCA anticipates that the research study will be completed in the Spring with completion of a white paper by June 2023. The results can be used to inform creation of a standard for the Food Code.

Conclusion:

On behalf of the coffee sector, we are interested in participating and supporting a process to create science-based, practical guidance to support creation and enforcement of cold brew coffee related food safety regulations to protect consumers.

Sincerely,

William (Bill) Murray, CAE
President & CEO
National Coffee Association
wmurray@ncausa.org



Mark Corey, Ph.D.
Director Science & Policy
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Comprehensive Reviews in Food Science and Food Safety

Evaluation and Definition of Potentially Hazardous Foods

A Report of the Institute of Food Technologists
for the Food and Drug Administration
of the United States Department of Health and Human Services

December 31, 2001

IFT/FDA Contract No. 223-98-2333
Task Order No. 4

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Comprehensive Reviews in Food Science and Food Safety

Chapter VIII
Framework Developed to Determine Whether Foods Need Time/ Temperature Control for Safety

1. Description of framework

The variety and novelty of the foods currently available to consumers has resulted in a complex situation when determining whether a food needs time/temperature control for safety. Although there are many foods that need time/temperature control for safety (TCS), other foods require specific evaluation in order to determine their status as TCS or non-TCS foods. To facilitate the decision as to whether a food needs time/temperature control for safety, the panel developed a framework based on: in-depth evaluation of criteria used by industry, government, and trade organizations; survey data collected by the panel (see Appendix B); available scientific literature; and the panelists' own experience on this subject. The framework provides a stepwise process that considers holding time and temperature, product description, pH and a_w interaction, product assessment, challenge testing, and mathematical models. Decisions as to whether or not a food should be designated as TCS can be made at various steps of the framework. Performing the initial steps requires only limited experience and/or minimum training, while subsequent steps require knowledge of the product's pH and a_w. More technical expertise is needed for the analysis step which is based on product assessment, challenge studies, and predictive modeling. If it is determined that the product needs (or may need) time/temperature control for safety, a number of alternatives are presented in the framework that might be considered. For example, a decision might be made that a challenge study is so costly that the best alternative is to reformulate the product or control the time or temperature.

The following is a description of the proposed framework that the panel has developed to determine whether a food needs time/temperature control for safety (see section 2 of this chapter).

Before proceeding with Step 1 of the evaluation process, the evaluator needs to make a succinct review of the food product in question, including intrinsic and extrinsic factors that may affect microbial growth and potential hazards. (Detailed descriptions of factors and potential hazards that will help with this review are presented in Chapters 3 and 4.) The food may already be held hot or cold for safety reasons. In this case, and if there is no desire to store the food at ambient temperature, the trained decision-maker need not proceed any further. Product history, in combination with a robust scientific rationale that justifies such safe history of use, may also be used as criteria to designate a food as a non-TCS food not requiring further evaluation (see also Chapter 3, section 4.2.).

Step 1. The panel concluded that the appropriate scientific evidence exists to allow for the evaluation of a food according to its pH, water activity, and pH/a_w interaction. The panel also agreed that a product that is processed to eliminate vegetative cells needs to be addressed differently than an unprocessed product that received no treatment or a less robust treatment. The concern of possible post-process contamination also needs to be addressed. If a food is processed to inactivate bacteria and packaged so that there is no post-process contamination, the tolerable range conditions of a_w and pH are more permissive, since spores would become the only microbial hazard. For these reasons, the panel designed two pH/a_w tables: one for the control of spores (Table A), and one for the control of spores and vegetative cells (Table B). The rationale for the ranges of pH and a_w in determining whether a food is non-TCS versus TCS is based on minimum pH and a_w requirements for the pathogens of concern; that is, *Bacillus cereus* and *Clostridium botulinum* toxin production when controlling spores, and *Listeria monocytogenes*, *Staphylococcus aureus, Salmonella* spp*, C. botulinum*, and *B. cereus* when controlling both vegetative cells and spores (see Chapter 3, sections 2.1. and 2.2. and Appendix C). If process technologies other than heat are applied, then the effectiveness of the process needs to be validated. For this decision, the evaluator needs to have an understanding of both the process and the validation of its effectiveness in reducing pathogens of concern. It should be noted that for some products, the analysis of pH and a_w may be inaccurate, especially in the case of combination products (see Chapter 4, section 10). Consequently, for these products the pH and a_w would not be considered as controlling factors without supporting data from challenge studies.

Step 2. After the product's assignment to a box inside one of the tables, if the product is designated as non-TCS, it may be safely stored at room temperature. If the product is placed in a box indicating with a question mark (?) that it may require temperature control for safety, an analysis may be performed to assess the microbial risk of holding the product at ambient temperature. The evaluator may also decide not to perform the analysis, in which case the time and temperature of the product should be controlled for safety.

Product assessment. A comprehensive description of the product is the first task in this product assessment. This entails a detailed description of such factors as (1) potential pathogens, (2) intrinsic factors (for example, preservatives, antimicrobials, humectants, acidulants, and nutrients), (3) extrinsic factors (for example, packaging, atmosphere (MAP), use/shelf life, and temperature range of storage and use), (4) effectiveness of the processing for control of pathogens, and (5) possible post-process recontamination opportunities that may be present. If any of the factors precludes the growth of pathogens (for example, acetic acid as an acidulant at a reasonably low pH), the product may be designated non-TCS. Historical information regarding product safety should be considered by determining whether the food in question, or

any of its ingredients, has been previously implicated as a common vehicle of foodborne disease after temperature abuse. Of particular importance are the microbiological agents that are responsible for illnesses associated with the food and the reported contributing factors that have led to documented illnesses. Has adequate temperature control been clearly documented as a factor that can prevent or reduce the risk of illness associated with the food? Lastly, product history alone should not be used as the sole factor in determining whether or not a food needs time/temperature control for safety, unless a scientific basis for such safe use could be rationalized. As intrinsic or extrinsic factors change (for example, MAP or greatly extended shelf life), historical evidence alone is not appropriate in determining potential risk. Therefore, for a product to be identified as non-TCS based on history, the intrinsic and extrinsic factors affecting microbial growth need to have remained constant, and a scientific rationale needs to have been provided for the product's safe use (see also Chapter 3, section 4.2.).

Microbial growth models and challenge studies. In addition to the usual considerations, time of expected storage and display might also play a significant role in determining the classification of the food. Foods that have combinations of pH, a_w, preservatives, or other factors that are restrictive (but not prohibitive) to microbial growth and/or toxin production may not require refrigeration to protect public health. For example, if the duration of storage and/or display is less than that needed for microbial growth and/or toxin production, adequate control may be achieved through a variety of time and temperature combinations. Under certain circumstances, time alone at ambient temperatures can be used to control product safety. These factors can be considered in light of the product assessment and the microbial hazards of concern. The following is an example of how storage or holding time alone at ambient temperatures could be used to control product safety. If the microbiological concern for a specific food is the growth of *S. aureus*, the USDA Pathogen Modeling Program v. 5.1 could be used to estimate the time of storage where pathogen growth could occur. Using Table 8-1 with data generated from the model, a product with an $a_w = 0.88$ and pH = 5.5 could be safely stored at ambient temperature for weeks, assuming *S. aureus* would be the only microbial concern.

Table 8-1—Time estimates required for 3-log growth of *Staphylococcus aureus* at various pH and water activities (a_w) based on the USDA Pathogen Modeling Program v. 5.1

	PH			
a_w	6.0	5.5	5.0	4.6
0.94	Hours	Hours	Hours	Hours
0.92	Hours	Hours	Days	Days
0.90	Hours	Days	Days	Weeks
0.88	Days	Weeks	Months	Months
0.86	Weeks	Months	Months	Months

Days = 2–13 days
Weeks = 13–60 days
Months = > 60 days

It must be emphasized, however, that general growth models such as the USDA Pathogen Modeling Program must be restricted in use because of limitations of the model parameters, microorganisms of concern, or other factors. Consequently, unless used conservatively, it is often more appropriate to use them in combination with challenge testing. Nevertheless, a general model can assist, for example, in selecting pathogens of concern for a challenge test. In the absence of an appropriate model, a challenge test alone could be used to determine whether pathogens of concern could grow under specified storage conditions (see Chapter 6 for guidelines on challenge testing). On the other hand, if an in-house model has been developed and validated for a particular food, it could be used to make such an assessment by itself or with challenge testing. At this point, a final decision needs to be made about the product's need to be time/temperature controlled. If the hazard analysis indicates that the product should be designated as non-TCS, the product can be stored at room temperature. If, on the contrary, the product is identified as TCS, the evaluator can either decide to modify the product, change the processing and handling it undergoes, control pathogen growth with time/temperature, or revisit the commercial feasibility of the product.

(See "2. Framework for determining if time/temperature control is required for safety" on next page)

2. Framework for determining if time/temperature conrol is required for safety

The food in question may already be held hot or cold for safety reasons. In this case, and if there is no desire for ambient temperature storage, an analysis using this framework is not needed. If the need to control the temperature of the product for safety reasons is unknown, a review of the food, its ingredients, and general methods of preparation should precede the evaluation of the food. If the food, as described, has a substantial and extensive history of safe use without time/temperature control, and there is enough scientific rationale that supports such safe history of use, then the food may continue to be classified as not requiring temperature control for safety, or non-TCS (see also Chapter 3, section 4.2.).

If there is no known history of safe use, proceed with Step 1.

Step 1—Was the food treated to destroy vegetative cells of potential pathogens and packaged to avoid recontamination? If yes, position your product in Table A according to its pH and water activity (a_w). If not, position your product in Table B according to its pH and a_w.

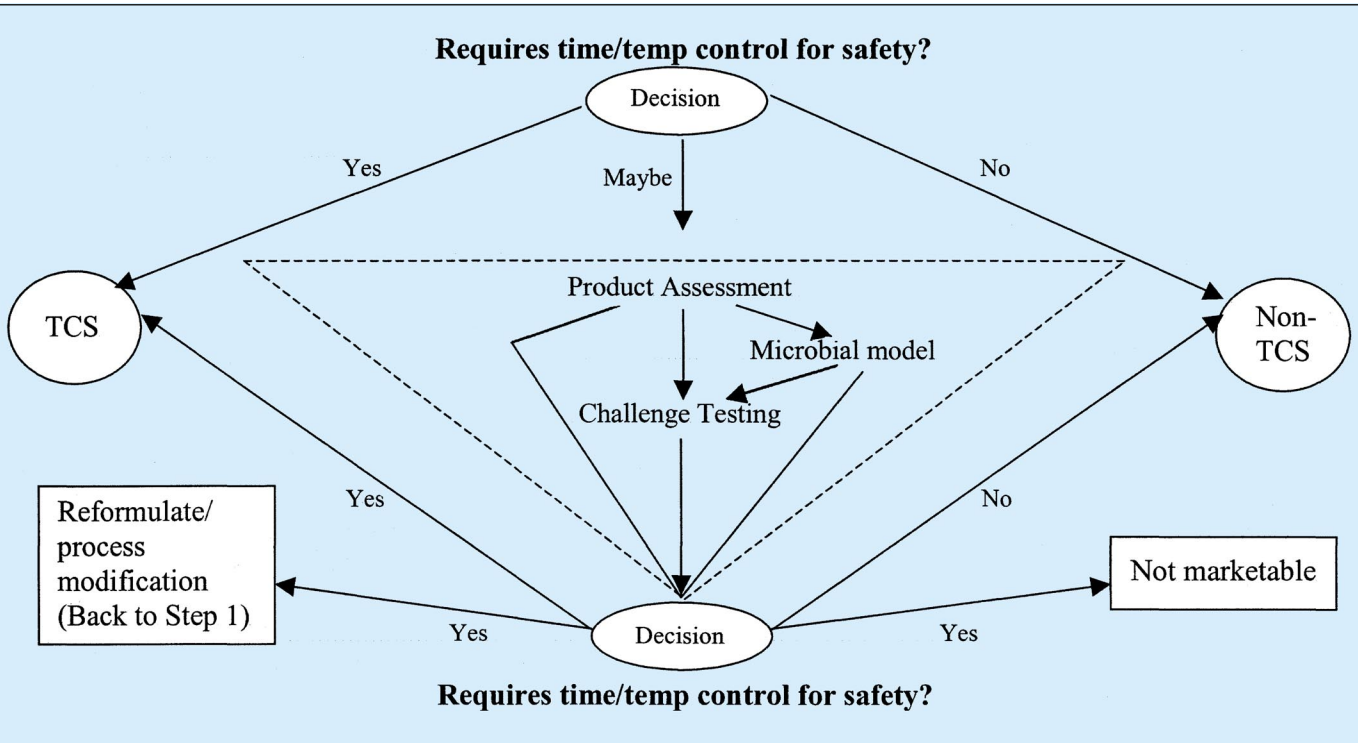
Table A—Control of spores: Product treated to control vegetative cells and protected from recontamination.

Critical a_w values	Critical pH values		
	4.6 or less	> 4.6 to 5.6	> 5.6
0.92 or less	Non-TCS	Non-TCS	Non-TCS
> 0.92 to .95	Non-TCS	Non-TCS	?
> 0.95	Non-TCS	?	?

Table B—Control of vegetative cells and spores: Product not treated or treated but not protected from recontamination

Critical a_w values	Critical pH values			
	< 4.2	4.2 to 4.6	> 4.6 to 5.0	> 5.0
< 0.88	Non-TCS	Non-TCS	Non-TCS	Non-TCS
0.88 to 0.90	Non-TCS	Non-TCS	Non-TCS	?
> 0.90 to .92	Non-TCS	Non-TCS	?	?
> 0.92	Non-TCS	?	?	?

Step 2—If the food is classified as a non-TCS food according to Step 1 above, it may be stored and held safely without regard to time or temperature. If the need for time/temperature control is questionable, the food should be held either hot or cold for safety, or subjected to a product assessment as the next step in determining the appropriate classification.



3. Critique of framework. Application of framework to foods.

The panel's framework on time/temperature control of foods for safety was applied to the following foods as examples. Each step of the framework has been described as it applies to the food under consideration. Most of the data presented were from industry studies submitted to the panel in response to a survey of industry practices to determine whether a food needs time/temperature control (see Appendix B).

3.1. Salad dressings

Product: Viscous, non-particulate[1] pourable salad dressing.

The product is not held hot or cold. The ingredients of the product are eggs, soybean oil, buttermilk, tomato paste, onion, garlic, spices, lemon juice, vinegar (2.5 – 5.4% salt), and potassium sorbate. Microbial hazards: *Clostridium botulinum*. The product is intended to be distributed and stored at ambient temperature for 7 to 9 mo. New product, so there is no history of use.

Step 1. Processing: Cold blended and filled in plastic or glass bottle. No heat applied.

Go to Table B.

Table: pH maximum of 4.2 and "high" (not specified) a_w.

Step 2. Decision: Product may be a temperature controlled for safety (TCS) food.

Product Assessment: Salad dressing is acidified with acetic acid. No microbiological hazard at pH 4.2.

Decision: Product is a Non-TCS.

[1]If salad dressing had particulate matter, then this product would need to be reevaluated.

3.2. Condiments: Mustard

Product: Viscous, non-particulate[1] mustard.

The product is not held hot or cold. The ingredients of the product are mustard seeds and vinegar (acetic acid). The product is intended to be distributed and stored at ambient temperature for extended shelf life. Microbial hazards: *Listeria monocytogenes, Salmonella* spp.*, Escherichia coli* O157:H7, *C. botulinum.* There is history of safe use without time/temperature control[2].

Step 1. Processing: Ground and blended. Go to Table B.

Table: pH maximum of 4.0 and "high" (not specified) a_w.

Decision: Product is a Non-TCS.

[1] If mustard had particulate matter, then this product needs to be reevaluated.

[2] If pH of mustard was above 4.2 or if acidulant was not acetic acid, then this product would need to be reevaluated.

3.3. Butter

Example 1

Product: Salted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution product is held at low temperatures for quality reasons. The ingredients of the product are cream and salt. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There is no history of safety problems when the consumer does not control time/temperature of commercial salted butter.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 5.41 and a_w 0.897.

Step 2. Decision: Product may be a TCS food.

Product Assessment: Product characteristics prevent *L. monocytogenes* growth. Predictive model (p 8-3) suggests that holding the product for hours at ambient temperature is safe.

Decision: Challenge testing, predictive microbial model, reformulation to decrease a_w, refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or product is not marketable.

Example 2

Product: Salted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution product is held at low temperatures for quality reasons. The ingredients of the product are cream and salt. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There is no history of safety problems when the consumer does not control time/temperature of commercial salted butter.

Step 1. Processing: Pasteurization of cream. Acidified by fermentation. No heat applied after butter is churned. Go to Table B.

Table: pH 4.25 and a_w 0.897.

Step 2. Decision: Product is a Non-TCS food.

Example 3

Product: Salted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution product is held at low temperatures for quality reasons. The ingredients of the product are cream and salt. The product is intended to be stored at ambient temperature. Microbiological hazard: *S. aureus, L. monocytogenes*. There is no history of safety problems when the consumer does not control time/temperature of commercial salted butter.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 5.94 and a_w 0.847.

Step 2. Decision: Product is a Non-TCS food.

Example 4

Product: Salted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution product is held at low temperatures for quality reasons. The ingredients of the product are cream, lactic acid bacteria, and salt. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There is no history of safety problems when the consumer does not control time/temperature of commercial salted butter.

Step 1. Processing: Pasteurization of cream. Acidified by fermentation. No heat applied after butter is churned. Go to Table B.

Table: pH 4.78 and a_w 0.863.

Step 2. Decision: Product is a Non-TCS.

Example 5

Product: Unsalted whipped butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution, the product is held at low temperatures for quality reasons. The ingredients of the product are cream and acidified natural flavoring. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There has been a report of unsafe handling of a whipped butter product.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 4.91 and a_w 0.921.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision: Challenge testing, predictive microbial model, reformulation to decrease a_w, refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or product is not marketable.

Example 6

Product: Unsalted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution , the product is held at low temperatures for quality

reasons. The ingredients of the product are cream and natural flavoring. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There is no history of unsafe use without time/temperature control.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 5.98 and a_w 0.941.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision: Challenge testing, predictive microbial model, reformulation to decrease a_w, refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or product is not marketable.

Example 7

Product: Unsalted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution , the product is held at low temperatures for quality reasons. The ingredients of the product are cream and natural flavoring. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There is no history of unsafe use without time/temperature control.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned. Go to Table B.

Table: pH 5.42 and a_w 0.907.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision: Challenge testing, predictive microbial model, reformulation to decrease a_w, refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or product is not marketable.

Example 8

Product: Salted light whipped butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution, the product is held at low temperatures for quality reasons. The ingredients of the product are cream, salt, water, tapioca, modified food starch, beta carotene, vitamin A, natural flavoring, lactic acid, vegetable mono and diglycerides, potasium sorbate, sodium benzoate. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There has been a report of unsafe handling of a whipped butter product.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 4.48 and a_w 0.985.

Step 2. Product may be a TCS food.

Product Assessment: Sodium benzoate and potassium sorbate may prevent pathogen growth.

Decision: Challenge testing, predictive microbial model, reformulation to decrease a_w, refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or product is not marketable.

Example 9

Product: Salted whipped butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution, the product is held at low temperatures for quality reasons. The ingredients of the product are cream and acidified natural flavoring. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There has been a report of unsafe handling of a whipped butter product.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 4.14 and a_w 0.822.

Step 2. Decision: Product is a Non-TCS food.

3.4. Margarine

Product: Margarine. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution, the product is held at low temperatures for quality reasons. The ingredients of the product are soybean oil (80%), water and milk protein (19%), salt (0.9%), and potassium sorbate (.1%). The product is intended to be distributed and stored at ambient temperature for 3 mo. Microbiological hazards: *S. aureus, L. monocytogenes*. There is history of safe use without time/temperature control.

Step 1. Processing: Emulsification of oil blend/water preservative mixture. No heat applied. Go to Table B.

Table: pH 4.8 and a_w unknown.

Step 2. Product may be a TCS food.

Product Assessment: Sorbic acid in formulation prevents pathogen growth. Historically product is safe and stable.

Decision: Product is a Non-TCS.

3.5. Garlic-in-oil[1]

Product: Garlic-in-oil. The product is not held hot or cold. The ingredients of the product are chopped fresh garlic and oil. The product is intended to be distributed and stored at ambient temperature for extended shelf life. Outbreaks have been associated with *C. botulinum* toxin in garlic-in-oil. Microbiological hazards: *C. botulinum* toxin production.

Step 1. Processing: Oil poured into chopped garlic in a bottle. Although no heat is applied, vegetative pathogens are not associated with this food. Go to Table A.

Table: pH > 4.6 and high a_w (not specified).

Step 2. Decision: Product may be a TCS food.

Product Assessment: No identified product characteristic that prevents spore-forming pathogen growth. Antimicrobial properties of garlic will prevent the growth of vegetative pathogens.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic or phosphoric acid to < 4.6, refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

[1]Flavored oil will present negligible hazard due to lack of *C. botulinum* survival or growth in 100% oil.

3.6. Cheeses

Example 1

Product: Cream cheese. The product is not held hot or cold during use. The ingredients of the product are milk, cream, salt, gums. The product is intended to be distributed and stored

at ≤ 7 °C (45 °F) for a maximum of 120 d. When in use, the tempered unopened product can be kept up to 48 h at ambient temperature. There is no history of botulism associated with cream-cheese products. Microbiological hazard: *C. botulinum.*

Step 1. Processing: Full fat, plain cream cheese, bulk packed and hot-filled > 68 °C (155 °F) in 3 lb/30 lb/ 50 lb tubs/blocks. Ready-to-eat after opening or baked. Go to Table A

Table: pH 4.7 to 5.1, $a_w > 0.97$.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic acid or phosphoric acid to < 4.6, keep refrigerated—that is, eliminate tempering at ambient (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: Separate products were inoculated with 100 – 500 spores/g of either proteolytic A & B or non-proteolytic B cocktails of *C. botulinum* and held at 30 °C (86 °F) for 10 d. No toxin was detected throughout the study. Conclusion is that the unopened product can be stored safely at ambient temperature for up to 7 d based on a safety factor of 1.3 times shelf life of the product. However, loss of product quality dictates storage at ambient temperature for no longer than 48 h. Without additional challenge studies on vegetative pathogens, opened product requires time/temperature control.

Example 2

Product: Process cheese sauce packed in 40 lb bag-in-box containers. The product is not held hot or cold during use. The ingredients of the product are cheddar cheese, milk, whey, milk fat, water, salt, sodium phosphate, sorbic acid, artificial color. The product is intended to be distributed and stored at ≤ 7 °C (45 °F) for a maximum of 9 mo. The tempered unopened product can be kept 24 h at ambient temperature in foodservice establishments prior to use. New product, so there is no history of use. Microbiological hazards: C*. botulinum.*

Step 1. Processing: Heated to 85 °C (185 °F) for 1 to 2 min and hot-filled at 68 to 69 °C (155 to 165 °F) into bag-in-box containers. Ready-to-eat or heated prior to consumption. Go to Table A.

Table: pH 5.7 (target) and $a_w > 0.95$.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No apparent product characteristic that prevents spore outgrowth. Possibly certain ingredients such as sodium phosphate and sorbic acid may inhibit pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic, lactic or phosphoric acid, refrigerate (that is, eliminate tempering at ambient temperature [TCS food]), or store at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Run formulation through a validated microbial model.

Predictive microbial modeling: Microbial model showed that the product would support the growth and toxigenesis of *C. botulinum.* A decision was made to reformulate by optimizing the controlling factors and their interactions. In this case, sorbic acid levels were adjusted from 0.08 % to 0.15 %. The reformulated product was run through the microbial model which gave a prediction of safety. Conclusion is that the reformulated unopened product may be tempered at room temperature for 24 h maximum. Without additional challenge studies on vegetative pathogens, opened product requires time/temperature control.

Example 3

Product: Pasteurized process cheese slices, bulk packaged. The product is not held hot or cold during use. The ingredients of the product are milk, whey, cheese, milk fat, water, salt, sodium citrate, sorbic acid, artificial color. The product is intended to be distributed and stored at ≤ 7 °C (45 °F) for a maximum of 8 mo. The tempered 96-slice pack can be kept for an 8 h shift at ambient temperature prior to use near to the grill in foodservice establishments to facilitate peeling of slices and melting on sandwiches. No history of pathogenic growth associated with commercial pasteurized process cheese slices. Product is subject to recontamination after opening. Microbial hazards: *L. monocytogenes, S. aureus, Salmonella* spp*., E. coli* O157:H7, *C. botulinum* (product does not receive a proteolytic botulinal cook).

Step 1. Processing: Heated to ≥ 66 °C (150 °F) for ≥ 30 s and cooled over a chill roll. Slices are then bulk packed in units of 96 slices. Ready-to-eat directly out of package or used in melt applications. Go to Table B.

Table: pH 5.7 to 5.8 and $a_w > 0.92$.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No apparent product characteristic that prevents spore outgrowth. Possibly sorbic acid may inhibit pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic, lactic, or phosphoric acid, refrigerate (that is, eliminate tempering at ambient temperature [TCS food]), or store at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: Product was inoculated with 10^3 CFU/g *L. monocytogenes, S. aureus, E. coli* O157:H7, *Salmonella* spp*.,* and *C. botulinum* (proteolytic strains only). Cocktails of each challenge organism were inoculated into separate samples. Inoculated product was incubated at 30°C (86°F) for 96 h. Results showed that *Salmonella* spp*, E. coli* O157:H7, and *L. monocytogenes* decreased in populations over the challenge period. *Staphylococcus aureus* levels remained constant during the challenge period, but were below levels that supported detectable enterotoxin production. No botulinal toxin was detected over the challenge period. From a safety perspective the opened product could be stored for 67 h at room temperature, based on a safety factor of 1.3 times shelf life of the product. Loss of product quality dictates that slices be tempered for no longer than 8 h.

Example 4

Product: Cheese blend for pizza topping. The product is not held hot or cold during use. The ingredients of the product are cheese, sodium chloride 1.81%, nitrite level < 1ppm. The product is intended to be stored at ambient temperature for a maximum of 10 h before being baked. This is a new intended use, so there is no history of safe use. The microbiological hazards are the heat-stable toxins of *S. aureus* and *B. cereus.*

Step 1. Processing: Baked, but heat-stable toxins may remain. Go to Table B.

Table: pH 5.56 and a_w 0.978.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic, lactic, or phosphoric acid, refrigerate (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: 1,000 CFU/g of product inoculated with *S. aureus* and *B. cereus* and incubated at 27 °C (80 °F) for various lengths of time: No toxin was detected at 10 h. Product can be stored safely at room temperature for 7 h, based on a safety factor of 1.3 shelf life of the product.

Example 5

Description: Cheese-filled bread. The product is not held hot or cold during use. The ingredients of the product are process cheese, pastry covering, salt, glycerol. The product is intended to be distributed and stored at 4.4 to 7.3 °C (40 to 45 °F) for a maximum of 90 d, and then stored at ambient temperature for sale. New product, so there is no history of use. Microbiological hazard: *Bacillus cereus* and *Clostridium botulinum* toxin production.

Step 1. Processing: Baked to internal temperature of 88 °C (190 °F) and MAP packed with 100% N_2. Go to Table B.

Table: pH 5.6 to 5.7 and a_w 0.93.

Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic acid or phosphoric acid, refrigerate (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: Separated inocula of 500 spores of *C. botulinum* and 500 spores of *B. cereus* incubated at 13, 18.5, 30 °C (55, 65, 86 °F) for various lengths of time. No toxin production or *B. cereus* growth at 30°C (86 °F) for 14 d. Product can be stored safely at room temperature for at least 10 d, based on a safety factor of 1.3 times shelf life of the product.

Example 6

Product : Monterey cheese slices. The product is not held hot or cold during use. The ingredients of the product are Monterey Jack cheese, milk fat, water, citrate and phosphate emulsifiers, salt (1.9 to 2.5%), sorbic acid (2000 ppm max), color. The product is intended to be distributed and stored refrigerated for 180 to 210 d, but used at room temperature in food service. New product, so there is no history of use. Microbiological hazards: *L. monocytogenes, S. aureus, Salmonella* spp.*, E. coli* O157:H7.

Step 1. Processing: 71 °C (160 °F) for 30 s, hot filled, and sliced, but recontamination is possible. Go to Table B.

Table: pH 5.7 to 6.0, and a_w 0.94 to 0.95.

Step 2. Decision: Product may be a TCS food.

Product Assessment: Sorbic acid as a preservative may prevent pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic acid or phosphoric acid, refrigerate (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: Inoculum with 1,000 CFU/g of *L. monocytogenes, S. aureus, Salmonella* spp.*, E. coli* O157:H7 incubated at 30 °C (86 °F) for various lengths of time: No growth of any pathogen tested at 24 h, no *S. aureus* toxin, *E. coli*, *L. monocytogenes* and *Salmonella* spp. were detected at 48 h. Although *E. coli*, *L. monocytogenes* and *Salmonella* spp. levels remain the same up to 72 h, *S. aureus* toxin was detected at 72 h. Product can be stored safely at room temperature for no more than 33 h, based on a safety factor of 1.3 times shelf life of the product.

3.7. Filled bakery product

Product: Cream-filled éclairs. The product is not held hot or cold during use. The ingredients of the product are pastry shell (water, eggs, flour, hydrogenated vegetable oil, baking powder, sodium acid pyrophosphate, baking soda, corn starch, monocalcium phosphate, salt, malted barley); filling (water, sugar, modified corn starch, dextrose, vegetable oil, cottonseed, mono and diglycerides, salt, carrageenan, glucono delta lactone, sodium benzoate and potassium sorbate (0.02%), polysorbate 60, soy lecithin, natural and artificial flavors colored w/Yellow). The product is intended to be distributed at = 0 °C (32 °F) or refrigerated for a maximum of 180 d or 3 d, respectively, and stored at room temperature for a maximum of 4 h. This is a new product, so there is no history of use. Microbiological hazards: *L. monocytogenes, S. aureus, Salmonella* spp.

Step 1. Processing: Filling 88 °C (190 °F), cooled to 5 °C (41 °F) in 4 h; shell > 93 °C (200 °F), cooled to ambient but recontamination is possible. Go to Table B.

Table: pH 7.2 (shell), 5.1 to 5.8 (filling), a_w 0.87 (shell), 0.96 to 0.98 (filling).

Step 2. Decision: Product may be a TCS food.

Product Assessment: Benzoate, sorbate, and glucono delta lactone as preservatives may prevent pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic acid or phosphoric acid, refrigerate (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: Filling inoculated (and placed in shell) with 100 to 1,000 CFU/g with *L. monocytogenes, S. aureus, Salmonella* spp. incubated at 7, 12 and 26 °C (44.6, 53.6 and 78.8 °F) for various lengths of time. There was pathogen growth at 1 d. Product as processed and formulated cannot be stored safely at room temperature.

3.8. Breads

Example 1

Product: Pepper focaccia. The product is not held hot or cold during use. The ingredients of the product are bread, roasted sliced red peppers, oil, Romano cheese, garlic powder, oregano. This is a new product, so there is no history of use. The microbiological hazards are: *S. aureus, Salmonella* spp, and *C. botulinum*.

Step 1. Processing: Baked, but recontamination is possible. Go to Table B.

Table: pH (pepper and bread) 3.9 to 4.1[1] and a_w 0.99.

Step 2. Decision: Product is a non-TCS food.

[1]If only the bread or the peppers have low pH, then a challenge study should be performed.

Example 2

Product: Plain focaccia. The product is not held hot or cold during use. The ingredients of the product are bread, oil, Romano cheese, garlic powder, oregano. This is a new product, so there is no history of use. The microbiological hazards are: *S. aureus, Salmonella* spp.

Step 1. Processing: Baked, but recontamination is possible. Go to Table B.

Table: pH 5.5 to 5.3, and a_w 0.95 to 0.97.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth. Although product has properties similar to white bread, with a long history of safe use, some ingredients would not be in the formulation of white bread; therefore, the product may be a TCS food and should be further analyzed.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic acid or phosphoric acid, refrigerate (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

Reference Document: 2013 FDA Food Code

Provision: 1-201.10

Document Name: Heat sealing without a vacuum v03

Date: January 4, 2017, Editorial change September 12, 2017, December 20, 2019

Question: When packaging food in a retail food establishment, does the 2013 Food Code definition of reduced oxygen packaging apply to the use of plastic bags or plastic films that have been heat sealed without drawing a vacuum?

Response:

No. The process of heat sealing a time temperature control for safety (TCS) food in packaging (a plastic bag or a plastic film on trays) without drawing a vacuum or otherwise modifying the atmosphere inside the package would not meet the 2013 Food Code definition of reduced oxygen packaging (ROP), provided the food being packaged has NOT been heated, just prior to packaging.

The 2013 FDA Food Code defines "Reduced Oxygen Packaging" (ROP) as:

- "The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and . . . .."

A reduced oxygen environment occurs in a package when less oxygen is present in the package relative to the amount of oxygen expected to be present in the atmosphere (typically 21% at sea level). The Food Code definition of reduced oxygen packaging is limited to the intentional or purposeful methods used by food establishments to create a reduced oxygen environment within a packaged TCS food product at the time of packaging.

The packaging and sealing, without drawing a vacuum, of a TCS food that has not been heated, just prior to packaging, is not considered to be removing oxygen to the degree that you are: 1) reducing the amount of oxygen in a package at the time of packaging, or 2) using an intentional or purposeful method to create a reduced oxygen environment within a packaged TCS food product at the time of packaging.

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Heat sealing a hot TCS food (which includes TCS foods cooked as specified in relevant Sections of Part 3-401 of the Food Code and TCS foods heated to hot holding temperatures) without modifying the atmosphere or drawing a vacuum raises a concern of *C. botulinum* growth in the packaged TCS food. This is because the process of cooking food drives off oxygen from the food thereby lowering the oxygen level in that food. After the bag is sealed, the oxygen level in the headspace and the oxygen level in the hot TCS food will begin to equilibrate. This results in a package with an oxygen level below what is normally found in the atmosphere, thereby creating a process that aligns with the Food Code definition of ROP.

The model Food Code is neither federal law nor federal regulation and is not preemptive. It represents FDA's best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented. The model Food Code provisions are designed to be consistent with federal food laws and regulations and are written for ease of legal adoption at all levels of government.

References:

1. 2013 FDA Food Code, 1-202.10 Statement of Application and Listing of Terms.

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Fish and Fishery Products Hazards and Controls Guidance

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
OFFICE OF FOOD SAFETY

CHAPTER 13: **Clostridium botulinum Toxin Formation**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

UNDERSTAND THE POTENTIAL HAZARD.

Clostridium botulinum (*C. botulinum*) toxin formation can result in consumer illness and death. It is the toxin responsible for botulism. About 10 outbreaks of foodborne botulism occur annually in the United States, from all sources. Symptoms include: weakness, vertigo, double vision, difficulty in speaking, swallowing and breathing, abdominal swelling, constipation, paralysis, and death. Symptoms start from 18 hours to 36 hours after consumption. Everyone is susceptible to intoxication by *C. botulinum* toxin; only a few micrograms of the toxin can cause illness in a healthy adult. Mortality is high; without the antitoxin and respiratory support, death is likely.

This chapter covers the hazard of *C. botulinum* growth and toxin formation as a result of time and temperature abuse during processing, storage, and distribution.

- **Strategies for controlling pathogen growth**

There are a number of strategies for the control of pathogens in fish and fishery products. They include:

- Controlling the level of acidity (pH) in the product (covered by the Acidified Foods regulation, 21 CFR 114, for shelf-stable acidified products, and by this chapter for refrigerated acidified products);
- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product (covered in this chapter);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by formulation (covered in this chapter);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by drying (covered in Chapter 14);
- Controlling the introduction of pathogenic bacteria after the pasteurization process and after the cooking process performed immediately before reduced oxygen packaging (covered in Chapter 18);
- Controlling the source of molluscan shellfish and the time from exposure to air (e.g., by harvest or receding tide) to refrigeration to control pathogens from the harvest area (covered in Chapter 4);
- Managing the amount of time that food is exposed to temperatures that are favorable for pathogenic bacteria growth and toxin production (covered generally in Chapter 12; for *C. botulinum*, in this chapter; and for *Staphylococcus aureus (S. aureus)* in hydrated batter mixes, in Chapter 15);
- Killing pathogenic bacteria by cooking or pasteurization (covered in Chapter 16), or retorting (covered by the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation, 21 CFR 113 (hereinafter, the Low-Acid Canned Foods (LACF) Regulation));
- Killing pathogenic bacteria by processes that retain the raw product characteristics (covered in Chapter 17).

- **Formation of *C. botulinum* toxin**

When *C. botulinum* grows, it can produce a potent toxin, one of the most poisonous naturally occurring substances known. The toxin can be destroyed by heat (e.g., boiling for 10 minutes), but, because of its potency, you should not rely on this as a means of control.

The strains of *C. botulinum* can be divided into two groups, the proteolytic group (i.e., those that break down proteins) and the non-proteolytic group (i.e., those that do not break down proteins). The proteolytic group includes *C. botulinum* type A and some of types B and F. The non-proteolytic group includes *C. botulinum* type E and some of types B and F.

The vegetative cells of all types of *C. botulinum* are easily killed by heat. However, *C. botulinum* is able to produce spores. In this state, the pathogen is very resistant to heat. The spores of the proteolytic group are much more resistant to heat than are those of the non-proteolytic group (i.e., they require a canning process to be destroyed). Table A-4 (Appendix 4) provides guidance about the conditions under which the spores of the most heat-resistant form of non-proteolytic *C. botulinum*, type B, are killed. However, there are some indications that substances that may be naturally present in some products (e.g., dungeness crabmeat), such as lysozyme, may enable non-proteolytic *C. botulinum* to more easily recover after heat damage, resulting in the need for a considerably more stringent process to ensure destruction.

C. botulinum is able to produce toxin when a product in which it is present is exposed to temperatures favorable for growth for sufficient time. Table A-1 (Appendix 4) provides guidance about the conditions under which *C. botulinum* and other pathogenic bacteria are able to grow. Table A-2 (Appendix 4) provides guidance about the time necessary at various temperatures for toxin formation to occur.

Packaging conditions that reduce the amount of oxygen present in the package (e.g., vacuum packaging and modified atmosphere packaging) extend the shelf life of a product by inhibiting the growth of aerobic spoilage bacteria. There is a safety concern with these products because there is an increased potential for the formation of *C. botulinum* toxin before spoilage makes the product unacceptable to consumers.

C. botulinum forms toxin more rapidly at higher temperatures than at lower temperatures. The minimum temperature for growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F is 38°F (3.3°C). For type A and proteolytic types B and F, the minimum temperature for growth is 50°F (10°C). As the shelf life of refrigerated foods is increased, more time is available for *C. botulinum* growth and toxin formation. As storage temperatures increase, the time required for toxin formation is significantly shortened. You should expect that at some point during storage, distribution, display, or consumer handling of refrigerated foods, safe refrigeration temperatures will not be maintained (especially for the non-proteolytic group). Surveys of retail display cases indicate that temperatures of 45 to 50°F (7 to 10°C) are not uncommon. Surveys of home refrigerators indicate that temperatures can exceed 50°F (10°C).

In reduced oxygen packaged products in which the spores of non-proteolytic *C. botulinum* are inhibited or destroyed (e.g., smoked fish, pasteurized crabmeat, and pasteurized surimi), a normal refrigeration temperature of 40°F (4.4°C) is appropriate because it will limit the growth of proteolytic *C. botulinum* and other pathogens that may be present. Even in pasteurized products where non-proteolytic *C. botulinum* is the target organism for the pasteurization process, and vegetative pathogens, such as *Listeria monocytogenes*, are not likely to be present (e.g., pasteurized crabmeat and pasteurized surimi), a storage temperature of 40°F (4.4°C) is still appropriate because of the potential for survival through the pasteurization process and recovery of spores of non-proteolytic *C. botulinum*, aided by naturally occurring

substances, such as lysozyme. In this case, refrigeration serves as a prudent second barrier.

However, in reduced oxygen packaged products in which refrigeration is the sole barrier to outgrowth of non-proteolytic *C. botulinum* and the spores have not been destroyed (e.g., vacuum-packaged refrigerated raw fish, vacuum-packaged refrigerated unpasteurized crayfish meat, and reduced oxygen packaged unpasteurized dungeness crabmeat), the temperature should be maintained below 38°F (3.3°C) from packing to consumption. Ordinarily you, as a processor, can ensure that temperatures are maintained below 38°F (3.3°C) while the product is in your control. However, the current U.S. food distribution system does not ensure the maintenance of these temperatures after the product leaves your control.

The use of a Time-Temperature Indicator (TTI) on each consumer package may be an appropriate means of overcoming these problems in the distribution system for reduced oxygen packaged products in which refrigeration is the sole barrier to outgrowth of non-proteolytic *C. botulinum* and in which the spores have not been destroyed. A TTI is a device that monitors the time and temperature of exposure of the package and alerts the consumer or end user if a safe exposure limit has been exceeded. If a TTI is used, it should be validated to ensure that it is fit for its intended purpose and verified that it is functional at the time of use. It should be designed to alert the consumer (e.g., a color change) that an unsafe time and temperature exposure has occurred that may result in *C. botulinum* toxin formation. Additionally, the alert should remain perpetually visible after it has been triggered, regardless of environmental conditions that could reasonably be expected to occur thereafter. Skinner, G. E., and J. W. Larkin in "Conservative prediction of time to *Clostridium botulinum* toxin formation for use with time-temperature indicators to ensure the safety of foods," Journal of Food Protection, 61:1154-1160 (1998), describe a safe time and temperature exposure curve ("Skinner-Larkin curve") that may be useful in evaluating the suitability of a TTI for control of *C. botulinum* toxin formation in reduced oxygen packaged fish and fishery products.

Alternatively, products of this type may be safely marketed frozen, with appropriate labeling to ensure that it is held frozen throughout distribution. For some reduced oxygen packaged products, control of *C. botulinum* can be achieved by breaking the vacuum seal before the product leaves the processor's control.

The guidance in this chapter emphasizes preventive measures for the control of non-proteolytic strains of *C. botulinum* in products that are contained in reduced oxygen packaging. As was previously described, this emphasis is because such an environment extends the shelf life of a refrigerated product in a way that, under moderate temperature abuse, favors *C. botulinum* growth and toxin formation over aerobic spoilage. It is also possible for both non-proteolytic and proteolytic *C. botulinum* to grow and produce toxin in a product that is not reduced oxygen packaged and is subjected to severe temperature abuse. This is the case because of the development within the product of microenvironments that support its growth. However, this type of severe temperature abuse of refrigerated products is not reasonably likely to occur in the processing environment of most fish or fishery products and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulation, 21 CFR 110, requires refrigeration of foods that support the growth of pathogenic microorganisms.

- **Sources of *C. botulinum***

C. botulinum can enter the process on raw materials. The spores of *C. botulinum* are very common. They have been found in the gills and viscera of finfish, crabs, and shellfish. *C. botulinum* type E is the most common form found in freshwater and marine environments. Types A and B are generally found on land but may also be occasionally found in water. It should be assumed that *C. botulinum* will be present in any raw fishery product, particularly in the viscera.

Because spores are known to be present in the viscera, any product that will be preserved by salting, drying, pickling, or fermentation should be eviscerated prior to processing (see the "Compliance Policy Guide," Sec. 540.650). Without evisceration, toxin formation is possible during the process, even with strict control of temperature. Evisceration of fish is the careful and complete removal of all internal organs in the body cavity without puncturing or cutting them, including gonads. If even a portion of the viscera or its contents is left behind, the risk of toxin formation by *C. botulinum* remains. Uneviscerated small fish, less than 5 inches in length (e.g., anchovies and herring sprats), for which processing eliminates preformed toxin, prevents toxin formation during processing and that reach a water phase salt content of 10% in refrigerated finished products, or a water activity of below 0.85 in shelf-stable finished products, or a pH of 4.6 or less in shelf-stable finished products, are not subject to the evisceration recommendation.

Note: The water phase salt content of 10% is based on the control of *C. botulinum* type A and proteolytic types B and F.

Note: The water activity value of below 0.85 is based on the minimum water activity for toxin production of *S. aureus*.

- **Reduced oxygen packaging**

A number of conditions can result in the creation of a reduced oxygen environment in packaged fish and fishery products. They include:

- Vacuum, modified, or controlled atmosphere packaging. These packaging methods generally directly reduce the amount of oxygen in the package;
- Packaging in hermetically sealed containers (e.g., double-seamed cans, glass jars with sealed lids, and heat-sealed plastic containers), or packing in deep containers from which the air is expressed (e.g., caviar in large containers), or packing in oil. These and similar processing and packaging techniques prevent the entry of oxygen into the container. Any oxygen present at the time of packaging (including oxygen that may be added during modified atmosphere packaging) may be rapidly depleted by the activity of spoilage bacteria, resulting in the formation of a reduced oxygen environment.

Packaging that provides an oxygen transmission rate (in the final package) of at least 10,000 cc/m^2/24 hours at 24ºC can be regarded as an oxygen-permeable packaging material for fishery products. The oxygen transmission rate of packaging material is listed in the packaging specifications that can be obtained from the packaging manufacturer.

An oxygen-permeable package should provide sufficient exchange of oxygen to allow aerobic spoilage organisms to grow and spoil the product before toxin is produced under moderate abuse temperatures. Particular care should be taken in determining the safety of a packaging material for a product in which the spoilage organisms have been eliminated or significantly reduced by processes such as high pressure processing. The generally recommended 10,000 cc/m^2/24 hours at 24ºC transmission rate may not be suitable in this case.

Use of an oxygen-permeable package may not compensate for the restriction to oxygen exchange created by practices such as packing in oil or in deep containers from which the air is expressed or the use of oxygen scavengers in the packaging.

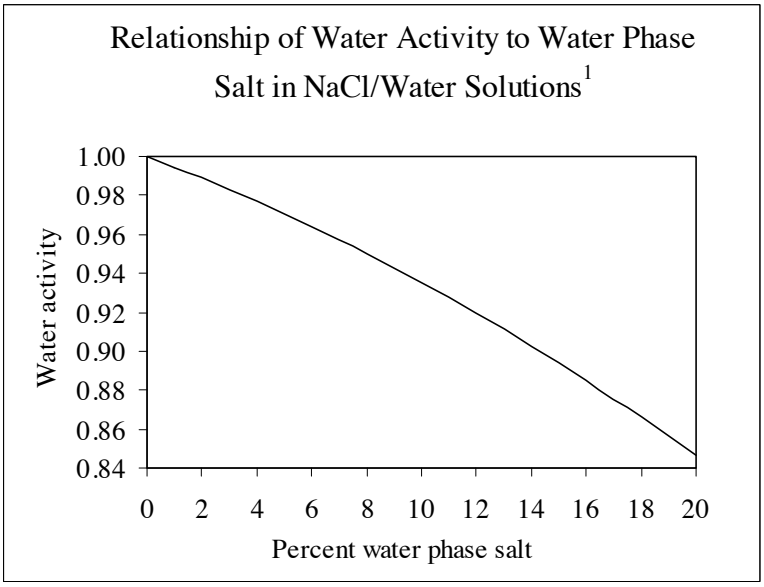
- **Control of *C. botulinum***

There are a number of strategies to prevent *C. botulinum* growth and toxin formation during processing, storage, and distribution of finished fish and fishery products. They include:

For products that do not require refrigeration (i.e., shelf-stable products):

- Heating the finished product in its final container sufficiently by retorting to destroy the spores of *C. botulinum* types A B, E, and F (e.g., canned fish). This strategy is covered by the LACF Regulation, 21 CFR 113, and these controls are not required to be included in your Hazard Analysis Critical Control Point (HACCP) plan;

- Controlling the level of acidity (pH) in the finished product to 4.6 or below, to prevent growth and toxin formation by *C. botulinum* types A, B, E, and F (e.g., shelf-stable acidified products). This strategy is covered by the Acidified Foods regulation, 21 CFR 114, and these controls are not required to be included in your HACCP plan;
- Controlling the amount of moisture that is available in the product (water activity) to 0.85 or below by drying, to prevent growth and toxin formation by *C. botulinum* types A, B, E, and F and other pathogens that may be present in the product (e.g., shelf-stable dried products). This strategy is covered by Chapter 14;
- Controlling the amount of salt in the product to 20% water phase salt (wps) or more, to prevent the growth of *C. botulinum* types A, B, E, and F and other pathogens that may be present in the product (e.g., shelf-stable salted products). This strategy is covered in this chapter. Water phase salt is the concentration of salt in the water-portion of the fish flesh and calculated as follows: (% NaCl X 100)/(% NaCl + % moisture) = % NaCl in water phase. The relationship between percent water phase salt and water activity in fish is described in the following graph.



1. This relationship is generally valid for fish products when salt (sodium chloride) is the primary means of binding water. The specific food matrix and the use of other salts or water binding agents could affect the exact relationship. If you intend to use this relationship in your control strategy, you should determine the exact relationship in your product by conducting a study.

For products that require refrigeration:

- Heating the finished product in its final container sufficiently by pasteurization to destroy the spores of *C. botulinum* type E and non-proteolytic types B and F, and then minimizing the risk of recontamination by controlling seam closures and cooling water, and next controlling the growth of the surviving *C. botulinum* type A and proteolytic types B and F in the finished product with refrigerated storage (e.g.. pasteurized crabmeat and some pasteurized surimi-based products). Pasteurization is covered in Chapter 16, controlling recontamination after pasteurization is covered in Chapter 18, and controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter;
- Heating the product sufficiently to destroy the spores of *C. botulinum* type E and non-proteolytic types B and F, and then minimizing the risk of recontamination by hot filling the product into the final container in a sanitary, continuous, closed filling system and controlling seam closures and cooling water, and next controlling the growth of the surviving *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product with refrigerated storage (e.g., vacuum packed soups, chowders, and sauces). Specialized cooking processes are covered in Chapter 16, prevention of recontamination after specialized cooking processes is covered in Chapter 18, controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12;
- Controlling the amount of moisture that is available in the product (water activity) to 0.97 or below to inhibit the growth of *C. botulinum* type E and non-proteolytic types B and F by drying, and then controlling the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product through refrigerated storage (e.g., refrigerated dried fish). Drying is covered in Chapter 14, controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12;
- Controlling the level of pH to 5 or below, salt to 5% wps or more, moisture (water activity) to 0.97 or below, or some combination of these barriers, in the finished product sufficiently to prevent the growth of *C. botulinum* type E and non-proteolytic types B and F by formulation, and then controlling the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product with refrigerated storage (e.g., refrigerated acidified (pickled) products). Controlling the growth of non-proteolytic *C. botulinum* through formulation is covered in this chapter, controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12;
- Controlling the amount of salt and preservatives, such as sodium nitrite, in the finished product, in combination with other barriers, such as smoke, heat damage, and competitive bacteria, sufficiently to prevent the growth of *C. botulinum* type E and non-proteolytic types B and F, and then controlling the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product with refrigerated storage (e.g., salted, smoked, or smoke-flavored fish). Controlling the growth of non-proteolytic *C. botulinum* through salting and smoking is covered in this chapter, controlling the growth of proteolytic *C. botulinum* through

refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12;

- Controlling the amount of salt in the finished product, in combination with heat damage from pasteurization in the finished product container, sufficiently to prevent the growth of *C. botulinum* type E and nonproteolytic types B and F, and then controlling the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product with refrigerated storage (e.g., some pasteurized surimi-based products). Controlling the growth of non-proteolytic *C. botulinum* through a combination of salt and heat damage is covered in this chapter, controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12.

Examples of *C. botulinum* control in specific products:

- **Refrigerated (not frozen), reduced oxygen packaged smoked and smoke-flavored fish**

  Achieving the proper concentration of salt and nitrite in the flesh of refrigerated, reduced oxygen packaged smoked and smoke-flavored fish is necessary to prevent the formation of toxin by *C. botulinum* type E and non-proteolytic types B and F during storage and distribution. Salt works along with smoke and any nitrites that are added to prevent growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F. Note that nitrites should be used only in salmon, sable, shad, chubs, and tuna, according to 21 CFR 172.175 and 21 CFR 172.177 , and should not exceed a level of 200 ppm in salmon, sable, shad, chubs and 10 ppm in tuna.

  In hot-smoked products, heat damage to the spores of *C. botulinum* type E and non-proteolytic types B and F also helps prevent toxin formation. In these products, control of the heating process is critical to the safety of the finished product. It is important to note, however, that this same heating process also reduces the numbers of naturally occurring spoilage organisms. The spoilage organisms would otherwise have competed with, and inhibited the growth of, *C. botulinum*.

  In cold-smoked fish, it is important that the product does not receive so much heat that the numbers of spoilage organisms are significantly reduced. This is important because spoilage organisms must be present to inhibit the growth and toxin formation of *C. botulinum* type E and non-proteolytic types B and F. This inhibition is important in cold-smoked fish because the heat applied during this process is not adequate to weaken the *C. botulinum* spores. Control of the temperature during the cold-smoking process to ensure survival of the spoilage organisms is, therefore, critical to the safety of the finished product.

  The interplay of these inhibitory effects (i.e., salt, temperature, smoke, and nitrite) is complex. Control of the brining or dry salting process is clearly critical to ensure that there is sufficient salt in the finished product. However, preventing toxin formation by *C. botulinum* type E and non-proteolytic types B and F is made even more complex by the fact that adequate salt levels are not usually achieved during brining. Proper drying during smoking is also critical in order to achieve the finished product water phase salt level (i.e., the concentration of salt in the water portion of the fish flesh) needed to inhibit growth and toxin formation by *C. botulinum*.

  This chapter covers the control procedures described above.

You should ordinarily restrict brining, dry salting, and smoking loads to single species and to fish portions of approximately uniform size. This restriction minimizes the complexity of controlling the operation. You should treat brine to minimize microbial contamination or periodically replace it as a good manufacturing practice control.

The combination of inhibitory effects that are present in smoked and smoke-flavored fish are not adequate to prevent toxin formation by *C. botulinum* type A and proteolytic types B and F. Strict refrigeration control (i.e., at or below 40°F (4.4°C)) during storage and distribution should be maintained to prevent growth and toxin formation by *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in these products. Controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12.

- **Refrigerated (not frozen), reduced oxygen packaged, pasteurized fishery products**

  Refrigerated, reduced oxygen packaged, pasteurized fishery products fall into two categories: (1) those which are pasteurized in the final container; and (2) those which are cooked in a kettle and then hot filled into the final container in a continuous, closed filling system (e.g., heat-and-fill soups, chowders, and sauces). In both cases, ordinarily the heating process should be sufficient to destroy the spores of *C. botulinum* type E and non-proteolytic types B and F. In neither case is it likely that the heating process will be sufficient to destroy the spores of *C. botulinum* type A and proteolytic types B and F. Therefore, strict refrigeration control (i.e., at or below 40°F (4.4°C)) should be maintained during storage and distribution to prevent growth and toxin formation by *C. botulinum* type A and proteolytic types B and F. Refrigeration also serves as a prudent second barrier because of the potential survival through the pasteurization process and recovery of spores of non-proteolytic *C. botulinum*, aided by naturally occurring substances, such as lysozyme. Cooking and pasteurization are covered in Chapter 16, and controlling the growth of *C. botulinum* through refrigeration is covered in this chapter.

  In the second category of products, filling the product into the final container while it is still hot in a continuous, closed filling system (i.e., hot filling) is also critical to the safety of the finished product because it minimizes the risk of recontamination of the product with pathogens, including *C. botulinum* type E and non-proteolytic types B and F. This control strategy applies to products such as soups, chowders, and sauces that are filled directly from the cooking kettle, where the risk of recontamination is minimized. It may not apply to products such as crabmeat, lobster meat, or crayfish meat or to other products that are handled between cooking and filling. Control of hot filling is covered in Chapter 18.

  Chapter 18 also covers other controls that may be necessary to prevent recontamination, including controlling container sealing and controlling contamination of container cooling water. These controls may be critical to the safety of both categories of products.

  Examples of properly pasteurized products follow: fish and fishery products generally (e.g., surimi-based products, soups, or sauces) pasteurized to a minimum cumulative total lethality of $F_{194°F}$ ($F_{90°C}$) = 10 minutes, where z = 12.6°F (7°C) for temperatures less than 194°F (90°C), and z = 18°F (10°C) for temperatures above 194°F (90°C); blue crabmeat pasteurized to a minimum cumulative total lethality of $F_{185°F}$ ($F_{85°C}$) = 31 minutes, where z = 16°F (9°C); and dungeness crabmeat pasteurized to a minimum cumulative total lethality of $F_{194°F}$ ($F_{90°C}$) = 57 minutes, where z = 15.5°F

(8.6°C). Equivalent processes at different temperatures can be calculated using the z values provided.

EXAMPLES OF PROPERLY PASTEURIZED PRODUCTS

PRODUCT	MINIMUM CUMULATIVE TOTAL LETHALITY	Z VALUE
Fish and fishery products generally (e.g., surimi-based products, soups, or sauces)	$F_{194°F}$ ($F_{90°C}$) = 10 minutes	12.6°F (7°C), for temperatures less than 194°F (90°C) 18°F (10°C) for temperatures above 194°F (90°C)
Blue crabmeat	$F_{185°F}$ ($F_{85°C}$) = 31 minutes	16°F (9°C)
Dungeness crabmeat	$F_{194°F}$ ($F_{90°C}$) = 57 minutes	15.5°F (8.6°C)

In some pasteurized surimi-based products, salt, in combination with a milder pasteurization process, in the finished product container works to prevent growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F. An example of a properly pasteurized surimi-based product in which 2.4% wps is present is one that has been pasteurized at an internal temperature of 185°F (85°C) for at least 15 minutes. This process may not be suitable for other types of products because of the unique formulation and processing involved in the manufacture of surimi-based products.

- **Refrigerated (not frozen), reduced oxygen packaged pickled fish, salted fish, caviar, and similar products**

  In pickled fish, salted fish, caviar, and similar products that have not been preserved sufficiently for them to be shelf stable, growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F is controlled by one of the following:

  - Adding sufficient salt to produce a water phase salt level (i.e., the concentration of salt in the water portion of the fish flesh) of at least 5%;
  - Adding sufficient acid to reduce the acidity (pH) to 5.0 or below;
  - Reducing the amount of moisture that is available for growth (water activity) to below 0.97 (e.g., by adding salt or other substances that "bind" the available water); or
  - Making a combination of salt, pH, and/or water activity adjustments that, when combined, prevents the growth of *C. botulinum* type E and non-proteolytic types B and F (to be established by a scientific study).

  Much like smoked products, in some of these products the interplay of these inhibitory effects (i.e., salt, water activity, and pH) can be complex. Control of the brining, pickling, or formulation steps is, therefore, critical to ensure that there are sufficient barriers in the finished product to prevent the growth and toxin formation of *C. botulinum* type E and non-proteolytic types B and F during storage and distribution. These control procedures are covered in this chapter.

  You should ordinarily restrict brining and pickling loads to single species and to fish portions of approximately uniform size. This restriction minimizes the complexity of controlling the operation. You should treat brine to minimize microbial contamination or periodically replace it as a good manufacturing practice control.

  The controls discussed above are not sufficient to prevent toxin formation by *C. botulinum* type A and proteolytic types B and F. Strict refrigeration control (i.e., at or below 40°F (4.4°C)) during storage and distribution should, therefore, be maintained to prevent growth and toxin formation by *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in these products. Controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the

growth of other pathogenic bacteria through refrigeration is covered in Chapter 12.

- **Refrigerated (not frozen), reduced oxygen packaged raw, unpreserved fish and unpasteurized, cooked fishery products**

  For refrigerated, reduced oxygen packaged raw, unpreserved fish (e.g., refrigerated, vacuum-packaged fish fillets) and refrigerated, reduced oxygen packaged, unpasteurized, cooked fishery products (e.g., refrigerated, vacuum-packaged, unpasteurized crabmeat, lobster meat, or crayfish meat), the sole barrier to toxin formation by *C. botulinum* type E and non-proteolytic types B and F during finished product storage and distribution is refrigeration. These types of *C. botulinum* will grow at temperatures as low as 38°F (3.3°C). As was previously noted, maintenance of temperatures below 38°F (3.3°C) after the product leaves your control and enters the distribution system cannot normally be ensured. The use of a TTI on the smallest unit of packaging (i.e., the unit of packaging that will not be distributed any further, usually consumer or end-user package) may be an appropriate means of overcoming these problems in the distribution system. This chapter provides controls for the application of TTIs for packaging.

  If you intend to package these products in a reduced oxygen package and you do not intend to apply a TTI on each consumer package, you should evaluate the effectiveness of other preventive measures, either singularly, or in combination, that may be effective in preventing growth and toxin formation by *C. botulinum*. Such evaluation is customarily accomplished by conducting an inoculated pack study under moderate abuse conditions. A suitable protocol for the performance of such studies is contained in a 1992 publication by the National Advisory Committee on Microbiological Criteria for Foods, "Vacuum or modified atmosphere packaging for refrigerated, raw fishery products."

- **Frozen, reduced oxygen packaged raw, unpreserved fish and unpasteurized, cooked fishery products**

  For frozen, reduced oxygen packaged raw, unpreserved fish (e.g., frozen, vacuum-packaged fish fillets) and frozen, reduced oxygen packaged, unpasteurized, cooked fishery products (e.g., frozen, vacuum-packaged, unpasteurized crabmeat, lobster meat, or crayfish meat), the sole barrier to toxin formation by *C. botulinum* type E and non-proteolytic types B and F during finished product storage and distribution is freezing. Because these products may appear to the retailer, consumer, or end user to be intended to be refrigerated, rather than frozen, labeling to ensure that they are held frozen throughout distribution is critical to their safety.

  Controls should be in place to ensure that such products are immediately frozen after processing, maintained frozen throughout storage in your facility, and labeled to be held frozen and to be thawed under refrigeration immediately before use (e.g., "Important, keep frozen until used, thaw under refrigeration immediately before use"). Frozen, reduced oxygen packaged products that are customarily cooked by the consumer or end user in the frozen state (e.g., boil-in-bag products and frozen fish sticks) need not be labeled to be thawed under refrigeration. For purposes of hazard analysis, other frozen products that do not contain the "keep frozen" statement should be evaluated as if they will be stored refrigerated because the consumer or end user would not have been warned to keep them frozen.

  Control procedures to ensure that product is properly labeled with "keep frozen" instructions are covered in this chapter.

- **Control in unrefrigerated (shelf-stable), reduced oxygen packaged fishery products**

  Examples of shelf-stable, reduced oxygen packaged fishery products are dried fish, acidified fish, canned fish, and salted fish. Because these products are marketed without refrigeration, either (1) the spores of *C. botulinum* types A, B, E, and F should be destroyed after the product is placed in the finished product container (covered by the LACF Regulation, 21 CFR 113) or (2) a barrier, or combination of barriers, should be in place that will prevent growth and toxin formation by *C. botulinum* types A, B, E, and F, and other pathogens that may be present in the product. Suitable barriers include:

  - Adding sufficient salt to produce a water phase salt level (i.e., the concentration of salt in the water portion of the fish flesh) of at least 20%. Note that this value is based on the maximum salt level for growth of *S. aureus*, covered in this chapter;
  - Reducing the amount of moisture that is available for growth (water activity) to below 0.85 (e.g., by adding salt or other substances that bind the available water). Note that this value is based on the minimum water activity for growth and toxin formation of *S. aureus*, covered in this chapter;
  - Adding sufficient acid to reduce the pH to 4.6 or below. This barrier is covered by the Acidified Foods regulation, 21 CFR 114, and these controls are not required to be included in your HACCP plan;
  - Drying the product sufficiently to reduce the water activity to 0.85 or below. Note that this value is based on the minimum water activity for growth and toxin formation of *S. aureus*, covered in Chapter 14.

  Note: A heat treatment, addition of chemical additives, or other treatment may be necessary to inhibit or eliminate spoilage organisms (e.g., mold) in shelf-stable products.

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether *C. botulinum* toxin formation is a significant hazard at a processing step:

1. Is it reasonably likely that *C. botulinum* will grow and produce toxin during finished product storage and distribution?

   The factors that make *C. botulinum* toxin formation during finished product storage and distribution reasonably likely to occur are those that may result in the formation of a reduced oxygen packaging environment. These are discussed in the section "Understand the potential hazard," under the heading, "Reduced oxygen packaging."

2. Can growth and toxin formation by *C. botulinum* that is reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step?

   C. botulinum toxin formation should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur.

   Preventive measures for *C. botulinum* toxin formation during finished product distribution and storage are discussed in the section, "Understand the potential hazard," under the heading, "Control of *C. botulinum*."

- **Intended use**

Because of the extremely toxic nature of *C. botulinum* toxin, it is unlikely that the significance of the hazard will be affected by the intended use of your product.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for *C. botulinum* toxin formation:

1. Is there an acidification step (equilibrium pH of 4.6 or below), a drying step, an in-package pasteurization step, a combination of cook and hot-fill steps, or a retorting step (commercial sterility) in the process?

    a. If there is, you should in most cases identify the acidification step, drying step, pasteurization step, cook and hot-fill steps, or retorting step as the CCP(s) for this hazard. Other processing steps where you have identified *C. botulinum* toxin formation as a significant hazard will then not require control and will not need to be identified as CCPs for the hazard. However, control should be provided for time and temperature exposure during finished product storage and distribution of the following products:

    - Products pasteurized in the final container to kill *C. botulinum* type E and non-proteolytic types B and F and refrigerated to control the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present (e.g., pasteurized crabmeat and pasteurized surimi);
    - Products cooked to kill *C. botulinum* type E and non-proteolytic types B and F, and then hot filled into the final container, and next refrigerated to control the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present;
    - Products dried to control the growth of *C. botulinum* type E and non-proteolytic types B and F and refrigerated to control the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present.

In these cases, you should also identify the finished product storage step as a CCP for the hazard. Control of refrigeration is covered in this chapter for *C. botulinum* and in Chapter 12 for other pathogenic bacteria.

Additionally, some pasteurized surimi-based products rely on a combination of salt and a relatively mild pasteurization process in the finished product container for the control of *C. botulinum* type E and non-proteolytic types B and F. In these products, you should also identify the formulation step as a CCP for the hazard. Guidance provided in "Control Strategy Example 4 - Pickling and Salting" may be useful in developing controls at this step.

Guidance for the *C. botulinum* control strategies listed above is contained in the following locations:

- Control of cooking and hot-filling is covered in Chapters 16 and 18;
- Control of pasteurization is covered in Chapters 16 and 18;
- Control of drying is covered in Chapter 14;
- Control of acidification is covered in the Acidified Foods regulation, 21 CFR 114;
- Control of retorting is covered in the LACF Regulation, 21 CFR 113.

Note: Acidification and retorting controls for *C. botulinum* required by 21 CFRs 113 and 114 need not be included in your HACCP plan.

b. If there is no acidification step (equilibrium pH of 4.6 or below), drying step, pasteurization step, cooking and hot-filling, or retorting (commercial sterility) step in the process, then decide which of the following categories best describes your product and refer to the guidance below:

- Smoked and smoke-flavored fish;
- Fishery products in which refrigeration is the sole barrier to prevent toxin formation;
- Fishery products in which freezing is the sole barrier to toxin formation;
- Pickled fish and similar products.

- **Smoked and smoke-flavored fish**

1. Is the water phase salt level and, when permitted, the nitrite level, important to the safety of the product?

   For all products in this category, the water phase salt level is critical to the safety of the product, and the brining, dry salting and, where applicable, drying steps should be identified as CCPs. Nitrite, when permitted, allows a lower level of salt to be used. Salt and nitrite are the principal inhibitors to *C. botulinum* type E and non-proteolytic types B and F toxin formation in these products. The water phase salt level needed to inhibit toxin formation is partially achieved during brining or dry salting and is partially achieved during drying. Control should be exercised over both operations.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Smoking (1a - Brining, Dry Salting, and Drying)."

2. Is the temperature of the heating or smoking process important to the safety of the product?

   For both cold-smoked and hot-smoked fish products, the temperature of smoking is critical, and the smoking step should be identified as a CCP for this hazard. The smoking step for hot-smoked fish should be sufficient to damage the spores and make them more susceptible to inhibition by salt. The smoking step for cold-smoked fish should not be so severe that it kills the natural spoilage bacteria. These bacteria are necessary so that the product will spoil before toxin production occurs. It is likely that they will also produce acid, which will further inhibit *C. botulinum* growth and toxin formation.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Smoking (1b - Cold Smoking and 1c - Hot Smoking)."

3. Is the storage temperature important to the safety of the product?

   Refrigerated (not frozen) finished product storage is critical to the safety of all products in this category and should be identified as a CCP. Toxin formation by *C. botulinum* type A and proteolytic types B and F is not inhibited by water phase salt levels below 10%, nor by the combination of inhibitors present in most smoked or smoke-flavored fish. *Bacillus cereus* can grow and form toxin at water phase salt concentrations as high as 18%.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Smoking (1d - Refrigerated Finished Product Storage)."

   In some cases, salted, smoked, or smoke-flavored fish are received as ingredients for assembly into another product, such as a salmon paté. In other cases, they are received simply for storage and further distribution (e.g., by a warehouse). In either case, the refrigerated (not frozen) storage step is critical to the safety of the product and should be identified as a CCP. Control is the same as that provided under "Control Strategy Example 1 - Smoking (1d - Refrigerated

Finished Product Storage)." Additionally, receiving of these products should be identified as a CCP, where control can be exercised over the time and temperature during transit.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Smoking (1e - Receipt of Products by Secondary Processor)."

- **Fishery products in which refrigeration is the sole barrier to prevent toxin formation**

1. Is the storage temperature important to the safety of the product?

Refrigerated finished product storage is critical to the safety of all products in this category and should be identified as a CCP. These products contain no barriers (other than refrigeration) to toxin formation by *C. botulinum* type E and non-proteolytic types B and F during finished product storage and distribution. These types of *C. botulinum* will grow at temperatures as low as 38°F (3.3°C), necessitating particularly stringent temperature control.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 2 - Refrigeration With TTI (2d - Refrigerated Finished Product Storage)."

In some cases, these products are received as ingredients for assembly into another product. In other cases, they are received simply for storage and further distribution (e.g., by a warehouse). In either case, the refrigerated storage step is critical to the safety of the product and should be identified as a CCP. Control is the same as that provided under "Control Strategy Example 2 - Refrigeration With a TTI (2d - Refrigerated Finished Product Storage)." Additionally, receiving of these products should be identified as a CCP, where control can be exercised over the time and temperature during transit.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 2 - Refrigeration With a TTI (2e - Receipt of Product by Secondary Processor)."

As previously noted, maintenance of temperatures below 38°F (3.3°C) after the product leaves your control and enters the distribution system cannot normally be ensured. The use of a TTI on the smallest unit of packaging (i.e., the unit of packaging that will not be distributed any further, usually consumer or end-user package) may be an appropriate means of overcoming these problems in the distribution system. When TTIs are used in this manner, their receipt, storage, and application and activation should be identified as CCPs.

This control approach is a control strategy referred to as "Control Strategy Example 2 - Refrigeration With TTI (2a - Unactivated TTI Receipt, 2b - Unactivated TTI Storage, and 2c - Application and Activation of TTI)."

- **Fishery products in which freezing is the sole barrier to toxin formation**

1. Is the storage temperature important to the safety of the product?

Frozen finished product storage is critical to the safety of all products in this category. These products contain no barriers (other than freezing) to toxin formation by *C. botulinum* type E and non-proteolytic types B and F during finished product storage and distribution. As previously noted, because these products may appear to the retailer, consumer, or end user to be intended to be refrigerated, rather than frozen, labeling to ensure that they are held frozen throughout distribution is critical to their safety and should be identified as a CCP.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 3 - Frozen With Labeling."

- **Pickled and salted fish and similar products**

1. Is the water phase salt level, water activity, and/or pH level important to the safety of the product?

   For all products in this category, the water phase salt level, water activity, and/or pH level are critical to the safety of the product because they are the principal inhibitors to growth and toxin formation by *C. botulinum* type E and non-proteolytic type B and F. The levels of these inhibitors needed to inhibit toxin formation are achieved during the pickling, brining, or formulation step. Control should be exercised over the relevant step.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 4 - Pickling and Salting (4a - Brining, Pickling, Salting, and Formulation)."

2. Is the storage temperature important to the safety of the product?

   Unless pickling, brining, or formulation results in a water phase salt level of at least 20% (note that this value is based on the maximum salt concentration for growth of *S. aureus*), a pH of 4.6 or below, or a water activity of 0.85 or below (note that this value is based on the minimum water activity for growth of *S. aureus*), refrigerated finished product storage is critical to ensure the safety of the product and should be identified as a CCP.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 4 - Pickling and Salting (4b - Refrigerated Finished Product Storage)."

   In some cases, pickled fish or similar products are received as ingredients for assembly into another product. In other cases, they are received simply for storage and further distribution (e.g., by a warehouse). In either case, the refrigerated storage step is critical to the safety of the product and should be identified as a CCP. Control is the same as that provided under "Control Strategy Example 4 - Pickling and Salting (4b - Refrigerated Finished Product Storage)." Additionally, receiving of these products should be identified as a CCP, where control can be exercised over time and temperature during transit.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 4 - Pickling and Salting (4c - Receipt of Product by Secondary Processor)."

DEVELOP A CONTROL STRATEGY.

The following guidance provides four control strategies for *C. botulinum* toxin formation. You may select a control strategy that is different from those which are suggested, provided it complies with the requirements of the applicable food safety laws and regulations. Control strategies contain several elements that may need to be used in combination to result in an effective control program.

The following are examples of control strategies included in this chapter:

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Smoking	✓	✓
Refrigeration with TTI	✓	✓
Frozen with labeling	✓	✓
Pickling and salting	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 - SMOKING**

This control strategy should include the following elements, as appropriate:

a. Brining, dry salting, and drying;

b. Cold smoking;

c. Hot smoking;

d. Refrigerated finished product storage;

e. Receipt of products by secondary processor.

1A. BRINING, DRY SALTING, AND DRYING

Set Critical Limits.

- The minimum or maximum values for the critical factors of the brining, dry salting, and/or drying processes established by a scientific study. The critical factors are those that are necessary to ensure that the finished product has not less than 3.5% wps or, where permitted, the combination of 3% wps and not less than 100 ppm nitrite. The critical factors may include: brine strength; brine to fish ratio; brining time; brining temperature; thickness, texture, fat content, quality, and species of fish; drying time; input/output air temperature, humidity, and velocity; smoke density; and drier loading.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The critical factors of the established brining, dry salting, and/or drying processes. These may include: brine strength; brine to fish ratio; brining time; brining temperature; thickness, texture, fat content, quality, and species of fish; drying time; input/output air temperature, humidity, and velocity; smoke density; and drier loading;

  OR

- The water phase salt and, where appropriate, nitrite level of the finished product.

» **How Will Monitoring Be Done?**

- For monitoring critical factors:
  - Monitor brine strength with a salinometer;

    AND

  - Monitor brine time with a clock;

    AND

  - Monitor brine temperature using:
    - A temperature-indicating device (e.g., a thermometer);

      OR

    - Monitor brine temperature at the start of the brining process with a temperature- indicating device (e.g., a thermometer), and then monitor ambient air temperature using a continuous temperature-recording device (e.g., a recording thermometer);

      AND

  - Monitor the drying time and the input/output air temperature (as specified by the study) using a continuous temperature-recording device (e.g., a recording thermometer);

    AND

  - Monitor all other critical factors specified by the study with equipment appropriate for the measurement;

  OR

- Collect a representative sample of the finished product and conduct water phase salt analysis and, when appropriate, nitrite analysis.

» **How Often Will Monitoring Be Done (Frequency)?**

- For brine strength:
  - At least at the start of the brining process;

  AND

- For brine time:
  - Once per batch;

  AND

- For manual brine temperature monitoring:
  - At the start of the brining process and at least every 2 hours thereafter;

  AND

- For continuous temperature-recording devices:
  - Continuous monitoring by the device itself, with a visual check of the recorded data at least once per batch;

AND

- For brine to fish ratio:
  - At the start of the brining process;

AND

- For time requirements of the drying process:
  - Each batch;

AND

- For all other critical factors specified by the study:
  - As often as necessary to maintain control;

OR

- For water phase salt and, when appropriate, nitrite:
  - Each lot or batch of finished product.

» **Who Will Do the Monitoring?**

- For continuous temperature-recording devices:
  - Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have been met consistently, may be performed by any person who has an understanding of the nature of the controls;

OR

- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Chill and hold the product until its safety can be evaluated;

OR

- Reprocess the product;

OR

- Divert the product to a use in which the critical limit is not applicable (e.g., packaging that is not hermetically sealed, or an LACF, or a frozen product);

OR

- Destroy the product;

OR

- Divert the product to a non-food use.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Adjust the salt and/or nitrite concentration in the brine;

OR

- Adjust the air velocity or input air temperature to the drying chamber;

OR

- Extend the drying process to compensate for a reduced air velocity or temperature or elevated humidity;

OR

- Adjust the brine strength or brine to fish ratio;

OR

- Cool the brine;

OR

- Move some or all of the product to another drying chamber;

OR

- Make repairs or adjustments to the drying chamber as necessary.

Establish a Recordkeeping System.

- Printouts, charts, or readings from continuous temperature-recording devices;

AND

- Record of visual checks of recorded data;

AND

- Appropriate records (e.g., processing record showing the results of the brine strength and temperature, brine to fish ratio, size

and species of fish, and time of brining) as necessary to document the monitoring of the critical factors of the brining, dry salting, and/or drying process, as established by a study;

OR

- Results of the finished product water phase salt determination and, when appropriate, nitrite determination.

Establish Verification Procedures.

- Process validation study (except where water phase salt analysis and, where appropriate, nitrite analysis of the finished product are the monitoring procedure):
    - The adequacy of the brining, dry salting, and drying processes should be established by a scientific study. It should be designed to consistently achieve a water phase salt level of 3.5% or 3% with not less than 100 ppm nitrite. Expert knowledge of salting and/or drying processes may be required to establish such a process. Such knowledge can be obtained by education or experience, or both. Process validation study for establishment of brining, dry salting, and drying processes may require access to adequate facilities and the application of recognized methods. The drying equipment should be designed, operated, and maintained to deliver the established drying process to every unit of product. In some instances, brining, dry salting, and/or drying studies may be required to establish minimum processes. In other instances, existing literature, which establishes minimum processes or adequacy of equipment, is available. Characteristics of the process, product, and/or equipment that affect the ability of the established minimum salting, dry salting, and drying process to deliver the desired finished product water phase salt and, where applicable, nitrite levels should be taken into consideration in the process establishment. A record of the process establishment should be maintained;

AND

- Before a temperature-indicating device (e.g., a thermometer) or temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
    - Immersing the sensor in an ice slurry (32°F (0°C)), if the device will be used at or near refrigeration temperature;

      OR
    - Immersing the sensor in boiling water (212°F (100°C)) if the device will be used at or near the boiling point. Note that the temperature should be adjusted to compensate for altitude, when necessary;

      OR
    - Doing a combination of the above if the device will be used at or near room temperature;

      OR
    - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a thermometer traceable to National Institute of Standards and Technology (NIST) standards) under conditions that are similar to how it will be used (e.g., air temperature, brine temperature, product internal temperature) within the temperature range at which it will be used;

AND

- Once in service, check the temperature-indicating device or temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended

by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

AND

- Calibrate the temperature-indicating device or temperature recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Devices subjected to high temperatures for extended periods of time may require more frequent calibration. Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- Perform other calibration procedures as necessary to ensure the accuracy of the monitoring instruments;

AND

- Do finished product sampling and analysis to determine water phase salt and, where appropriate, nitrite analysis at least once every 3 months (except where such testing is performed as part of monitoring);

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

1B. COLD SMOKING

Set Critical Limits.

- The smoker temperature must not exceed 90°F (32.2°C).

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The smoker temperature.

» **How Will Monitoring Be Done?**

- Measure ambient smoker chamber temperature using a continuous temperature-recording device (e.g., a recording thermometer).

» **How Often Will Monitoring Be Done (Frequency)?**

- Continuous monitoring by the device itself, with a visual check of the recorded data at least once per batch.

» **Who Will Do the Monitoring?**

- Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have been met consistently, may be performed by any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Chill and hold the product until its safety can be evaluated;

OR

- Divert the product to a use in which the critical limit is not applicable (e.g., packaging that is not hermetically sealed, or an LACF, or a frozen product);

OR

- Destroy the product;

  OR

- Divert the product to a non-food use.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Make repairs or adjustments to the smoking chamber;

  AND/OR

- Move some or all of the product to another smoking chamber.

Establish a Recordkeeping System.

- Printouts, charts, or readings from continuous temperature-recording devices;

  AND

- Record of visual checks of recorded data.

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR

  - Immersing the sensor in boiling water (212°F (100°C)) if the device will be used at or near the boiling point. Note that the temperature should be adjusted to compensate for altitude, when necessary;

    OR

  - Doing a combination of the above if the device will be used at or near room temperature;

    OR

  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

  AND

- Once in service, check the temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

  AND

- Calibrate the temperature-recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

  AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

1C. HOT SMOKING

Set Critical Limits.

- The internal temperature of the fish must be maintained at or above 145°F (62.8°C) throughout the fish for at least 30 minutes.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The internal temperature at the thickest portion of three of the largest fish in the smoking chamber.

» **How Will Monitoring Be Done?**

- Use a continuous temperature-recording device (e.g., a recording thermometer) equipped with three temperature-sensing probes.

» **How Often Will Monitoring Be Done (Frequency)?**

- Continuous monitoring by the device itself, with visual check of the recorded data at least once per batch.

» **Who Will Do the Monitoring?**

- Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have been met consistently, may be performed by any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Chill and hold the product until its safety can be evaluated;

  OR

- Reprocess the product;

  OR

- Divert the product to a use in which the critical limit is not applicable (e.g., packaging that is not hermetically sealed, or a LACF, or a frozen product);

  OR

- Destroy the product;

  OR

- Divert the product to a non-food use.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Make repairs or adjustments to the heating chamber;

  OR

- Move some or all of the product to another heating chamber.

Establish a Recordkeeping System.

- Printouts, charts, or readings from continuous temperature-recording devices;

  AND

- Record of visual checks of recorded data.

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR

  - Immersing the sensor in boiling water (212°F (100°C)) if the device will be used at or near the boiling point. Note that the temperature should be adjusted to compensate for altitude, when necessary;

    OR

  - Doing a combination of the above if the device will be used at or near room temperature;

    OR

- Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

AND

- Once in service, check the temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

AND

- Calibrate the temperature-recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

1D. REFRIGERATED FINISHED PRODUCT STORAGE

Set Critical Limits.

- For refrigerated (not frozen) finished product storage:
  - The product is held at a cooler temperature of 40°F (4.4°C) or below. Note that allowance for routine refrigeration defrost cycles may be necessary. Also note that you may choose to set a critical limit that specifies a time and temperature of exposure to temperatures above 40°F (4.4°C);

OR

- For finished product stored under ice:
  - The product is completely and continuously surrounded by ice throughout the storage time.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- For refrigerated finished product storage:
  - The temperature of the cooler;

OR

- For finished product storage under ice:
  - The adequacy of ice surrounding the product.

» **How Will Monitoring Be Done?**

- For refrigerated finished product storage:
  - Use a continuous temperature-recording device (e.g., a recording thermometer);

OR

- For finished product storage under ice:
  - Make visual observations of the adequacy of ice in a representative number of containers (e.g., cartons and totes) from throughout the cooler.

» **How Often Will Monitoring Be Done (Frequency)?**

- For continuous temperature-recording devices:
  - Continuous monitoring by the device itself, with a visual check of the recorded data at least once per day;

  OR
- For finished product storage under ice:
  - Sufficient frequency to ensure control.

» **Who Will Do the Monitoring?**

- For continuous temperature-recording devices:
  - Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have been met consistently, may be performed by any person who has an understanding of the nature of the controls;

  OR
- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Chill and hold the affected product until an evaluation of the total time and temperature exposure is performed;

  OR
- Destroy the product;

  OR
- Divert the product to a non-food use.

AND

Take the following corrective actions to regain control over the operation after a critical limit deviation:

- Prevent further deterioration:
  - Add ice to the product;

    OR
  - Move some or all of the product in the malfunctioning cooler to another cooler;

    OR
  - Freeze the product;

  AND
- Address the root cause:
  - Make repairs or adjustments to the malfunctioning cooler;

    OR
  - Make adjustments to the ice application operations.

Establish a Recordkeeping System.

- For refrigerated finished product storage:
  - Printouts, charts, or readings from continuous temperature-recording devices;

    AND
  - Record of visual checks of recorded data;

  OR
- For finished product storage under ice:
  - Results of ice checks:
    - The number of containers examined and the sufficiency of ice for each;

      AND
    - The approximate number of containers in the cooler.

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR

- Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

AND

- Once in service, check the temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

AND

- Calibrate the temperature-recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- When visual checks of ice are used, periodically measure internal temperatures of fish to ensure that the ice is sufficient to maintain product temperatures at 40°F (4.4°C) or less;

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

1E. RECEIPT OF PRODUCTS BY SECONDARY PROCESSOR

Set Critical Limits.

- For fish or fishery products delivered refrigerated (not frozen):
  - All lots received are accompanied by transportation records that show that the product was held at or below 40°F (4.4°C) throughout transit. Note that allowance for routine refrigeration defrost cycles may be necessary;

OR

- For products delivered under ice:
  - Product is completely surrounded by ice at the time of delivery;

OR

- For products delivered under chemical cooling media, such as gel packs:
  - There is an adequate quantity of cooling media that remain frozen to have maintained product at 40°F (4.4°C) or below throughout transit;

AND

  - The internal temperature of the product at the time of delivery is 40°F (4.4°C) or below;

OR

- For products delivered refrigerated (not frozen) with a transit time (including all time outside a controlled temperature environment) of 4 hours or less (optional control strategy):

- Time of transit does not exceed 4 hours;

  AND

- Temperature of the product at the time of delivery does not exceed 40°F (4.4°C).

Note: Processors receiving product with transit times of 4 hours or less may elect to use one of the controls described for longer transit times.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- For products delivered refrigerated (not frozen):
  - The internal temperature of the product throughout transportation;

    OR

  - The temperature within the truck or other carrier throughout transportation;

  OR
- For products delivered under ice:
  - The adequacy of ice surrounding the product at the time of delivery;

  OR
- For products held under chemical cooling media, such as gel packs:
  - The quantity and frozen status of cooling media at the time of delivery;

    AND

  - The internal temperature of a representative number of product containers (e.g., cartons and totes) at time of delivery;

  OR
- For products delivered refrigerated (not frozen) with a transit time of 4 hours or less:
  - The date and time fish were removed from a controlled temperature environment before shipment and the date and time delivered;

    AND

  - The internal temperature of a representative number of product containers (e.g., cartons and totes) at the time of delivery.

» **How Will Monitoring Be Done?**

- For products delivered refrigerated (not frozen):
  - Use a continuous temperature-recording device (e.g., a recording thermometer) for internal product temperature or ambient air temperature monitoring during transit;

  OR
- For products delivered under ice:
  - Make visual observations of the adequacy of ice in a representative number of containers (e.g., cartons and totes) from throughout the shipment, at delivery;

  OR
- For products delivered under chemical cooling media, such as gel packs:
  - Make visual observations of the adequacy and frozen state of the cooling media in a representative number of containers (e.g., cartons and totes) from throughout the shipment, at delivery;

    AND

  - Use a temperature-indicating device (e.g., a thermometer) to determine internal product temperatures in a representative number of product containers from throughout the shipment, at delivery;

  OR
- For products delivered refrigerated (not frozen) with a transit time of 4 hours or less:
  - Review carrier records to determine the date and time the product was removed from a controlled temperature environment before shipment and the date and time delivered;

    AND

- Use a temperature-indicating device (e.g., a thermometer) to determine internal product temperatures in a representative number of product containers (e.g., cartons and totes) randomly selected from throughout the shipment, at delivery. Measure a minimum of 12 product containers, unless there are fewer than 12 product containers in a lot, in which case measure all of the containers. Lots that show a high level of temperature variability may require a larger sample size.

» **How Often Will Monitoring Be Done (Frequency)?**

- Each lot received.

» **Who Will Do the Monitoring?**

- For continuous temperature-recording devices:
  - Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have been met consistently, may be performed by any person who has an understanding of the nature of the controls;

  OR
- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Chill and hold the affected product until an evaluation of the total time and temperature exposure is performed;

  OR
- Reject the lot.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Discontinue use of the supplier or carrier until evidence is obtained that the identified transportation-handling practices have been improved.

Establish a Recordkeeping System.

- Receiving records showing:
  - Results of continuous temperature monitoring:
    - Printouts, charts, or readings from continuous temperature-recording devices;

      AND
    - Visual check of recorded data;

    OR
  - Results of ice checks, including:
    - The number of containers examined and the sufficiency of ice for each;

      AND
    - The number of containers in the lot;

    OR
  - Results of the chemical media checks, including:
    - The number of containers examined and the frozen status of the media for each;

      AND
    - The number of containers in the lot;

    AND/OR
  - Results of internal product temperature monitoring, including:
    - The number of containers examined and the internal temperatures observed for each;

      AND
    - The number of containers in the lot;

      AND
    - Date and time fish were initially removed from a controlled

temperature environment and date and time fish were delivered, when applicable.

Establish Verification Procedures.

- Before a temperature-indicating device (e.g., a thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
    - Immersing the sensor in an ice slurry (32°F (0°C)), if the device will be used at or near refrigeration temperature;

      OR
    - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

  AND
- Once in service, check the temperature-indicating device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational;

  AND
- Calibrate the temperature-indicating device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

  AND
- Check the accuracy of temperature-recording devices that are used for monitoring transit conditions, for all new suppliers and at least quarterly for each supplier thereafter. Additional checks may be warranted based on observations at receipt (e.g., refrigeration units appear to be in poor repair or readings appear to be erroneous). The accuracy of the device can be checked by comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

  AND
- When visual checks of ice are used, periodically measure internal temperatures of fish to ensure that the ice or is sufficient to maintain product temperatures at 40°F (4.4°C) or less;

  AND
- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 13-1

CONTROL STRATEGY EXAMPLE 1 - SMOKING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1 - Smoking." This example illustrates how a processor of vacuum-packaged hot-smoked salmon can control C. botulinum toxin formation. It is provided for illustrative purposes only.

C. botulinum toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, growth of other pathogenic bacteria, survival of other pathogenic bacteria through the cook step, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE*	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Brining	C. botulinum toxin formation in the finished product	Minimum brining time: 6 hours Maximum brine temperature: 40°F	Start time and end time of the brining process Brine temperature	Clock Dial thermometer	Every batch Every 2 hours	Brine room employee	Extend the brining process Hold and evaluate the product Cool the brine	Production record	Establish a brining and drying process Check the dial thermometer for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Monthly calibration of the scale Quarterly water phase salt analysis of the finished product Review monitoring, corrective action, and verification records within 1 week of preparation
		Minimum salt concentration of brine at the start of brining: 60° salinometer	Salt concentration of brine	Salinometer	Start of each brining process	Brine room employee	Add salt	Production record	
		Minimum ratio of brine to fish: 2:1	Weight of brine (as determined by volume)	Visual, to mark on the tank	Start of each brining process	Brine room employee	Add brine	Production record	
			Weight of fish	Scale	Each batch		Remove some fish and reweigh		
		Maximum fish thickness 1½ in. Note: To produce a minimum water phase salt level in the loin muscle of 3.5%	Fish thickness	Caliper	Each batch (10 largest fish)	Brine room employee	Hold and evaluate based on finished product water phase salt analysis	Production record	

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C. botulinum toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, growth of other pathogenic bacteria, survival of other pathogenic bacteria through the cook step, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE*	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Smoking and drying	C. botulinum toxin formation in finished product	Minimum time open vent: 2 hours	Time of open vent	Clock	Each batch	Smoker employee	Extend the drying process Hold and evaluate based on finished product water phase salt analysis	Production record	Establish a brining and drying process Quarterly water phase salt analysis of the finished product Review monitoring, corrective action, and verification records within 1 week of preparation
Heating	C. botulinum toxin formation in the finished product	Internal temperature of fish held at or above 145°F for at least 30 minutes	Internal temperature of fish and time at that temperature	Digital data logger with three probes in thickest fish in cold spot of smoking chamber	Continuous, with visual check of recorded data at the end of the batch	Smoker employee	Extend the heating process Make repairs or adjustments to the smoking chamber Hold and evaluate the product	Data logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation
Finished product storage	C. botulinum toxin formation during finished product storage	Maximum cooler temperature: 40°F (based on growth of vegetative pathogens)	Cooler air temperature	Digital data logger	Continuous, with visual check of recorded data once per day	Production employee	Adjust or repair the cooler Hold and evaluate the product based on time and temperature of exposure	Digital data logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation

*Note: The critical limits in this example are for illustrative purposes only and are not related to any recommended process.

- **CONTROL STRATEGY EXAMPLE 2 - REFRIGERATION WITH TTI**

This control strategy should include the following elements, as appropriate:

a. Unactivated TTI receipt;

b. Unactivated TTI storage;

c. Application and activation of TTI;

d. Refrigerated finished product storage;

e. Receipt of product by secondary processor.

2A. UNACTIVATED TTI RECEIPT

Set Critical Limits.

- The TTI is suitable for use. It should be designed to perform properly under the conditions that it will be used. It should also be designed to produce an alert indicator (e.g., a color change of the device) at a combination of time and temperature exposures that will prevent the formation of non-proteolytic *C. botulinum* toxin formation (e.g., consistent with the "Skinner-Larkin curve");

  AND

- Where transportation conditions (e.g., temperature) could affect the functionality of the TTI, all lots of TTIs are accompanied by transportation records that show that they were held at conditions that do not result in loss of functionality throughout transit;

  AND

- The TTI functions (i.e., produces an alert indicator, such as a color change of the device, when exposed to time and temperature abuse) at time of receipt.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- For suitability of use:
  - Performance data from the manufacturer;

  AND
- For transportation conditions:
  - The temperature within the truck or other carrier throughout transportation;

    OR
  - Other conditions that affect the functionality of the TTI, where applicable;

  AND
- For functionality at receipt:
  - The ability of the TTI to produce an alert indicator, such as a color change of the device, when exposed to time and temperature abuse at time of receipt.

» **How Will Monitoring Be Done?**

- For suitability of use:
  - Review performance data;

  AND
- For transportation conditions:
  - Use a continuous temperature-recording device (e.g., a recording thermometer) for ambient air temperature monitoring during transit;

  AND
- For functionality at receipt:
  - Activate and then expose a TTI from the lot to ambient air temperature for sufficient time to determine whether it is functional (i.e., produces an alert indicator, such as a color change of the device).

» **How Often Will Monitoring Be Done (Frequency)?**

- For suitability of use:
  - The first shipment of a TTI model;

  AND
- For transportation conditions and functionality at receipt:
  - Every shipment.

» **Who Will Do the Monitoring?**

- For suitability of use:
  - Anyone with an understanding of TTI validation studies and of the intended conditions of use;

  AND
- For transportation conditions and functionality at receipt:
  - Anyone with an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Reject or return the shipment.

AND

Take the following corrective actions to regain control over the operation after a critical limit deviation:

- For suitability of use:
  - Discontinue use of the supplier until documentation of validation has been provided;

  AND
- For transportation conditions and functionality at receipt:
  - Discontinue use of the supplier or carrier until evidence is obtained that the identified production or transportation practices have been improved.

Establish a Recordkeeping System.

- For suitability of use:
  - Manufacturer's performance data;

  AND
- For transportation conditions:
  - Printouts, charts, or readings from continuous temperature-recording devices;

    AND
  - Records of visual checks of recorded data;

  AND
- For functionality at receipt:
  - Results of a TTI challenge test (i.e., whether the TTI produces an alert indicator, such as a color change of the device, when exposed to time and temperature abuse).

Establish Verification Procedures.

- Check the accuracy of temperature-recording devices that are used for monitoring transit conditions, for all new suppliers and at least quarterly for each supplier thereafter. Additional checks may be warranted based on observations at receipt (e.g., refrigeration units appear to be in poor repair or readings appear to be erroneous). The accuracy of the device can be checked by comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

  AND
- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

2B. UNACTIVATED TTI STORAGE

Set Critical Limits.

- The combination of storage conditions (e.g., temperature) that prevent loss of functionality throughout storage (based on manufacturer's specifications).

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Storage air temperature, where temperature affects functionality of the TTI;

  AND/OR

- Other storage conditions that affect functionality of the TTI.

» **How Will Monitoring Be Done?**

- For temperature:
  - Use a continuous temperature-recording device (e.g., a recording thermometer);

  AND/OR

- For other conditions:
  - Use instruments appropriate for the purpose.

» **How Often Will Monitoring Be Done (Frequency)?**

- For temperature:
  - Continuous monitoring by the device itself, with a visual check of the recorded data at least once per day;

  AND/OR

- For other conditions:
  - With sufficient frequency to ensure control.

» **Who Will Do the Monitoring?**

- With continuous temperature-recording devices:
  - Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have been met consistently, may be performed by any person who has an understanding of the nature of the controls;

  AND

- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a TTI involved in a critical limit deviation:

- Destroy the lot of TTIs.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Make repairs or adjustments to the malfunctioning cooler;

  AND/OR

- Make other repairs or adjustment appropriate for the condition.

Establish a Recordkeeping System.

- For refrigerated storage:
  - Printouts, charts, or readings from continuous temperature-recording devices;

    AND
  - Record of visual checks of recorded data;

  AND/OR

- Storage record showing the results of monitoring of other conditions.

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR
  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

AND

- Once in service, check the temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

AND

- Calibrate the temperature-recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- Perform other instrument calibration, as appropriate;

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

2C. APPLICATION AND ACTIVATION OF TTI

Set Critical Limits.

- Each consumer package has an activated TTI.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Packages for the presence of an activated TTI.

» **How Will Monitoring Be Done?**

- Visual examination.

» **How Often Will Monitoring Be Done (Frequency)?**

- Representative number of packages from each lot of product.

» **Who Will Do the Monitoring?**

- Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Hold the lot below 38°F (3.3°C) until TTIs are applied and activated.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Identify and correct the cause of the TTI application or activation deficiency.

Establish a Recordkeeping System.

- Packaging control record that shows the results of the TTI checks.

Establish Verification Procedures.

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

2D. REFRIGERATED FINISHED PRODUCT STORAGE

Follow the guidance for "Control Strategy Example 1 - Smoking (1d - Refrigerated Finished Product Storage)," except that the where the critical limits list 40°F (4.4°C), they should list 38°F (3.3°C).

2E. RECEIPT OF PRODUCTS BY SECONDARY PROCESSOR

Follow the guidance for "Control Strategy Example 1 - Smoking (1e - Receipt of Products by Secondary Processor)," except that the where the critical limits list 40°F (4.4°C), they should list 38°F (3.3°C).

TABLE 13-2

CONTROL STRATEGY EXAMPLE 2 - REFRIGERATION WITH TTI

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Refrigeration With TTI." This example illustrates how a processor of refrigerated, vacuum-packaged, raw fish fillets can control C. botulinum toxin formation. It is provided for illustrative purposes only.

C. Botulinum toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, growth of other pathogenic bacteria, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receipt of TTI	C. botulinum toxin formation in the finished product	TTI is suitable for use	Performance data from the manufacturer	Review of performance data	First shipment of a TTI model	Quality assurance supervisor	Reject the shipment Discontinue use of the supplier until appropriate validation documentation is provided	Manufacturer's performance data	Review monitoring, corrective action records within 1 week of preparation
		All lots received are accompanied by truck records that show temperature was maintained at or below 40°F	Truck temperature	Digital time and temperature data logger	Continuous, with visual review and evaluation of temperature-monitoring records for each shipment	Receiving employee	Discontinue use of the supplier or carrier until evidence is obtained that the identified transportation- handling practices have been improved Reject the shipment	Receiving record	Check the data logger for all new suppliers and for all suppliers at least quarterly thereafter Review monitoring, corrective action records within 1 week of preparation
		The TTI functions at receipt	The ability of the TTI to change color when exposed to room air temperature	Expose a TTI from the lot to room air temperature for sufficient time to determine whether it changes color	Every shipment	Quality assurance staff	Discontinue use of the supplier or carrier until evidence is obtained that the identified production or transportation-handling practices have been improved	TTI challenge record	Review monitoring, corrective action records within 1 week of preparation

TABLE 13-2

CONTROL STRATEGY EXAMPLE 2 - REFRIGERATION WITH TTI

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Refrigeration With TTI." This example illustrates how a processor of refrigerated, vacuum-packaged, raw fish fillets can control C. botulinum toxin formation. It is provided for illustrative purposes only.

C. Botulinum toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, growth of other pathogenic bacteria, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
TTI storage	C. botulinum toxin formation in the finished product	Cooler maintained below 38°F	Cooler temperature	Digital time and temperature data logger	Continuous, with visual check of recorded data once per day	Quality assurance staff	Repair or adjust cooler Destroy the lot of TTIs	Data logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation
TTI attachment and activation	C. botulinum toxin formation in the finished product	Each package has an activated TTI	Packages for the presence of an activated TTI	Visual examination	Representative number of packages from each lot of product	Production employee	Hold lot below 38°F, and apply and activate TTIs Identify and correct the cause of TTI application deviation	Packaging control record	Review monitoring, and corrective action and verification records within 1 week of preparation

TABLE 13-2

CONTROL STRATEGY EXAMPLE 2 - REFRIGERATION WITH TTI

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Refrigeration With TTI." This example illustrates how a processor of refrigerated, vacuum-packaged, raw fish fillets can control C. botulinum toxin formation. It is provided for illustrative purposes only.

C. Botulinum toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, growth of other pathogenic bacteria, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Finished product storage	C. botulinum toxin formation during finished product storage	Maximum cooler temperature 38°F	Cooler air temperature	Digital data logger	Continuous, with visual check of recorded data once per day	Production employee	Adjust or repair cooler Hold and evaluate the product based on time and temperature of exposure	Digital logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation

*Note: The critical limits in this example are for illustrative purposes only and are not related to any recommended process.

- **CONTROL STRATEGY EXAMPLE 3 - FROZEN WITH LABELING**

Set Critical Limits.

- All finished product labels must contain a "keep frozen" statement (e.g., "Important, keep frozen until used, thaw under refrigeration immediately before use").

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Finished product labels for the presence of a "keep frozen" statement.

» **How Will Monitoring Be Done?**

- Visual examination.

» **How Often Will Monitoring Be Done (Frequency)?**

- Representative number of packages from each lot of product.

» **Who Will Do the Monitoring?**

- Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Segregate and relabel any improperly labeled product.

AND

Take the following corrective actions to regain control over the operation after a critical limit deviation:

- Segregate and return or destroy any label stock or pre-labeled packaging stock that does not contain the proper statement;

  AND

- Determine and correct the cause of improper labels.

Establish a Recordkeeping System.

- Record of labeling checks.

Establish Verification Procedures.

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 13-3

CONTROL STRATEGY EXAMPLE 3 - FROZEN WITH LABELING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 3 - Frozen With Labeling." This example illustrates how a processor of frozen, vacuum-packaged, raw fish fillets can control C. botulinum toxin formation. It is provided for illustrative purposes only.

C. Botulinum toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receipt of labeling	C. botulinum toxin formation during finished product storage	All finished product labels must contain a "keep frozen" statement	Finished product labels for the presence of a "keep frozen" statement	Visual examination	Representative number of packages from each lot of product	Receiving employee	Segregate and relabel any improperly labeled product Segregate and destroy any label stock that does not contain the proper statement Determine and correct the cause of improper labels	Label receiving record	Review monitoring and correction action records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 4 - PICKLING AND SALTING**

This control strategy should include the following elements, as appropriate:

a. Brining, pickling, salting, and formulation;

b. Refrigerated finished product storage;

c. Receipt of Product by secondary processor.

4A. BRINING, PICKLING, SALTING, AND FORMULATION

Set Critical Limits.

- The minimum or maximum values for the critical factors of the brining, pickling, or formulation process established by a scientific study. The critical factors are those that are necessary to ensure that the finished product has:

For refrigerated, reduced oxygen-packaged fishery products:

- A water phase salt level of at least 5%;

  OR

- A pH of 5.0 or below;

  OR

- A water activity of below 0.97;

  OR

- A water phase salt level of at least 2.4% in surimi-based products, when combined with a pasteurization process in the finished product container of 185°F (85°C) for 15 minutes (pasteurization controls are covered in Chapter 16);

  OR

- A combination of water phase salt, pH, and/or water activity that, when combined, have been demonstrated to prevent the growth of *C. botulinum* type E and non-proteolytic types B and F.

For unrefrigerated (shelf-stable), reduced oxygen-packaged products:

- A water phase salt level of at least 20% (based on the maximum salt level for growth of *S. aureus*);

  OR

- A pH of 4.6 or below;

  OR

- A water activity of 0.85 or below (based on the minimum water activity for growth and toxin formation of *S. aureus*).

A heat treatment, addition of chemical additives, or other treatment may be necessary to inhibit or eliminate spoilage organisms (e.g., mold) in shelf-stable products.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The critical factors of the established pickling, brining, or formulation process. These may include: brine and acid strength; brine or acid to fish ratio; brining and pickling time; brine and acid temperature; thickness, texture, fat content, quality, and species of fish;

  OR

- The water phase salt, pH, and/or water activity of the finished product.

» **How Will Monitoring Be Done?**

- For brine strength:
  - Use a salinometer;

  AND

- For acid strength:
  - Use a pH meter or titrate for acid concentration;

  AND

- For brine/acid temperature:
  - Use a temperature-indicating device (e.g., a thermometer);

  AND

- For all other critical factors specified by the study:
  - Use equipment appropriate for the measurement;

  OR
- For water phase salt, pH, and/or water activity:
  - Collect a representative sample of the finished product, and conduct water phase salt, pH, and/or water activity analysis, as appropriate.

» **How Often Will Monitoring Be Done (Frequency)?**

- For brine and acid strength:
  - At the start of each brining, pickling, and formulation process;

  AND
- For brine and acid temperature:
  - At the start of each brining, pickling, and formulation process and at least every 2 hours thereafter;

  AND
- For brine or acid to fish ratio:
  - At the start of each brining, pickling, and formulation process;

  AND
- For other critical factors specified by the study:
  - As often as necessary to maintain control;

  OR
- Water phase salt, pH, and/or water activity analysis should be determined for each batch of finished product.

» **Who Will Do the Monitoring?**

- For water activity:
  - Any person with sufficient training to perform the analysis;

  OR
- For other checks:
  - Any person with an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Chill and hold the product until it can be evaluated based on its water phase salt, pH, and/or water activity level;

  OR
- Reprocess the product (if reprocessing does not jeopardize the safety of the product);

  OR
- Divert the product to a use in which the critical limit is not applicable (e.g., packaging that is not hermetically sealed, or a LACF, or a frozen product);

  OR
- Divert the product to a non-food use;

  OR
- Destroy the product.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Adjust the brine or acid strength or brine or acid to fish ratio;

  OR
- Extend the brining or pickling time to compensate for an improper brine or acid temperature.

Establish a Recordkeeping System.

- Records, as necessary, to document the monitoring of the critical factors of the brining or pickling process, as established by a study (e.g., a processing record showing the results of the brine or acid strength and temperature, brine or acid to fish ratio, size and species of fish, time of brining or pickling);

  OR
- Record of determinations of the finished product water phase salt, pH, or water activity.

Establish Verification Procedures.

- Process validation study (except where water phase salt, pH, or water activity analysis of the finished product is the monitoring procedure):
    - The adequacy of the pickling, brining, and formulation process steps should be established by a scientific study. For refrigerated, reduced oxygen-packaged products, it should be designed to consistently achieve: a water phase salt level of at least 5%; a pH of 5.0 or below; a water activity of below 0.97; a water phase salt level of at least 2.4% in surimi-based products, when combined with a pasteurization process in the finished product container of 185°F (85°C) for at least 15 minutes; or a combination of salt, pH, and/or water activity that, when combined, prevent the growth of *C. botulinum* type E and non-proteolytic types B and F (established by a scientific study). For unrefrigerated (shelf-stable), reduced oxygen-packaged products, it should be designed to consistently achieve: a water phase salt level of at least 20% (based on the maximum water phase salt level for the growth of *S. aureus*); a pH of 4.6 or below; or a water activity of 0.85 or below (based on the minimum water activity for the growth of *S. aureus*). Expert knowledge of pickling, brining, and formulation processes may be required to establish such a process. Such knowledge can be obtained by education or experience, or both. Establishment of pickling, brining, and formulation processes may require access to adequate facilities and the application of recognized methods. In some instances, pickling, brining, and formulation studies may be required to establish minimum processes. In other instances, existing literature, which establishes minimum processes, is available. Characteristics of the process and/or product that affect the ability of the established minimum pickling, brining, and formulation process should be taken into consideration in the process establishment. A record of the process establishment should be maintained;

AND

- Before a temperature-indicating device (e.g., a thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
    - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

      OR
    - Immersing the sensor in boiling water (212°F (100°C)) if the device will be used at or near the boiling point. Note that the temperature should be adjusted to compensate for altitude, when necessary);

      OR
    - Doing a combination of the above if the device will be used at or near room temperature;

      OR
    - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., brine temperature) within the temperature range at which it will be used;

  AND
- Once in service, check the temperature-indicating device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your

facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational;

AND

- Calibrate the temperature-indicating device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- Perform daily calibration of pH meters against standard buffers;

AND

- Perform other calibration procedures as necessary to ensure the accuracy of the monitoring instruments;

AND

- Do finished product sampling and analysis to determine water phase salt, pH, or water activity level, as appropriate, at least once every 3 months (except where such testing is performed as part of monitoring);

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

4B. REFRIGERATED FINISHED PRODUCT STORAGE

Follow the guidance for "Control Strategy Example 1 - Smoking (1d - Refrigerated Finished Product Storage)."

4C. RECEIPT OF PRODUCT BY SECONDARY PROCESSOR

Follow the guidance for "Control Strategy Example 1 - Smoking (1e - Receipt of Product by Secondary Processor)."

TABLE 13-4

CONTROL STRATEGY EXAMPLE 4 - PICKLING AND SALTING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 4 - Pickling and Salting." This example illustrates how a pickled herring processor can control C. botulinum toxin formation. It is provided for illustrative purposes only.

C. botulinum toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., histamine, environmental and chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Pickling	C. botulinum toxin formation in the finished product	Maximum finished product pH in the loin muscle of 5.0	Finished product pH in the loin muscle	Collect a sample of the product from each pickling tank at the end of each pickling cycle and analyze for pH using a pH meter	Each pickling tank, each cycle	Quality control personnel	Continue the pickling process until pH meets the critical limit	Pickling control record	Daily calibration of the pH meter Review monitoring, corrective action, and verification records within 1 week of preparation
Finished product storage	C. botulinum toxin formation during finished product storage	Maximum cooler temperature: 40°F (based on growth of vegetative pathogens)	Cooler air temperature	Time and temperature data logger	Continuous, with visual check of recorded data once per day	Production employee	Adjust or repair cooler Hold and evaluate the product based on time and temperature of exposure	Data logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation

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We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of March 29, 2011, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after March 29, 2011.

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NOTES:

CHAPTER 14: **Pathogenic Bacteria Growth and Toxin Formation as a Result of Inadequate Drying**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

UNDERSTAND THE POTENTIAL HAZARD.

Pathogenic bacteria growth and toxin formation in the finished product as a result of inadequate drying of fishery products can cause consumer illness. The primary pathogens of concern are *Staphylococcus aureus* (*S. aureus*) and *Clostridium botulinum* (*C. botulinum*). See Appendix 7 for a description of the public health impacts of these pathogens.

- **Control by Drying**

Dried products are usually considered shelf stable and are, therefore, often stored and distributed unrefrigerated. Examples of shelf-stable dried fish products are salmon jerky, octopus chips, dried shrimp, stock fish, and shark cartilage. The characteristic of dried foods that makes them shelf stable is their low water activity (A_w). Water activity is the measure of the amount of water in a food that is available for the growth of microorganisms, including pathogenic bacteria. A water activity of 0.85 or below will prevent the growth and toxin production of all pathogenic bacteria, including *S. aureus* and *C. botulinum*, and is critical for the safety of a shelf-stable dried product. *S. aureus* grows at a lower water activity than other pathogenic bacteria, and should, therefore, be considered the target pathogen for drying for shelf-stable products.

You should select a packaging material that will prevent rehydration of the product under the expected conditions of storage and distribution. Additionally, finished product package closures should be free of gross defects that could expose the product to moisture during storage and distribution. Chapter 18 provides guidance on control of container closures.

Some dried products that are reduced oxygen packaged (e.g., vacuum packaged, modified atmosphere packaged) are dried only enough to control growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F (i.e., types that will not form toxin with a water activity of below 0.97). These dried products are then refrigerated to control growth and toxin formation by *C. botulinum* type A and proteolytic types B and F and by other pathogenic bacteria that may be present in the product, including *S. aureus*. The products might have the appearance of a fully dried product. Therefore, their packaging should include "keep refrigerated" labeling to ensure that temperature controls are applied throughout distribution.

Distributing partially dried, reduced oxygen packaged products frozen also could be used to control these pathogens. However, labeling with "keep frozen" instructions would then be important to ensure food safety. More information on *C. botulinum* and reduced oxygen packaging is contained in Chapter 13.

This chapter does not cover the growth of pathogenic bacteria, including *S. aureus*, which may occur as a result of time and temperature

abuse during processing, including before or during the drying process. That hazard is covered in Chapter 12. It also does not cover the control of *C. botulinum* type A and proteolytic types B and F and that of other pathogenic bacteria that may be present, including *S. aureus,* during refrigerated storage of reduced oxygen packaged, partially dried products. That hazard is covered in Chapters 12 and 13, respectively.

Controlling pathogenic bacteria growth and toxin formation by drying is best accomplished by:

- Scientifically establishing a drying process that reduces the water activity to 0.85 or below if the product will be stored and distributed unrefrigerated (shelf stable). Note that a heat treatment, addition of chemical additives, further drying, or other treatment may be necessary to inhibit or eliminate spoilage organisms, for example, mold;
- Scientifically establishing a drying process that reduces the water activity to below 0.97 if the product will be stored refrigerated (not frozen) in reduced oxygen packaging;
- Designing and operating the drying equipment so that every unit of a product receives at least the established minimum process;
- Packaging the finished product in a container that will prevent rehydration.

The drying operation used in the production of smoked or smoke-flavored fish is not designed to result in a finished product water activity of 0.85 or below. The controls for these products are described in Chapter 13.

Because spores of *C. botulinum* are known to be present in the viscera of fish, any product that will be preserved by salting, drying, pickling, or fermentation should be eviscerated prior to processing (see the "Compliance Policy Guide," Sec. 540.650). Without evisceration, toxin formation is possible during the process even with strict control of temperature. Evisceration should be thorough and performed to minimize contamination of the fish flesh. If even a portion of the viscera or its contents is left behind, the risk of toxin formation by *C. botulinum* remains. Small fish, less than 5 inches in length, that are processed in a manner that eliminates preformed toxin and prevents toxin formation and that reach (1) a water phase salt content of 10%, a value based on the control of *C. botulinum* type A and proteolytic types B and F, in refrigerated products; or (2) a water activity of 0.85 or below (note that this is a value based on the minimum water activity for toxin production by *S. aureus*, in shelf-stable products); or (3) a pH (acidity) level of 4.6 or less in shelf-stable products are not subject to the evisceration recommendation.

- **Strategies for controlling pathogenic bacteria growth**

Pathogens can enter the process on raw materials. They can also be introduced into foods during processing, from the air, unclean hands, insanitary utensils and equipment, contaminated water, and sewage. There are a number of strategies for the control of pathogenic bacteria in fish and fishery products. They include:

- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by drying (covered in this chapter);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by formulation (covered in Chapter 13);
- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product (covered in Chapter 13);
- Controlling the pH in the product (covered by the Acidified Foods regulation, 21 CFR 114, for shelf-stable acidified products, and by Chapter 13 for refrigerated acidified products);
- Controlling the source of molluscan shellfish and the time from exposure to air (e.g., by harvest or receding tide) to refrigeration to control pathogens from the harvest area (covered in Chapter 12);

- Controlling the introduction of pathogenic bacteria after the pasteurization process (covered in Chapter 18);
- Managing the amount of time that food is exposed to temperatures that are favorable for pathogenic bacteria growth and toxin production (covered generally in Chapter 12; for *C. botulinum*, in Chapter 13; and for *S. aureus* in hydrated batter mixes, in Chapter 15);
- Killing pathogenic bacteria by cooking or pasteurization (covered in Chapter 16) or by retorting (covered by the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation, 21 CFR 113 (called the Low-Acid Canned Foods Regulation in this guidance document));
- Killing pathogenic bacteria by processes that retain raw product characteristics (covered in Chapter 17).

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether pathogenic bacteria growth and toxin formation as a result of inadequate drying is a significant hazard at a processing step:

1. For shelf-stable, dried products, is it reasonably likely that *S. aureus* will grow and form toxin in the finished product if the product is inadequately dried?

   Table A-1 (Appendix 4) provides information on the conditions under which *S. aureus* will grow. If your food that is not distributed refrigerated or frozen and meets these conditions (i.e., in Table A-1) before drying, then drying will usually be important to the safety of the product, because it provides the barrier to *S. aureus* growth and toxin formation. Under ordinary circumstances, it would be reasonably likely that *S. aureus* will grow and form toxin in such products during finished product storage and distribution if drying is not properly performed. Note that drying to control toxin formation by *S. aureus* will also control toxin formation by *C. botulinum* in these products.

2. For shelf-stable, dried products, can *S. aureus* toxin formation that is reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step?

   Pathogenic bacteria growth and toxin formation as a result of inadequate drying should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard of *S. aureus* toxin formation (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. The preventive measure that can be applied for pathogenic bacteria growth and toxin formation as a result of inadequate drying are:

   - Proper design and control of the drying process (covered in this chapter);

3. For refrigerated or frozen, partially dried (i.e., not shelf stable) products, is it reasonably likely that *C. botulinum* type E and nonproteolytic types B and F will grow and form toxin in the finished product if the product is inadequately dried?

   Table A-1 (Appendix 4) provides information on the conditions under which *C. botulinum* type E and non-proteolytic types B and F will grow. Because of the need to prevent rehydration of dried products, these products generally will be contained in a reduced oxygen package. If your refrigerated (not frozen), reduced oxygen packaged food meets these conditions (i.e., Table A-1) before drying, then drying will usually be important to the safety of the product, because it provides the barrier to growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F. Note that refrigeration will control toxin formation by *S. aureus* and *C. botulinum* type A and non-proteolytic types B and F in these products. Under ordinary

circumstances, it would be reasonably likely that *C. botulinum* type E and non-proteolytic types B and F will grow and form toxin in such products during finished product storage and distribution if drying is not properly performed. In addition, controlling labeling (e.g., "keep refrigerated" labeling) to ensure that the product is held refrigerated throughout distribution may be important to the safety of the product, because the product may appear to retailers, consumers, and end users to be shelf stable.

However, if your dried, reduced oxygen packaged product is distributed frozen, then freezing may provide the barrier to growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F, rather than drying. In this case, labeling to ensure that the product is distributed frozen may be important to the safety of the product. Chapter 13 provides guidance on labeling controls to ensure that frozen product that supports the growth of non-proteolytic *C. botulinum* is distributed frozen.

4. For refrigerated or frozen, partially dried, reduced oxygen packaged dried products, can growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F that are reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step?

   Pathogenic bacteria growth and toxin formation as a result of inadequate drying should be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. The preventive measures that can be applied for pathogenic bacteria growth and toxin formation as a result of inadequate drying for refrigerated or frozen, partially dried, reduced oxygen packaged products are:

   - Proper design and control of the drying process (covered in this chapter);
   - Refrigeration (covered in Chapter 12) and labeling to ensure that the product is held refrigerated throughout distribution (covered in this chapter);
   - Freezing (Chapter 13 provides guidance on labeling controls to ensure that a frozen product that otherwise supports the growth of non-proteolytic *C. botulinum* is distributed frozen).

- **Intended use**

Because of the highly stable nature of *S. aureus* toxin and the extremely toxic nature of *C. botulinum* toxin, it is unlikely that the intended use will affect the significance of the hazard.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for pathogenic bacteria growth and toxin formation as a result of inadequate drying:

1. If you identified the hazard of pathogenic bacteria growth and toxin formation as a result of inadequate drying as significant because drying (rather than, or in addition to, refrigeration) is important to the safety of the product, you should identify the drying step as a CCP for this hazard.

   Example:

   A salmon jerky processor that distributes the product unrefrigerated should set the CCP for controlling the hazard of pathogenic bacteria growth and toxin formation as a result of inadequate drying at the drying step. The processor would not need to identify the processing steps prior to drying as CCPs for that hazard. However, these steps may be CCPs for the control of other hazards, such as the growth of pathogenic bacteria as a result of time and temperature abuse during processing, covered by Chapter 12.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Control by Drying."

2. If you identified the hazard of pathogenic bacteria growth and toxin formation as a result of inadequate drying as significant because refrigeration (in addition to drying) is important to the safety of the product, you should identify the finished product storage step and the labeling step, where you will ensure that the "keep refrigerated" labeling is included on every package, as a CCP, for this hazard.

   Example:

   A partially dried catfish processor that distributes the product refrigerated and reduced oxygen packaged should set the CCPs for controlling the hazard of pathogenic bacteria growth and toxin formation as a result of inadequate drying at the drying step, finished product labeling step, and finished product storage step. The processor would not need to identify the processing steps prior to drying as CCPs for that hazard. However, these steps may be CCPs for the control of other hazards, such as the growth of pathogenic bacteria as a result of time and temperature abuse during processing, covered by Chapter 12.

The control by drying is covered in "Control Strategy Example 1 - Control by Drying." Control of labeling is referred to in this chapter as "Control Strategy Example 2 - Control by Refrigeration With Labeling." It should be used along with "Control Strategy Example 1 - Control by Drying." Note that control of refrigerated finished product storage is covered in Chapter 12. Note also that Chapter 13 provides guidance on labeling controls to ensure that a frozen product that otherwise supports the growth of non-proteolytic *C. botulinum* is distributed frozen.

DEVELOP A CONTROL STRATEGY.

The following guidance provides examples of two control strategies for pathogenic bacteria growth and toxin formation that occurs as a result of inadequate drying. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation. It is important to note that you may select a control strategy that is different from those that are suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

The following are examples of control strategies included in this chapter:

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Control by drying	✓	✓
Control by refrigeration with labeling	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 - CONTROL BY DRYING**

It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Set Critical Limits.

- The minimum or maximum values for the critical factors established by a scientific study (i.e., for shelf-stable products, those which must be met in order to ensure that the finished product has a water activity of 0.85 or below; for refrigerated (not frozen), reduced oxygen packaged products, those which must be met in order to ensure that the finished product has a water activity of less than 0.97). These will likely include drying time, input/output air temperature, humidity, and velocity, as well as flesh thickness. Other critical factors that affect the rate of drying of the product may also be established by the study;

OR

- The minimum percent weight loss established by a scientific study (i.e., for shelf-stable products, that which must be met in order to ensure that the finished product has a water activity of 0.85 or below; for refrigerated (not frozen), reduced oxygen packaged products, that which must be met in order to ensure that the finished product has a water activity of less than 0.97);

OR

- For shelf-stable products:
  - Maximum finished product water activity of 0.85 or above;

OR

- For refrigerated (not frozen), reduced oxygen packaged products:
  - Maximum finished product water activity of less than 0.97.

Note: A heat treatment, addition of chemical additives, further drying, or other treatment may be necessary to inhibit or eliminate spoilage organisms (e.g., mold) in shelf-stable products.

Establish Monitoring Procedures.

» What Will Be Monitored?

- Critical factors of the established drying process that affect the ability of the process to ensure the desired finished product water activity (i.e., 0.85 or below for shelf-stable products, less than 0.97 for refrigerated (not frozen), reduced oxygen packaged products). These may include drying time, air temperature, humidity, and velocity, as well as flesh thickness;

OR

- Percent weight loss;

OR

- Water activity of the finished product.

» How Will Monitoring Be Done?

For batch drying equipment:

- For drying time and input/output air temperature:
  - Use a continuous temperature-recording device (e.g., a recording thermometer);

AND

- For all other critical factors specified by the study:
  - Use equipment appropriate for the measurement;

OR

- For percent weight loss:
  - Weigh all, or a portion, of the batch before and after drying;

OR

- For water activity analysis:
  - Collect a representative sample of the finished product and conduct water activity analysis.

For continuous drying equipment:

- For input/output air temperature:
  - Use a continuous temperature-recording device (e.g., a recording thermometer);

AND

- For drying time:
  - Measure:
    - The revolutions per minute (RPM) of the belt drive wheel, using a stopwatch or tachometer;

    OR

    - The time necessary for a test unit or belt marking to pass through the equipment, using a stopwatch;

AND

- For all other critical factors specified by the study:
  - Use equipment appropriate for the measurement;

OR

- For percent weight loss:
  - Weigh all, or a portion, of the batch before and after drying;

OR

- For water activity:
  - Collect a representative sample of the finished product and conduct water activity analysis.

» **How Often Will Monitoring Be Done (Frequency)?**

For batch drying equipment:

- For time and temperature:
  - Continuous monitoring, with a visual check of the recorded data at least once during each batch;

  AND
- For all other critical factors specified by the study:
  - As often as necessary to maintain control;

  OR
- For percent weight loss:
  - Each batch;

  OR
- For water activity:
  - Each batch.

For continuous drying equipment:

- For temperature:
  - Continuous monitoring, with a visual check of the recorded data at least once per day;

  AND
- For time:
  - At least once per day, and whenever any changes in belt speed are made;

  AND
- For all other critical factors specified by the study:
  - As often as necessary to maintain control;

  OR
- For percent weight loss:
  - Each lot of finished product;

  OR
- For water activity:
  - Each lot of finished product.

» **Who Will Do the Monitoring?**

- For continuous temperature-recording devices:
  - Monitoring is performed by the equipment itself. The visual check of the data generated by this equipment, to ensure that the critical limits have consistently been met, may be performed by any person who has an understanding of the nature of the controls;

  AND
- For all other critical factors specified by the study:
  - Any person who has an understanding of the nature of the controls;

  OR
- For percent weight loss:
  - Any person who has an understanding of the nature of the controls;

  OR
- For water activity:
  - Any person with sufficient training to perform the analysis.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Redry the product (provided that redrying does not present an unacceptable opportunity for pathogenic bacteria growth);

  OR
- Chill and hold the product for an evaluation of the adequacy of the drying process. The evaluation may involve water activity determination on a representative sample of the finished product. If the evaluation shows that the product has not received an adequate drying process, the product should be destroyed, diverted to a use in which

pathogenic bacteria growth in the finished product will be controlled by means other than drying, diverted to a non-food use, or redried;

OR

- Divert the product to a use in which the critical limit is not applicable because pathogenic bacteria growth in the finished product will be controlled by means other than drying (e.g., divert inadequately dried fish to a frozen fish operation);

OR

- Divert the product to a non-food use;

OR

- Destroy the product.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Adjust the air temperature or velocity;

OR

- Adjust the length of the drying cycle to compensate for a temperature or velocity drop, humidity increase, or inadequate percent weight loss;

OR

- Adjust the belt speed to increase the length of the drying cycle.

Establish a Recordkeeping System.

For batch drying equipment:

- Record of continuous temperature monitoring;

AND

- Record of visual checks of recorded data;

AND

- Record of notation of the start time and end time of the drying periods;

AND

- Records that are appropriate for the other critical factors (e.g., a drying log that indicates input/output air humidity and/or velocity);

OR

- Record of weight before and after drying;

OR

- Record of water activity analysis.

For continuous drying equipment:

- Record of continuous temperature monitoring;

AND

- Record of visual checks of recorded data;

AND

- Drying log that indicates the RPM of the belt drive wheel or the time necessary for a test unit or belt marking to pass through the drier;

AND

- Records that are appropriate for the other critical factors (e.g., a drying log that indicates input/output air humidity and/or velocity);

OR

- Record of weight before and after drying;

OR

- Record of water activity analysis.

Establish Verification Procedures.

- Process validation study (except where a water activity analysis of the finished product is the monitoring procedure):
    - The adequacy of the drying process should be established by a scientific study. For shelf-stable products, the drying process should be designed to ensure the production of a shelf-stable product with a water activity of 0.85. For refrigerated (not frozen), reduced oxygen packaged products, it should be designed to ensure a finished product water activity of less than 0.97. Expert knowledge of drying process calculations and the dynamics of mass transfer in processing equipment may be required

to establish such a drying process. Such knowledge can be obtained by education or experience or both. Establishment of drying processes may require access to adequate facilities and the application of recognized methods. The drying equipment should be designed, operated, and maintained to deliver the established drying process to every unit of a product. In some instances, drying studies may be required to establish the minimum process. In other instances, existing literature that establishes minimum processes or adequacy of equipment is available. Characteristics of the process, product, and/or equipment that affect the ability to achive the established minimum drying process should be taken into consideration in the process establishment. A record of the process establishment should be maintained;

AND

- Finished product sampling and analysis to determine water activity at least once every 3 months (except where such testing is performed as part of monitoring);

  AND

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR
  - Immersing the sensor in boiling water (212°F (100°C)) if the device will be used at or near the boiling point. Note that the temperature should be adjusted to compensate for altitude, when necessary;

    OR
  - Doing a combination of the above if the device will be used at or near room temperature;

    OR
  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a thermometer traceable to National Institute of Standards and Technology (NIST) standards) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

  AND

- Once in service, check the temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

  AND

- Calibrate the temperature-recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable

device). For example, devices subjected to high temperatures for extended periods of time may require more frequent calibration. Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- Calibrate other instruments as necessary to ensure their accuracy;

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 14-1

CONTROL STRATEGY EXAMPLE 1 - CONTROL BY DRYING

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 1 - Control by Drying." This example illustrates how a processor of shelf-stable salmon jerky can control pathogenic bacteria growth and toxin formation as a result of inadequate drying. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Drying (forced convection oven)	Pathogenic bacteria growth and toxin formation	Maximum product thickness: ¼ inch	Product thickness	Preset slicer to just less than ¼ inch	Once per day before operations	Slicer operator	Re-adjust slicer	Processing log	Documentation of drying process establishment Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Analyze the finished product sample once every 3 months for water activity Review of monitoring, corrective action and verification, records within 1 week of preparation

TABLE 14-1

CONTROL STRATEGY EXAMPLE 1 - CONTROL BY DRYING

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 1 - Control by Drying." This example illustrates how a processor of shelf-stable salmon jerky can control pathogenic bacteria growth and toxin formation as a result of inadequate drying. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Drying (forced convection oven)	Pathogenic bacteria growth and toxin formation	Minimum drying time: 5 hours	Drying time	Digital time and temperature data logger	Continuous, with visual check of recorded data each batch	Oven operator	Continue drying	Data logger printout	Documentation of drying process establishment Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Analyze the finished product sample once every 3 months for water activity Review of monitoring, corrective action and verification, records within 1 week of preparation

TABLE 14-1

CONTROL STRATEGY EXAMPLE 1 - CONTROL BY DRYING

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 1 - Control by Drying." This example illustrates how a processor of shelf-stable salmon jerky can control pathogenic bacteria growth and toxin formation as a result of inadequate drying. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Drying (forced convection oven)	Pathogenic bacteria growth and toxin formation	Minimum oven temperature: 140°F To achieve a final water activity of 0.85 or less	Oven air input temperature	Digital time and temperature data logger	Continuous, with visual check of recorded data each batch	Oven operator	Extend drying process Segregate the product and hold under refrigeration for evaluation Evaluate by performing water activity analysis on finished product Redry if less than 0.85	Data logger printout	Documentation of drying process establishment Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Analyze the finished product sample once every 3 months for water activity Review of monitoring, corrective action and verification, records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 2 - CONTROL BY REFRIGERATION WITH LABELING**

It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Set Critical Limits.

- All finished product labels must contain a "keep refrigerated" statement (e.g., "Important, keep refrigerated until used").

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Finished product labels for presence of "keep refrigerated" statement.

» **How Will Monitoring Be Done?**

- Visual examination.

» **How Often Will Monitoring Be Done (Frequency)?**

- Representative number of packages from each lot of a finished product.

» **Who Will Do the Monitoring?**

- Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Segregate and relabel any improperly labeled product.

AND

Take the following corrective actions to regain control over the operation after a critical limit deviation:

- Segregate and return or destroy any label stock or pre-labeled packaging stock that does not contain the proper statement;

AND

- Determine and correct the cause of improper labels.

Establish a Recordkeeping System.

- Record of labeling checks.

Establish Verification Procedures.

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 14-2

CONTROL STRATEGY EXAMPLE 2 - CONTROL BY REFRIGERATION WITH LABELING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Control by Refrigeration With Labeling." This example illustrates how a processor of refrigerated, partially dried catfish can control pathogenic bacteria growth and toxin formation as a result of inadequate drying. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receipt of labeling	C. botulinum toxin formation during finished product storage	All finished product labels must contain a "keep refrigerated" statement	Finished product labels for the presence of the "keep refrigerated" statement	Visual examination	One label from each case of labels at receipt	Receiving employee	Segregate and re-label any improperly labeled product Segregate and return or destroy any label stock that does not contain the proper statement Determine and correct the cause of improper labels	Label receiving record	Review monitoring and correction action records within 1 week of preparation

*Note: Chapter 12 covers control of pathogenic bacteria growth at the CCP of finished product storage.

BIBLIOGRAPHY.

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APPENDIX 1: **FORMS**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

This appendix contains the following templates:

- Hazard Analysis Worksheet;

And

- Hazard Analysis Critical Control Point (HACCP) Plan Form.

HAZARD ANALYSIS WORKSHEET

Product Name

Firm Name:	Product Description:
Firm Address:	Method of Distribution and Storage:
	Intended Use and Consumer:

(1)	(2)	(3)	(4)	(5)	(6)
Ingredient/Processing Step	**Identify Potential Biological, Chemical, and Physical Hazards Associated with this Product and Process**	**Are Any Potential Food Safety Hazards Significant at this Step? (Yes/No)**	**Justify Your Decision for Column 3**	**What Preventive Measure(s) can be Applied for the Significant Hazards?**	**Is this Step a Critical Control Point? (Yes/No)**

HAZARD ANALYSIS WORKSHEET

(1)	(2)	(3)	(4)	(5)	(6)
Ingredient/Processing Step	**Identify Potential Biological, Chemical, and Physical Hazards Associated with this Product and Process**	**Are Any Potential Food Safety Hazards Significant at this Step? (Yes/No)**	**Justify Your Decision for Column 3**	**What Preventive Measure(s) can be Applied for the Significant Hazards?**	**Is this Step a Critical Control Point? (Yes/No)**

HACCP PLAN FORM

HACCP PLAN NAME

Firm Name:	Product Description:
Firm Address:	Method of Distribution and Storage:
	Intended Use and Consumer:

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	Significant Hazard(s)	Critical Limits	What	How	Frequency	Who	Corrective Action(s)	Records	Verification

Signature of Company Official: _____ Date: _____

HACCP PLAN FORM

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	Significant Hazard(s)	Critical Limits	What	How	Frequency	Who	Corrective Action(s)	Records	Verification

Signature of Company Official: _____ Date: _____

NOTES:

APPENDIX 2: **PRODUCT FLOW DIAGRAM - EXAMPLE**

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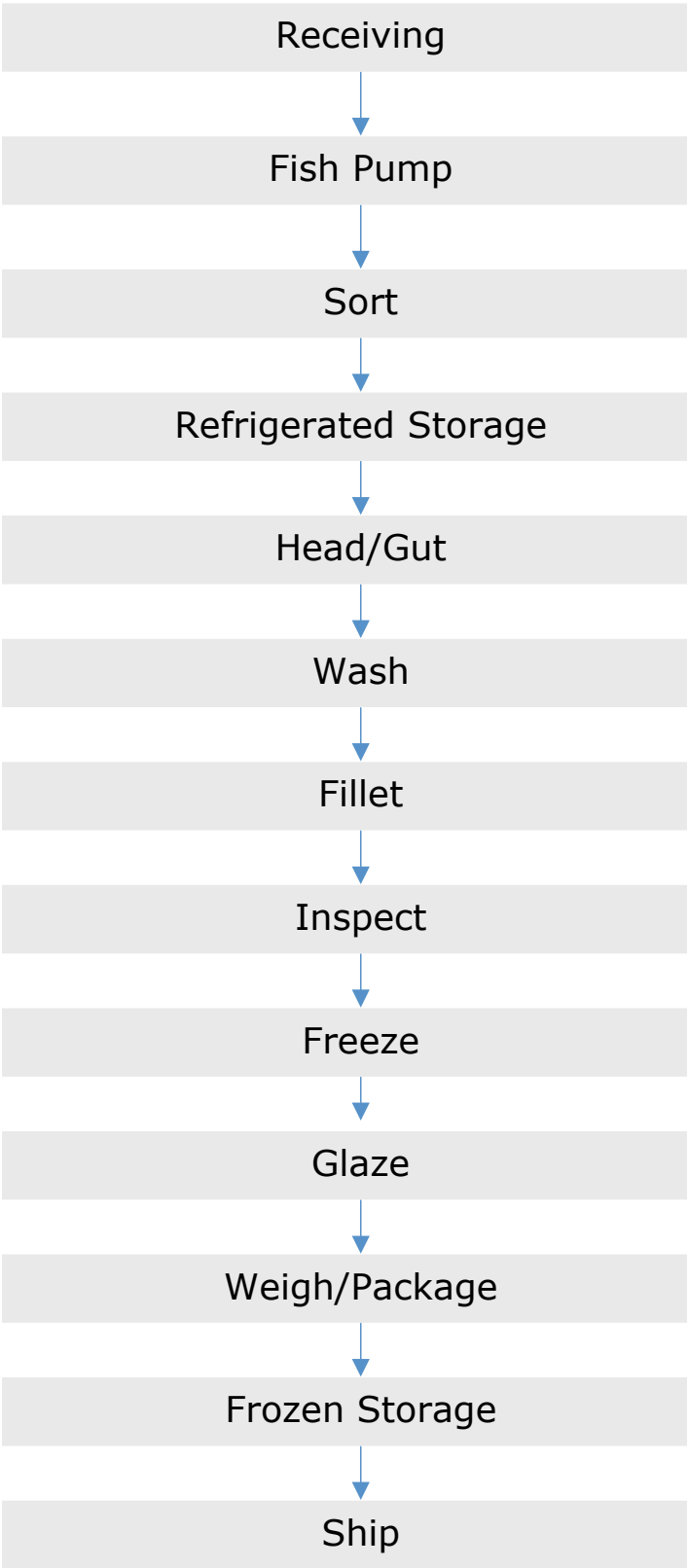
This appendix contains a product flow diagram that can be used as an example when you develop your own flow diagram.

FIGURE A-1:
PRODUCT FLOW DIAGRAM EXAMPLE:
FROZEN SALMON FILLETS



NOTES:

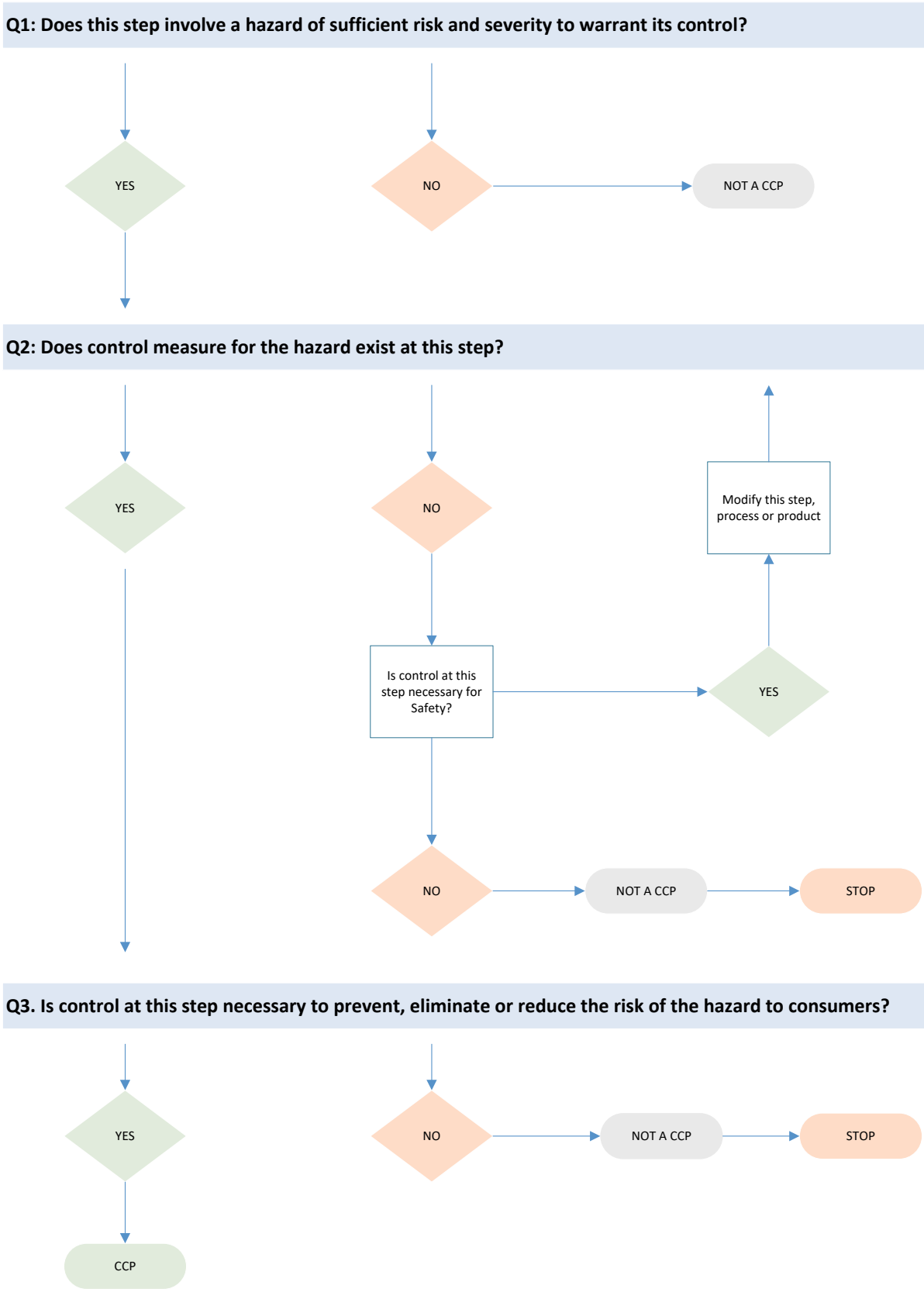
APPENDIX 3: **CRITICAL CONTROL POINT DECISION TREE**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

This appendix contains a decision tree that may be used to assist you with the identification of critical control points (CCPs). You should not rely exclusively on the decision tree, because error may result.

The following decision tree is derived from one that was developed by the National Advisory Committee on Microbiological Criteria for Foods.

FIGURE A-2: CCP DECISION TREE



BIBLIOGRAPHY

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- National Advisory Committee on Microbiological Criteria for Foods. 1992. *Hazard Analysis and Critical Control Point System.* Intl. J. Food Microbiol. 16:1-23.

NOTES:

APPENDIX 4: **Bacterial Pathogen Growth and Inactivation**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

This appendix contains information on the growth and inactivation of bacterial pathogens.

Table A-1 contains information on the minimum water activity (a_w), acidity (pH), and temperature; the maximum, pH, water phase salt, and temperature; and oxygen requirements that will sustain growth for the bacterial pathogens that are of greatest concern in seafood processing. Data shown are the minimum or maximum values, the extreme limits reported among the references cited. These values may not apply to your processing conditions.

Table A-2 contains information on maximum, cumulative time and internal temperature combinations for exposure of fish and fishery products that, under ordinary circumstances, will be safe for the bacterial pathogens that are of greatest concern in seafood processing. These maximum, cumulative exposure times are derived from published scientific information.

Because the nature of bacterial growth is logarithmic, linear interpolation using the time and temperature guidance may not be appropriate. Furthermore, the food matrix effects bacterial growth (e.g., presence of competing microorganisms, available nutrients, growth restrictive agents). Consideration of such attributes is needed when using the information in Tables A-1 and A-2.

In summary, Table A-2 indicates that:

For raw, ready-to-eat products:

- If at any time the product is held at internal temperatures above 70°F (21.1°C), exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135ºF (57.2ºC)) should be limited to 2 hours (3 hours if *Staphylococcus aureus* (*S. aureus*) is the only pathogen of concern),

  OR

  Alternatively, exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135ºF (57.2ºC)) should be limited to 4 hours, as long as no more than 2 of those hours are between 70°F (21.1°C) and 135ºF (57.2ºC);

OR

- If at any time the product is held at internal temperatures above 50°F (10°C) but never above 70°F (21.1°C), exposure time at internal temperatures above 50°F (10°C) should be limited to 5 hours (12 hours if *S. aureus* is the only pathogen of concern);

OR

- The product is held at internal temperatures below 50°F (10°C) throughout processing,

  OR

  Alternatively, the product is held at ambient air temperatures below 50°F (10°C) throughout processing.

For cooked, ready-to-eat products:

- If at any time the product is held at internal temperatures above 80°F (26.7°C), exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135ºF (57.2ºC)) should be limited to 1 hour (3 hours if *S. aureus* is the only pathogen of concern),

  OR

Alternatively, if at any time the product is held at internal temperatures above 80°F (26.7°C), exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135°F (57.2°C)) should be limited to 4 hours, as long as no more than 1 of those hours is above 70°F (21.1°C);

OR

- If at any time the product is held at internal temperatures above 70°F (21.1°C) but never above 80°F (26.7°C), exposure time at internal temperatures above 50°F (10°C) should be limited to 2 hours (3 hours if *S. aureus* is the only pathogen of concern),

  OR

  Alternatively, if the product is never held at internal temperatures above 80°F (26.7°C), exposure times at internal temperatures above 50°F (10°C) should be limited to 4 hours, as long as no more than 2 of those hours are above 70°F (21.1°C);

OR

- If at any time the product is held at internal temperatures above 50°F (10°C) but never above 70°F (21.1°C), exposure time at internal temperatures above 50°F (10°C) should be limited to 5 hours (12 hours if *S. aureus* is the only pathogen of concern);

OR

- The product is held at internal temperatures below 50°F (10°C) throughout processing,

  OR

  Alternatively, the product is held at ambient air temperatures below 50°F (10°C) throughout processing.

Note that the preceding recommended critical limits do not address internal product temperatures between 40°F (4.4°C), the recommended maximum storage temperature for refrigerated fish and fishery products, and 50°F (10°C). That is because growth of foodborne pathogenic bacteria is very slow at these temperatures and the time necessary for significant growth is longer than would be reasonably likely to occur in most fish and fishery product processing steps. However, if you have processing steps that occur at these temperatures that approach the maximum cumulative exposure times listed in Table A-2 below for the pathogenic bacteria of concern in your product, you should consider development of a critical limit for control at these temperatures.

It is not possible to furnish recommendations for each pathogenic bacteria, process, type of fish and fishery product, and temperature or combination of temperatures. Programmable models to predict growth rates for certain pathogens associated with various foods under differing conditions have been developed by the U.S. Department of Agriculture's (Pathogen Modeling Program (PMP)) and the United Kingdom's (Food MicroModel (FMM) program). These programs can provide growth curves for selected pathogens. You indicate the conditions, such as pH, temperature, and salt concentration that you are interested in and the models provide pathogen growth predictions (e.g., growth curve, time of doubling, time of lag phase, and generation time). FDA does not endorse or require the use of such modeling programs, but recognizes that the predictive growth information they provide may be of assistance to some processors. However, you are cautioned that significant deviations between actual microbiological data in specific products and the predictions do occur, including those for the lag phase of growth. Therefore, you should validate the time and temperature limits derived from such predictive models.

Table A-3 contains information on the destruction of *Listeria monocytogenes* (*L. monocytogenes*). Lethal rate, as used in this table, is the relative lethality of 1 minute at the designated internal product temperature as compared with the lethality of 1 minute at the reference internal product temperature of 158°F (70°C) (i.e., z = 13.5°F (7.5°C)). For example, 1

minute at 145°F (63°C) is 0.117 times as lethal as 1 minute at 158°F (70°C). The times provided are the length of time at the designated internal product temperature necessary to deliver a 6D process for *L. monocytogenes*. The length of time at a particular internal product temperature needed to accomplish a six logarithm reduction in the number of *L. monocytogenes* (6D) is, in part, dependent upon the food in which it is being heated. The values in the table are generally conservative and apply to all foods. You may be able to establish a shorter process time for your food by conducting scientific thermal death time studies. Additionally, lower degrees of destruction may be acceptable in your food if supported by a scientific study of the normal initial levels in the food. It is also possible that higher levels of destruction may be necessary in some foods, if especially high initial levels are anticipated.

Table A-4 contains information on the destruction of *Clostridium botulinum* (*C. botulinum*) type B (the most heat- resistant form of non-proteolytic *C. botulinum*). Lethal rate, as used in this table, is the relative lethality of 1 minute at the designated internal product temperature as compared with the lethality of 1 minute at the reference product internal temperature of 194°F (90°C) (i.e., for temperatures less than 194°F (90°C), z = 12.6°F (7.0°C); for temperatures above 194°F (90°C), z = 18°F (10°C)). The times provided are the length of time at the designated internal product temperature necessary to deliver a 6D process for *C. botulinum*. The values in the table are generally conservative. However, these values may not be sufficient for the destruction of non-proteolytic *C. botulinum* in dungeness crabmeat because of the potential protective effect of lysozyme. You may be able to establish a shorter process time for your food by conducting scientific thermal death time studies. Additionally, lower degrees of destruction may be acceptable in your food if supported by a scientific study of the normal innoculum in the food.

TABLE A-1
LIMITING CONDITIONS FOR PATHOGEN GROWTH

PATHOGEN	MIN. A_w (USING SALT)	MIN. pH	MAX. pH	MAX. % WATER PHASE SALT	MIN. TEMP.	MAX. TEMP.	OXYGEN REQUIREMENT
BACILLUS CEREUS	0.92	4.3	9.3	10	39.2°F 4°C	131°F[1] 55°C	facultative anaerobe[4]
CAMPYLOBACTER JEJUNI	0.987	4.9	9.5	1.7	86°F 30°C	113°F 45°C	micro-aerophile[2]
CLOSTRIDIUM BOTULINUM, TYPE A, AND PROTEOLYTIC TYPES B AND F	0.935	4.6	9	10	50°F 10°C	118.4°F 48°C	anaerobe[3]
CLOSTRIDIUM BOTULINUM, TYPE E, AND NON-PROTEOLYTIC TYPES B AND F	0.97	5	9	5	37.9°F 3.3°C	113°F 45°C	anaerobe[3]
CLOSTRIDIUM PERFRINGENS	0.93	5	9	7	50°F 10°C	125.6°F 52°C	anaerobe[3]
PATHOGENIC STRAINS OF ESCHERICHIA COLI	0.95	4	10	6.5	43.7°F 6.5°C	120.9°F 49.4°C	facultative anaerobe[4]
LISTERIA MONOCYTOGENES	0.92	4.4	9.4	10	31.3°F -0.4°C	113°F 45°C	facultative anaerobe[4]
SALMONELLA SPP.	0.94	3.7	9.5	8	41.4°F 5.2°C	115.2°F 46.2°C	facultative anaerobe[4]
SHIGELLA SPP.	0.96	4.8	9.3	5.2	43°F 6.1°C	116.8°F 47.1°C	facultative anaerobe[4]
STAPHYLOCOCCUS AUREUS GROWTH	0.83	4	10	20	44.6°F 7°C	122°F 50°C	facultative anaerobe[4]
STAPHYLOCOCCUS AUREUS TOXIN FORMATION	0.85	4	9.8	10	50°F 10°C	118°F 48°C	facultative anaerobe[4]
VIBRIO CHOLERAE	0.97	5	10	6	50°F 10°C	109.4°F 43°C	facultative anaerobe[4]
VIBRIO PARAHAEMOLYTICUS	0.94	4.8	11	10	41°F 5°C	113.5°F 45.3°C	facultative anaerobe[4]
VIBRIO VULNIFICUS	0.96	5	10	5	46.4°F 8°C	109.4°F 43°C	facultative anaerobe[4]
YERSINIA ENTEROCOLITICA	0.945	4.2	10	7	29.7°F -1.3°C	107.6°F 42°C	facultative anaerobe[4]

1. Has significantly delayed growth (>24 hours) at 131°F (55°C).
2. Requires limited levels of oxygen.
3. Requires the absence of oxygen.
4. Grows either with or without oxygen.

TABLE A-2 TIME AND TEMPERATURE GUIDANCE FOR CONTROLLING PATHOGEN GROWTH AND TOXIN FORMATION IN FISH AND FISHERY PRODUCTS		
POTENTIALLY HAZARDOUS CONDITION	PRODUCT TEMPERATURE	MAXIMUM CUMULATIVE EXPOSURE TIME
GROWTH AND TOXIN FORMATION BY ***BACILLUS CEREUS***	39.2-43°F (4-6°C) 44-59°F (7-15°C) 60-70°F (16-21°C) Above 70°F (21°C)	5 days 1 day 6 hours 3 hours
GROWTH OF ***CAMPYLOBACTER JEJUNI***	86-93°F (30-34°C) Above 93°F (34°C)	48 hours 12 hours
GERMINATION, GROWTH, AND TOXIN FORMATION BY ***CLOSTRIDIUM BOTULINUM*** TYPE A, AND PROTEOLYTIC TYPES B AND F	50-70°F (10-21°C) Above 70°F (21°C)	11 hours 2 hours
GERMINATION, GROWTH, AND TOXIN FORMATION BY ***CLOSTRIDIUM BOTULINUM*** TYPE E, AND NON-PROTEOLYTIC TYPES B AND F	37.9-41°F (3.3-5°C) 42-50°F (6-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	7 days 2 days 11 hours 6 hours
GROWTH OF ***CLOSTRIDIUM PERFRINGENS***	50-54°F (10-12°C) 55-57°F (13-14 °C) 58-70°F (15-21°C) Above 70°F (21°C)	21 days 1 day 6 hours[1] 2 hours
GROWTH OF PATHOGENIC STRAINS OF ***ESCHERICHIA COLI***	43.7-50°F (6.6-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
GROWTH OF ***LISTERIA MONOCYTOGENES***	31.3-41°F (-0.4-5°C) 42-50°F (6-10°C) 51-70°F (11-21°C) 71-86°F (22-30°C) Above 86°F (30°C)	7 days 1 day 7 hours 3 hours 1 hour
GROWTH OF ***SALMONELLA*** SPECIES	41.4-50°F (5.2-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
GROWTH OF ***SHIGELLA*** SPECIES	43-50°F (6.1-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
GROWTH AND TOXIN FORMATION BY ***STAPHYLOCOCCUS AUREUS***	50°F (7-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	14 days 12 hours[1] 3 hours
GROWTH OF ***VIBRIO CHOLERAE***	50°F (10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80ºF (27ºC)	21 days 6 hours 2 hours 1 hour[2]
GROWTH OF ***VIBRIO PARAHAEMOLYTICUS***	41-50°F (5-10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80ºF (27ºC)	21 days 6 hours 2 hours 1 hour[2]
GROWTH OF ***VIBRIO VULNIFICUS***	46.4-50°F (8-10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80ºF (27ºC)	21 days 6 hours 2 hours 1 hour[2]
GROWTH OF ***YERSINIA ENTEROCOLITICA***	29.7-50°F (-1.3-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	1 day 6 hours 2.5 hours

1. Additional data needed.
2. Applies to cooked, ready-to-eat foods only.

TABLE A-3 INACTIVATION OF LISTERIA MONOCYTOGENES			
INTERNAL PRODUCT TEMPERATURE (°F)	INTERNAL PRODUCT TEMPERATURE (°C)	LETHAL RATE	TIME FOR 6D PROCESS (MINUTES)
145	63	0.117	17.0
147	64	0.158	12.7
149	65	0.215	9.3
151	66	0.293	6.8
153	67	0.398	5.0
154	68	0.541	3.7
156	69	0.736	2.7
158	70	1.000	2.0
160	71	1.359	1.5
162	72	1.848	1.0
163	73	2.512	0.8
165	74	3.415	0.6
167	75	4.642	0.4
169	76	6.310	0.3
171	77	8.577	0.2
172	78	11.659	0.2
174	79	15.849	0.1
176	80	21.544	0.09
178	81	29.286	0.07
180	82	39.810	0.05
182	83	54.116	0.03
183	84	73.564	0.03
185	85	100.000	0.02
Note: z = 13.5°F (7.5°C).			

TABLE A-4 INACTIVATION OF NON-PROTEOLYTIC CLOSTRIDIUM BOTULINUM TYPE B			
INTERNAL PRODUCT TEMPERATURE (°F)	INTERNAL PRODUCT TEMPERATURE (°C)	LETHAL RATE*	TIME FOR 6D PROCESS (MINUTES)
185	85	0.193	51.8
187	86	0.270	37.0
189	87	0.370	27.0
190	88	0.520	19.2
192	89	0.720	13.9
194	90	1.000	10.0
196	91	1.260	7.9
198	92	1.600	6.3
199	93	2.000	5.0
201	94	2.510	4.0
203	95	3.160	3.2
205	96	3.980	2.5
207	97	5.010	2.0
208	98	6.310	1.6
210	99	7.940	1.3
212	100	10.000	1.0

Note: For temperatures less than 194°F (90°C), z = 12.6°F (7.0°C); for temperatures above 194°F (90°C), z = 18°F (10°C).

*Note: These lethal rates and process times may not be sufficient for the destruction of non-proteolytic C. botulinum in dungeness crabmeat because of the potential that substances that may be naturally present, such as lysozyme, may enable the pathogen to more easily recover from heat damage.

BIBLIOGRAPHY.

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NOTES:

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

Reference Document: 2013 FDA Food Code

Provision: 1-201.10

Document Name: Heat sealing without a vacuum v03

Date: January 4, 2017, Editorial change September 12, 2017, December 20, 2019

Question: When packaging food in a retail food establishment, does the 2013 Food Code definition of reduced oxygen packaging apply to the use of plastic bags or plastic films that have been heat sealed without drawing a vacuum?

Response:

No. The process of heat sealing a time temperature control for safety (TCS) food in packaging (a plastic bag or a plastic film on trays) without drawing a vacuum or otherwise modifying the atmosphere inside the package would not meet the 2013 Food Code definition of reduced oxygen packaging (ROP), provided the food being packaged has NOT been heated, just prior to packaging.

The 2013 FDA Food Code defines "Reduced Oxygen Packaging" (ROP) as:

- "The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and . . . .."

A reduced oxygen environment occurs in a package when less oxygen is present in the package relative to the amount of oxygen expected to be present in the atmosphere (typically 21% at sea level). The Food Code definition of reduced oxygen packaging is limited to the intentional or purposeful methods used by food establishments to create a reduced oxygen environment within a packaged TCS food product at the time of packaging.

The packaging and sealing, without drawing a vacuum, of a TCS food that has not been heated, just prior to packaging, is not considered to be removing oxygen to the degree that you are: 1) reducing the amount of oxygen in a package at the time of packaging, or 2) using an intentional or purposeful method to create a reduced oxygen environment within a packaged TCS food product at the time of packaging.

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Heat sealing a hot TCS food (which includes TCS foods cooked as specified in relevant Sections of Part 3-401 of the Food Code and TCS foods heated to hot holding temperatures) without modifying the atmosphere or drawing a vacuum raises a concern of *C. botulinum* growth in the packaged TCS food. This is because the process of cooking food drives off oxygen from the food thereby lowering the oxygen level in that food. After the bag is sealed, the oxygen level in the headspace and the oxygen level in the hot TCS food will begin to equilibrate. This results in a package with an oxygen level below what is normally found in the atmosphere, thereby creating a process that aligns with the Food Code definition of ROP.

The model Food Code is neither federal law nor federal regulation and is not preemptive. It represents FDA's best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented. The model Food Code provisions are designed to be consistent with federal food laws and regulations and are written for ease of legal adoption at all levels of government.

References:

1. 2013 FDA Food Code, 1-202.10 Statement of Application and Listing of Terms.

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Reference Document: 2013 Food Code

Provision(s): 1-201.10; 3-502.12; 8-103.10; 8-103.11

Document Name: Vacuum packaging and oxygen transfer rate of the packaging material

Date: October 6, 2016

Question: Does the Food Code definition for "Reduced Oxygen Packaging" apply to fish, not frozen, that is vacuum packaged using packaging material with a greater than or equal to oxygen transfer rate (OTR) of 10,000 cc/m^2/24 hours at 24°C (10K)?

Response:

Vacuum packaging by definition is a reduced oxygen packaging process. The oxygen transfer rate (OTR) of the packaging material used in vacuum packaging a food item does not change this designation.

Paragraph 3-502.12 (C) of the 2013 FDA Food Code specifically states, "except for fish that is frozen before, during, and after packaging, a food establishment may not package fish using a reduced oxygen packaging method." This provision is intended to apply irrespective of the oxygen transfer rate of the packaging material used.

The 2013 FDA Food Code defines "Reduced Oxygen Packaging" (ROP) as:

a) The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and

b) A process as specified in (a) of this definition that involves a food for which the hazards *Clostridium botulinum* or *Listeria monocytogenes* require control in the final packaged form. "Reduced oxygen packaging" includes Vacuum packaging, in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package…"

Unfrozen raw fish and other seafood are excluded from being reduced oxygen packaged at retail because of these products' natural association with non-proteolytic *Clostridium botulinum* (primarily type E) which grows at 3.3°C (38°F). If a food establishment wants to employ a reduced oxygen packaging method for fish that is not frozen before, during and after packaging it is recommended that the food establishment seek a variance (8-103.10 Modifications and

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Waivers) from the regulatory authority that has jurisdiction.

FDA acknowledges that the reduced oxygen environment created in a reduced oxygen packaged product at the time of packaging can be impacted over time by the oxygen-permeability of the packaging material. As such, the FDA-CFSAN Retail Food Policy Team would not object to a variance request being approved based upon information that shows the OTR of the packaging material provides sufficient exchange of oxygen to allow naturally occurring, aerobic spoilage organisms on the fishery product to grow and spoil the product (under moderate abuse temperatures) before *Clostridium botulinum* toxin is produced.

Food Code Section 8-103.10 Modifications and Waivers, provides the regulatory authority the means to grant a variance by modifying or waiving the requirements of the Code, if in the opinion of the regulatory authority a health hazard or nuisance will not result from the variance. Food Code Section 8-103.11 Documentation of Proposed Variance and Justification, provides a means for the regulatory authority to obtain information from the operator regarding the proposed variance prior to approval. If the operator intends to produce and package the product for wholesale, it would be subject to federal and state food manufacturing regulations.

The FDA Food Code is neither federal law nor federal regulation and is not preemptive. It represents FDA's best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented. The FDA Food Code provisions are designed to be consistent with federal food laws and regulations, and are written for ease of legal adoption at all levels of government.

References:

1. 2013 Food Code, Section 3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria; Section 1-201.10 Statement of Application and Listing of Terms; Section 8-103.10 Modifications and Waivers; Section 8-103.11 Documentation of Proposed Variance and Justification

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Controlling the Hazard of *Clostridium botulinum* Growth and Toxin Formation in Reduced Oxygen Packaged Fish and Fishery Products Including Refrigerated, Vacuum-Packed Crawfish Tail Meat

It has come to FDA's attention that processors of refrigerated, vacuum-packed crawfish tail meat may not be controlling the hazard of *Clostridium botulinum* growth and toxin formation. FDA considers the hazard of *C. botulinum* growth and toxin formation reasonably likely to occur in reduced oxygen packaged (ROP) fish and fishery products including refrigerated, vacuum-packed crawfish tail meat. All seafood processors are required to conduct a hazard analysis and implement a written HACCP plan to control hazards that are reasonably likely to occur within and outside the processing plant according to 21 CFR Part 123.6. FDA's Fish and Fishery Products Hazards and Controls Guidance provides recommendations to assist processors with assessing hazards and developing HACCP plans.

FDA considers ROP fish and fishery products including refrigerated, vacuum-packed crawfish tail meat to be adulterated under section 402 (a)(4) of the Food, Drug and Cosmetic Act when the hazard of *C. botulinum* growth and toxin formation is not controlled. Specific sections addressing primary processors and secondary processors including distributors are provided below in this document.

Background

ROP encompasses a large variety of packaging methods including vacuum packaging, modified atmosphere packaging, hermetically sealed containers, sealed plastic or laminated packaging, packing in oil, and using a material that is not considered oxygen-permeable. Packaging that is not considered oxygen-permeable restricts the exchange of oxygen and can lead to any oxygen present in the packaging being utilized by spoilage organisms resulting in a reduced oxygen environment. By reducing or preventing the exchange of oxygen, a processor introduces the hazard of *C. botulinum* growth and toxin formation.

C. botulinum is an anaerobic bacterium, meaning it can grow in low oxygen conditions, that is widely distributed in nature, in soil, the sediment of streams, lakes, and coastal waters, and in the intestinal tracts of fish and mammals. The toxin produced by *C. botulinum* is considered one of the most poisonous naturally occurring substances known and when ingested can result in paralysis, leading to death from asphyxiation. There are two major groups of *C. botulinum*, the proteolytic and non-proteolytic. Proteolytic strains can grow at 50°F and above. Non-proteolytic strains, commonly found in seafood, can grow at 38°F and above to render a food toxic without any apparent signs of spoilage.

Primary Processors

1. When refrigeration below 38°F is the sole control for the hazard *C. botulinum,* processors should use a Time-Temperature Indicator (TTI) on each reduced oxygen package of product and maintain the product below 38°F. Since product will likely not be maintained below 38°F during distribution, TTIs are needed to monitor time and temperatures exposures throughout distribution until consumption. TTIs should be designed specifically for *C. botulinum* and alert consumers and end users of potentially unsafe time and temperature exposures that could result in toxin formation.

Processors that use a TTI on each ROP package and maintain the product below 38°F should have a HACCP plan that, at a minimum, lists critical control points for finished product storage below 38°F, and TTI use and application. The critical control points and critical limits for the TTIs should be based on the TTI manufacturer's specifications.

2. For seafood, packaging that has an oxygen transmission rate (OTR) of 10,000 cc/m^2/24 hours at 24°C, or higher (often referred to as 10K OTR and occasionally printed on the packaging) is considered oxygen permeable and not ROP by FDA. Oxygen permeable packaging should provide a sufficient exchange of oxygen to allow naturally occurring aerobic spoilage organisms on the fishery product to grow and spoil the product before *C. botulinum* toxin is produced under moderate abuse temperatures.

3. Product can be frozen with proper labeling. The product should be immediately frozen after being placed in a reduced oxygen package. The HACCP plan should list a labeling critical control point for each package to be labeled "Important, keep frozen until used, thaw under refrigeration immediately before use."

Secondary Processors Including Distributors

The term secondary processor includes distributors that hold or store product because holding and storing is defined as processing in 21 CFR Part 123.3 (k)(1). Secondary processors should assess the hazard of *C. botulinum* when receiving ROP products and ensure the product is received with proper controls, in addition to implementing proper controls within their own facility, as necessary. For example, distributors of refrigerated ROP products including vacuum-packed crawfish tail meat, should receive product below 38°F with TTIs and have a HACCP plan that lists critical control points for receiving and storage with critical limits that maintain the product below 38°F.

For more information on *C. botulinum* and controls see Chapter 13 of FDA's Fish and Fishery Products Hazards and Controls Guidance (4th ed.) and FDA's Seafood HACCP Video titled "Time-Temperature Indicators" available at www.fda.gov/seafood.

Response to your Case 299700: Food Code [ref:_00D60KbN0._5003d5N9HNAA0:ref]

1 message

"FCIC Inquiry" <fcicinquiry@fda.hhs.gov> <fcicinquiry@fda.hhs.gov> Thu, Nov 17, 2022 at 10:02 AM
To: "troy.huffman@state.co.us" <troy.huffman@state.co.us>

This message is being sent in response to the following submitted inquiry:

When packaging food that has been heated just prior to packaging in a retail food establishment using a breathable plastic bag or plastic film and then allowing that product to cool, does the 2017 Food Code definition of reduced oxygen packaging apply? Does the film or bag have to be 10K OTR or greater to be considered breathable?

The Food and Drug Administration's (FDA) Food and Cosmetic Information Center (FCIC)/Technical Assistance Network (TAN) has prepared a response for case number 299700.

Response:

Thank you for your inquiry on the 2017 Food code definition of reduced oxygen packaging. The Food Code defines Reduced oxygen packaging (ROP) as:

(a) The reduction of the amount of oxygen in a PACKAGE by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and

(b) A process as specified in Subparagraph (1)(a) of this definition that involves a FOOD for which the HAZARDS Clostridium botulinum or Listeria monocytogenes require control in the final PACKAGED form.

ROP also includes:

1. Vacuum packaging
2. Modified atmosphere packaging
3. Controlled atmosphere packaging
4. Cook chill packaging
5. Sous Vide packaging

Based on the information provided in this inquiry, the trays are sealed with a film that allows oxygen transmission and the trays contain ambient air (no removal of oxygen by vacuum or displacement with another gas such as nitrogen), therefore, it is not considered ROP. It seems like the film is a measure to protect the food contents from contamination. Barrier properties of a container are not used to define what we mean by ROP. With the information provided, this practice would not be considered ROP as defined in the Food Code.

It is important to note that although it appears based on the information provided that this is not considered an ROP process, it can potentially create a ROP environment depending on the temperature at which the product is packaged (which is the case with many foods in many different storage containers). Heating temperatures were not provided in the inquiry. Heating a food drives off the oxygen. Also, when hot food cools in a package, it can draw a slight vacuum, thereby reducing oxygen, although oxygen can reenter the package once the food cools if the package material is oxygen permeable. In addition, there can be areas in a packaged food that have reduced oxygen capable of supporting growth of pathogens such as Clostridium botulinum if the food is not maintained at a temperature to prevent such growth.

We do not have a definition of "breathable." Note also that breathable packaging is usually designed to provide oxygen levels that will allow spoilage organisms to grow and spoil food before it becomes toxic, not as a measure to prevent growth of C. botulinum.

The Food Code is a model for adoption by state, local, tribal, territorial regulatory jurisdictions although some local laws may differ from the model Food Code.

For the most up to date information on the FDA Food Code, please go to: https://www.fda.gov/food/fda-food-code/food-code-2017.

Thank you for contacting FDA's FCIC/TAN.

View popular Food Safety Modernization Act (FSMA) questions and answers identified by the Technical Assistance Network (TAN), on our website.

This communication is intended for the exclusive use of the inquirer and does not constitute an advisory opinion (21 CFR 10.85(k)). Also note that this response is not intended to be a comprehensive list of all applicable requirements. Please check FDA's web page (www.fda.gov) regularly for guidance reflecting our current thinking. Additional information on FSMA can be found on FDA's FSMA web page (www.fda.gov/fsma). This communication may contain information that is protected, privileged, or confidential. If you have received it in error, please immediately delete all copies.

**Please do not reply to this email box. If you would like to submit a follow-up question or need clarification to this inquiry, please click here www.fda.gov/fcic and reference this inquiry's case number.

In order to improve our service, we'd like your opinion about your experiences using the FSMA TAN - http://cfsan.force.com/Responsesurvey

STATE OF COLORADO

Huffman - CDPHE, Troy <troy.huffman@state.co.us>

Response to your Case 301854: Food Code [ref:_00D60KbN0._5003d5tAlMAAU:ref]

1 message

"FCIC Inquiry" <fcicinquiry@fda.hhs.gov> <fcicinquiry@fda.hhs.gov> Fri, Nov 18, 2022 at 5:29 AM
To: "troy.huffman@state.co.us" <troy.huffman@state.co.us>

This message is being sent in response to the following submitted inquiry:

This is a follow-up to assigned case number 299700. The package is sealed with the breathable film and the product temperature is above 135F and then allowed to cool while still sealed with a breathable film. Would that be considered ROP if sealed hot then allowed to cool?

The Food and Drug Administration's (FDA) Food and Cosmetic Information Center (FCIC)/Technical Assistance Network (TAN) has prepared a response for case number 301854.

Response:

As explained in our response to case #299700, based on the limited information provided in your inquiry, the trays are sealed with a film that allows oxygen transmission and the trays contain ambient air (no removal of oxygen by vacuum or displacement with another gas such as nitrogen), therefore, it is not considered ROP as defined in the Food Code.

Thank you for contacting FDA's FCIC/TAN.

View popular Food Safety Modernization Act (FSMA) questions and answers identified by the Technical Assistance Network (TAN), on our website.

This communication is intended for the exclusive use of the inquirer and does not constitute an advisory opinion (21 CFR 10.85(k)). Also note that

this response is not intended to be a comprehensive list of all applicable requirements. Please check FDA's web page (www.fda.gov) regularly for guidance reflecting our current thinking. Additional information on FSMA can be found on FDA's FSMA web page (www.fda.gov/fsma). This communication may contain information that is protected, privileged, or confidential. If you have received it in error, please immediately delete all copies.

**Please do not reply to this email box. If you would like to submit a follow-up question or need clarification to this inquiry, please click here www.fda.gov/fcic and reference this inquiry's case number.

In order to improve our service, we'd like your opinion about your experiences using the FSMA TAN - http://cfsan.force.com/Responsesurvey

January 16, 2023

Revised January 17, 2023

Lodge Cast Iron

Research & Development Report

VGSRN: 434

Cleaning Effectiveness of Cast Iron Pans and Glass and Plastic Plates when Machine Washed

Prepared For:

David Fletcher

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Prepared By:

Rachel Corken

Scientist, Research & Development

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OBJECTIVE

The objective of this study was to validate the reduction of *E. coli* and *Staphylococcus aureus* on cast iron pans and plates when place and cycled through a machine dishwasher.

MATERIAL AND METHODS

Test Product

Lodge Cast Iron provided a sufficient amount of product for inoculation to pass through a machine dishwasher. SGS North America provided all other testing supplies.

Test Organisms

A strain of generic *Escherichia coli* (ATCC 25922) and *Staphylococcus aureus* (ATCC 6538) was used to inoculate the products. The cultures were grown overnight in Brain Heart Infusion Broth (BHI) individually and diluted to achieve an inoculum level of approximately 8 log CFU/g sample.

Inoculation of Product

The product was inoculated with freshly prepared inoculum. The inoculum was combined with a 1% solution of reconstituted non-fat dry milk that served as a "soil". The pan surfaces were inoculated with a concentration between $1.0x10^8$ to $9.9x10^8$ cells/ml on the product. The inoculum was then allowed to dry overnight at room temperature.

Product Processing

Twelve of each Pioneer Woman 13.5" cast iron skillets, Mainstays 12" cast iron skillets, Lodge 8" cast iron skillets, Lodge cast iron oval servers pre-own and used by Chattanooga State University Culinary program, Corelle Pioneer Women Blue plates, and Mainstays black plastic plates were inoculated and tested for generic *E. coli* and *S. aureus*. For each test organism, three of each product were used to measure the viable bacteria after overnight drying without washing to serve as the untreated controls for each microorganism. The other nine of each pan type for each test organism were washed in triplicate in 3 separate wash cycles. After the wash cycle were complete, the products were tested for residual bacterial count. For both the treated and untreated products, the level of organisms remaining on the products was determined by swabbing the product surfaces with EZ-10NB-PUR swabs.

Microbial Analyses

Each of the swabs was serially diluted to obtain a countable range and plated in duplicate using 15 mL to 20 mL of TSA agar. The plates were incubated at 35±1°C for 48±2h. All typical colonies were enumerated.

DATA ANALYSIS AND REPORT

The cleaning effectiveness of cast iron pans, glass plates, and plastic plates was determined by comparing the level of organisms on the washed product to that of the unwashed product.

After the inoculation and drying of *Staphylococcus aureus,* the untreated Pioneer Woman Cast Iron had an average of 6.977 log CFU/g, Mainstays Cast Iron of 6.854 log CFU/g, Lodge 8in Cast Iron of 6.700 log CFU/g, Lodge Cast Iron Oval Server (pre-own and used by Chattanooga State University Culinary program) of 6.767 log CFU/g, Corelle Plate of 6.585 log CFU/g and Mainstays Plate of 6.729 log CFU/g (Table 1). Once the products where washed (treated) the Pioneer Woman Cast Iron had an average of 0.300 log CFU/g, Mainstays Cast Iron of 0.978 log CFU/g, Lodge 8in Cast Iron of 0.487 log CFU/g, Lodge Cast Iron Oval Server of 1.120 log CFU/g, Corelle Plate of 0.689 log CFU/g and Mainstays Plate of 1.034 log CFU/g.

For the inoculation of *Escherichia coli*, the untreated Pioneer Woman Cast Iron had an average of 4.472 log CFU/g, Mainstays Cast Iron of 2.867 log CFU/g, Lodge 8in Cast Iron of 4.000 log CFU/g, Lodge Cast Iron Oval Server (pre-own and used by Chattanooga State University Culinary program) of 4.667 log CFU/g, Corelle Plate of 2.767 log CFU/g and Mainstays Plate of 4.460 log CFU/g (Table 2). Ones the products where washed(treated) the Pioneer Woman Cast Iron had an average of 0.942 log CFU/g, Mainstays Cast Iron of 0.622 log CFU/g, Lodge 8in Cast Iron of 1.115 log CFU/g, Lodge Cast Iron Oval Server of 0.817 log CFU/g, Corelle Plate of 0.589 log CFU/g and Mainstays Plate of 0.742 log CFU/g.

The washing process effectively reduced the level of inoculated *Staphylococcus aureus* in Pioneer Woman Cast Iron by at least 6.677 log CFU/g, Mainstays Cast Iron by 5.876 log CFU/g, Lodge 8in Cast Iron by 6.213 log CFU/g, Lodge Cast Iron Oval Server (pre-own and used by Chattanooga State University Culinary program) by 5.647 log CFU/g, Corelle Plate by 5.896 log CFU/g and Mainstays Plate by 5.695 log CFU/g.

The washing process effectively reduced the level of inoculated *Escherichia coli* in Pioneer Woman Cast Iron by at least 3.530 log CFU/g, Mainstays Cast Iron by 2.245 log CFU/g, Lodge 8in Cast Iron by 2.885 log CFU/g, Lodge Cast Iron Oval Server (pre-own and used by Chattanooga State University Culinary program) by 3.850 log CFU/g, Corelle Plate by 2.178 log CFU/g and Mainstays Plate by 3.718log CFU/g.

Consumer dishwashing of cast iron, Correlle, and plastic plates, effectively reduced the level of inoculated *S. aureus* and *E. coli* on all three surface types.

Table 1: Comparison of level of *Staphylococcus aureus* in treated and untreated products.

Sample	Average Untreated (Log CFU/g)	Average Treated (Log CFU/g)	Reduction (Log CFU/g)
Pioneer Woman Cast Iron	6.977 (σ=0.046)	0.300 (σ=0.585)	6.677
Mainstays Cast Iron	6.854 (σ=0.052)	0.978 (σ=0.593)	5.876
Lodge 8in Cast Iron	6.700 (σ=0.062)	0.487 (σ=0.692)	6.213
Lodge Cast Iron Oval Server	6.767 (σ=0.087)	1.120 (σ=0.454)	5.647
Corelle Plate	6.585 (σ=0.108)	0.689 (σ=0.655)	5.896
Mainstays Plate	6.729 (σ=0.027)	1.034 (σ=0.765)	5.695

Table 2: Comparison of level of *Escherichia coli* in treated and untreated products.

Sample	Average Untreated (Log CFU/g)	Average Treated (Log CFU/g)	Reduction (Log CFU/g)
Pioneer Woman Cast Iron	4.472 (σ=0.470)	0.942 (σ=0.555)	3.530
Mainstays Cast Iron	2.867 (σ=2.042)	0.622 (σ=0.585)	2.245
Lodge 8in Cast Iron	4.000 (σ=0.000)	1.115 (σ=0.555)	2.885
Lodge Cast Iron Oval Server	4.667 (σ=0.046)	0.817 (σ=0.847)	3.850
Corelle Plate	2.767 (σ=1.960)	0.589 (σ=0.694)	2.178
Mainstays Plate	4.460 (σ=0.225)	0.742 (σ=0.681)	3.718

Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel

Final Report

December 18, 2019

Version 1

Project Identification Number

QL # 19269-2B

Test Articles

Cast Iron Cookware and Food Grade Stainless Steel Carriers

Study Director

Benjamin J. Bastin

Study Sponsor

Lodge Manufacturing
204 East 5th Street
South Pittsburgh, TN 37380

Performing Laboratory

Q Laboratories
1930 Radcliff Drive
Cincinnati, OH 45204

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Test Summary

Title: Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel

Study Design: This study was designed to demonstrate that microorganisms can be removed from cast iron cookware with similar effectiveness as from stainless steel surfaces. The equivalence of recovery was demonstrated by inoculating both materials with equivalent numbers of each microorganism. For this study the following microorganisms were used: *Staphylococcus aureus*, *Escherichia coli*, *Salmonella* Enteritidis, *Listeria monocytogenes*, and *Clostridium perfringens*. Following inoculation, surfaces were sampled.

Test Articles:

The test articles evaluated were provided to the testing facility by the study sponsor, complete with appropriate documentation. Test articles were sterilized via autoclave upon receipt and stored at ambient temperature (20 - 25 °C) in autoclaved aluminum foil.

1. Cast Iron Cookware
   - 1.1 14 Ounce Round Cast Iron Mini Server (SKU: HMSRD)
   - 1.2 12 Ounce Cast Iron Mini Serving Bowl (SKU: HMSB)
   - 1.3 16 Ounce Oval Cast Iron Mini Server (SKU: HM16OS)
   - 1.4 9 Ounce Oval Cast Iron Mini Server (SKU: HMSOV)
   - 1.5 14 Ounce Rectangular Cast Iron Mini Server (SKU: HMS14RC)
   - 1.6 10 Ounce Square Cast Iron Mini Server (SKU: HMSS)
2. Food Grade Stainless Steel Carriers (18 GA 300 series, brush finish)

Sponsor: Lodge Manufacturing
204 East 5th Street
South Pittsburgh, TN 37380

Testing Conditions

Challenge Microorganisms:

1. *Staphylococcus aureus* American Type Culture Collection (ATCC) 6538
2. *Escherichia coli* ATCC 8739
3. *Salmonella* Enteritidis ATCC 13076
4. *Listeria monocytogenes* ATCC 7644
5. *Clostridium perfringens* ATCC 12915

Note: Appropriate laboratory safety conditions was employed while working with enriched culture suspensions. These conditions included, but were not limited to, the use of appropriate PPE (including disposable gloves, beard nets, hair nets, and lab coats), Biological Safety Cabinets, and protective eyewear.

Testing Conditions:

The evaluation was conducted at ambient temperature (20 - 25 °C).

Media/Reagents:

1. Tryptic Soy Agar with 5% Sheep Blood (SBA) (Fisher Scientific, PN 221261) or equivalent
2. Microbial Content Test (MCT) agar MP107
3. Tryptic Soy Broth (TSB) MP058
4. Phosphate Buffered Saline (PBS) MP416
5. Columbia Blood Agar (CBA) with 5% Sheep Blood MP086
6. Reinforced Clostridial Medium (RCM) MP158

Equipment/Supplies:

1. Incubator, temperature range 35 ± 1 °C
2. Incubator thermometer, NIST traceable
3. Sterile containers
4. Steam autoclave
5. Vortex mixer
6. Calibrated, traceable minute/second timer
7. Refrigerator, temperature range 2 - 8 °C
8. Refrigerator thermometer, NIST traceable
9. Traceable thermometer/clock/humidity monitor
10. Adjustable pipettor, 1 µL - 200 µL capacity
11. Adjustable pipettor, 100 µL - 1000 µL capacity
12. Sterile serological pipettes
13. Sterile 100 µL and 1000 µL micropipette tips
14. Reichert Quebec® Colony Counter, or equivalent
15. Hand tally

16. Test tubes, sterilized
17. Sterile disposable Petri dishes, 100 x 15 mm
18. Sterile polyurethane tip swabs
19. Sterile disposable loops
20. Rotator/shaker
21. Anaerobic Sachets, BBL GasPaks or equivalent

Study Dates and Facility

The analysis phase of this test was conducted at Q Laboratories in the Microbiology Research and Development Laboratory, 1930 Radcliff Drive, Cincinnati, Ohio 45204, from 10-28-19 to 11-11-19. The study sponsor and study director signed the protocol on 10-31-19. The final report was released 12-16-19.

Records to be Maintained

All testing data, protocol, protocol modifications, test material records, the final report, and correspondence between Q Laboratories and the sponsor will be stored in the archives at Q Laboratories, 1930 Radcliff Drive, Cincinnati, Ohio 45204 for a period of at least seven (7) years.

Test Procedure

Test Microorganism Preparation:

Staphylococcus aureus ATCC 6538, *Escherichia coli* ATCC 8739, *Salmonella* Enteritidis ATCC 13076, and *Listeria monocytogenes* ATCC 7644 were propagated on Tryptic Soy Agar with 5% Sheep Blood (SBA) from a Q Laboratories frozen stock culture stored at -70 °C. SBA plates were incubated aerobically at 35 ± 1 °C for 24 ± 2 hours. After incubation, an isolated colony was picked to Tryptic Soy Broth (TSB) and incubated at 35 ± 1 °C for 24 ± 2 hours. Test articles were inoculated with the 24 hour TSB culture.

Clostridium perfringens ATCC 12915 was propagated on SBA from a Q Laboratories frozen stock culture stored at -70 °C. The SBA plate was incubated anaerobically at 35 ± 1 °C for 24 ± 2 hours. After incubation, an isolated colony was transferred to pre-reduced Reinforced Clostridial Medium (RCM) and incubated anaerobically at 35 ± 1 °C for 24 ± 2 hours. Test articles were inoculated with the 24 hour RCM culture.

Pre-Inoculation Preparation:

The study sponsor reported that the test articles were pre-cleaned using one cycle in an industrial dishwasher prior to shipping.

Test articles and stainless-steel control carriers were placed in a sterile container and autoclaved after receipt by the testing facility. This step was done to ensure there is no residual bioburden prior to inoculation.

Using sterile gloves, the test article was placed on a disinfected flat surface. One (1) 1” x 1” location on each test article was marked for evaluation, depicted as red squares in Figures 1 - 4.

Inoculation of Test Articles:

A 100 µL aliquot of each test culture was applied to the 1” x 1” marked areas. The culture was uniformly spread over the sample area using 100 - 1000 µL micropipette tip to prevent areas of pooling.

After inoculation, the test articles were allowed to dry for 18 - 24 hours at ambient temperature (20 - 25 °C). After 18-24 hours, the test article was visually inspected to ensure the test culture suspension was uniformly dried and testing was initiated.

The inoculation steps above were repeated for the stainless-steel control carriers.

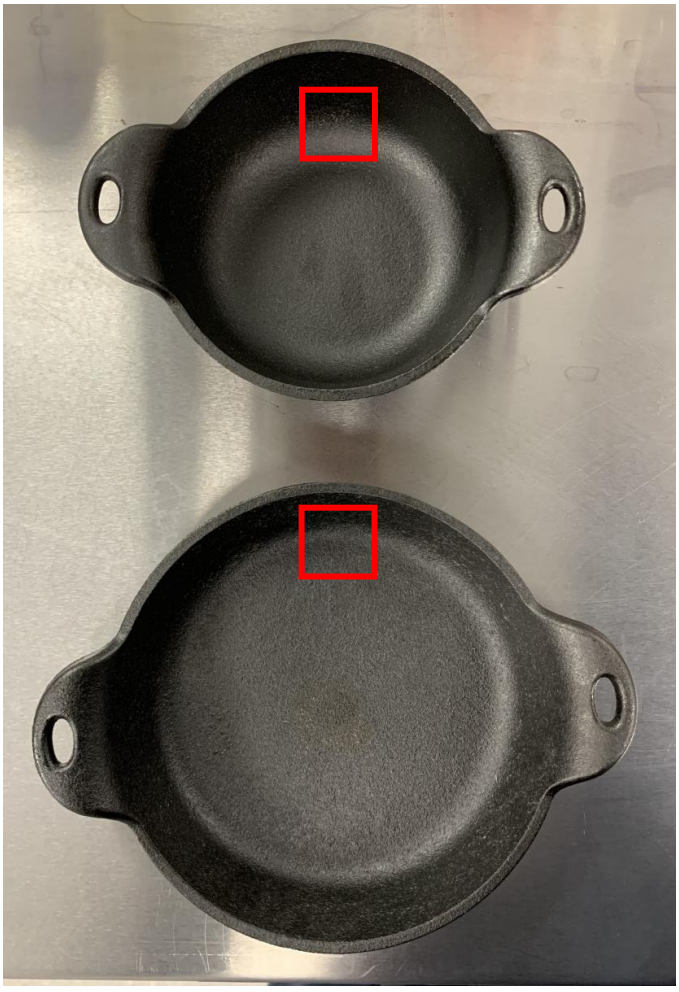

Figure 1. 12 Ounce Cast Iron Mini Serving Bowl and 14 Ounce Round Cast Iron Mini Server Sample Areas.

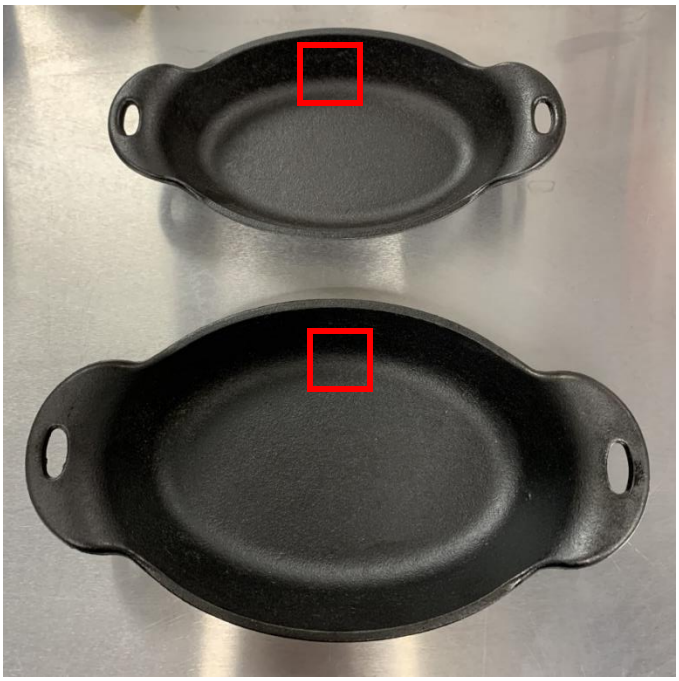

Figure 2. 9 Ounce Oval Cast Iron Mini Server and 16 Ounce Oval Cast Iron Mini Server Sample Areas.

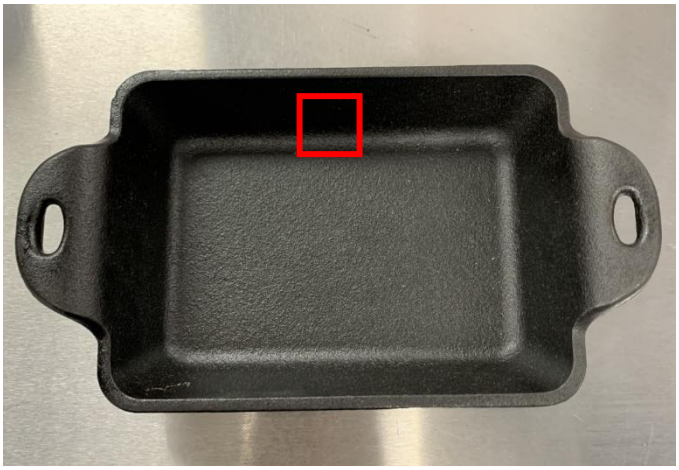

Figure 3. 14 Ounce Rectangular Cast Iron Mini Server Sample Area.

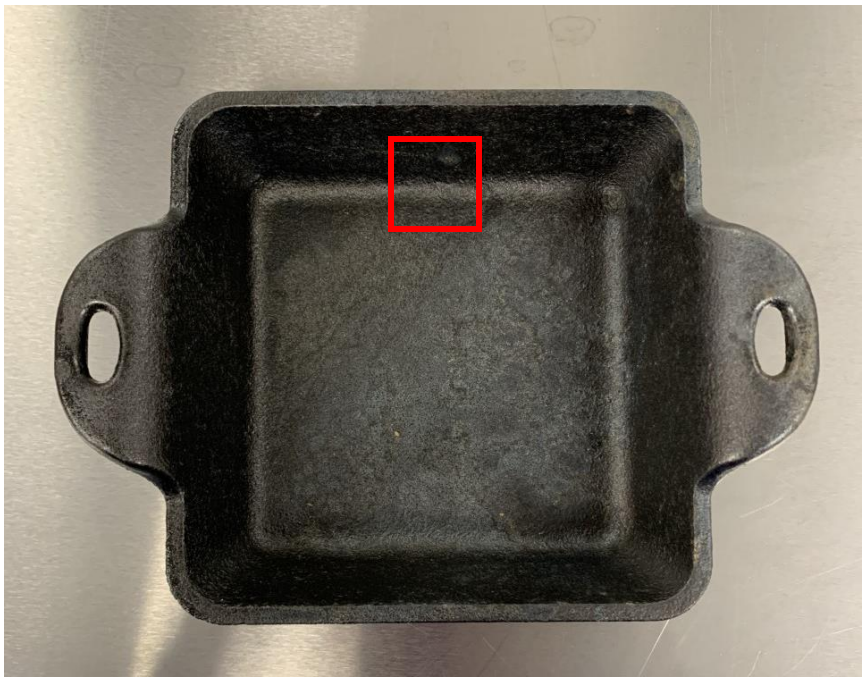

Figure 4. 10 Ounce Square Cast Iron Mini Server Sample Area.

Three (3) replicates of the test articles and three (3) replicates using food grade stainless steel carries were evaluated for each microorganism. A summary of the recovery study parameters is presented in Table 1.

Table 1. Summary of Recovery Study Parameters

Test Organisms	Test Article	No. of Test Replicates	No. of Stainless-Steel Control Replicates
S. aureus, *E. coli*, *S.* Enteritidis, *L. monocytogenes*, *C. perfringens*	14 Ounce Round Cast Iron Mini Server	3	3
	12 Ounce Cast Iron Mini Serving Bowl	3	3
	16 Ounce Oval Cast Iron Mini Server	3	3
	9 Ounce Oval Cast Iron Mini Server	3	3
	14 Ounce Rectangular Cast Iron Mini Server	3	3
	10 Ounce Square Cast Iron Mini Server	3	3

Recovery and Enumeration Procedure:

A 1.0 mL aliquot of PBS was added to a sterile swab. The marked 1" x 1" sample area was thoroughly swabbed in an up and down vertical motion and a left and right horizontal motion. This process was designed to remove viable microorganisms from the surface of the test article for enumeration.

The swab was placed in a test tube containing 9.0 mL of PBS. The swab was expressed into the test tube and thoroughly vortexed for 30 ± 5 seconds. Ten-fold serial dilutions of the sample were prepared by transferring 1.0 mL from the initial dilution into 9.0 mL of PBS.

For *S. aureus*, *E. coli*, *S.* Enteritidis and *L. monocytogenes*, each dilution was plated into duplicate sterile Petri dishes and 12 - 15 mL of tempered MCT was added. Plates were mixed thoroughly and allowed to solidify. Plates were inverted and incubated at 35 ± 1 °C for 48 ± 2 hours.

For *C. perfringens* each dilution was spread plated with sterile plating beads onto duplicate pre-poured plates of Columbia Blood Agar (CBA) with 5% Sheep Blood (CBA). Plates were inverted and incubated anaerobically at 35 ± 1 °C for 48 ± 2 hours.

After incubation, typical colonies were enumerated, and raw data was recorded as CFU/plate. Duplicate plates were averaged and multiplied by the dilution factor to arrive at CFU/test article. Raw values were recorded and used for the calculations in Tables 2-6.

Study Controls:

Food Grade Stainless Steel Controls – Three (3) 4" x 4" food grade stainless steel test articles were inoculated according to the test procedure. The recovered microorganisms were determined following the procedures found in Recovery and Enumeration. In order for the testing to be considered acceptable, the recovery data from the cast iron test articles had to be comparable to the food grade stainless steel.

Statistical Analysis

A logarithmic transformation measuring surviving microbial populations of the positive control article and test replicates for each microorganism were performed.

Equivalence of Recovery was calculated as follows:

ΔLog10 = Equivalence Recovery
TR1 = Test Article Replicate 1
TR2 = Test Article Replicate 2
TR3 = Test Article Replicate 3
SS1 = Stainless Steel 1
SS2 = Stainless Steel 2
SS3 = Stainless Steel 3

$$\left(\frac{TR1 + TR2 + TR3}{3}\right) - \left(\frac{SS1 + SS2 + SS3}{3}\right) = \Delta\text{Log10}$$

Media Quality Controls

The MCT plating media was inoculated with an aliquot of each *S. aureus, E. coli, S.* Enteritidis, and *L. monocytogenes* suspension and incubated at 35 ± 1 °C for 48 ± 2 hours. These plates served as positive growth controls for the media.

The CBA and RCM media were inoculated with an aliquot of the *C. perfringens* suspension and incubated anaerobically at 35 ± 1 °C for 48 ± 2 hours. These served as positive growth controls for the media.

The acceptance criterion for these bacterial media controls was "typical growth" of the organisms.

For negative sterility controls, two tubes each of TSB, PBS, and three plates of MCT were incubated at 35 ± 2 °C for 48 ± 2 hours.

The acceptance criterion for these uninoculated media controls was "negative for growth".

References

U. S. Food and Drug Administration *Bacteriological Analytical Manual*, Chapter 3 *Aerobic Plate Count* (January 2001). (Accessed October 2019)
http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm063346.htm

Summary of Results

The results of the initial microorganism recovery comparison are presented in Tables 2-6. The results of the retested test articles are presented in Tables 7-10. The mean Log values were obtained from duplicate plates. The Equivalence of Recovery was calculated as follows:

ΔLog10 = Equivalence Recovery
TR1 = Test Article Replicate 1
TR2 = Test Article Replicate 2
TR3 = Test Article Replicate 3
SS1 = Stainless Steel 1
SS2 = Stainless Steel 2
SS3 = Stainless Steel 3

$$\left(\frac{TR1 + TR2 + TR3}{3}\right) - \left(\frac{SS1 + SS2 + SS3}{3}\right) = \Delta\text{Log10}$$

Results

Table 2: *Staphylococcus aureus* ATCC 6538 Recovery Comparison Reported in CFU/mL recovered.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
14 Ounce Round Cast Iron Mini Server	CFU/mL	2.6E+05	3.2E+05	3.8E+05	1.1E+05	2.6E+05	1.1E+05	0.3340
	Log CFU/mL	5.4150	5.5051	5.5798	5.0414	5.4150	5.0414	
12 Ounce Cast Iron Mini Serving Bowl	CFU/mL	3.3E+05	4.2E+05	2.8E+05	1.2E+05	1.2E+05	1.1E+05	0.4630
	Log CFU/mL	5.5185	5.6232	5.4472	5.0792	5.0792	5.0414	
16 Ounce Oval Cast Iron Mini Server	CFU/mL	3.0E+05	2.4E+05	2.1E+05	1.7E+05	1.5E+05	1.4E+05	0.2090
	Log CFU/mL	5.4771	5.3802	5.3222	5.2304	5.1761	5.1461	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	4.2E+05	5.0E+05	1.2E+05	1.6E+05	1.1E+05	1.2E+05	0.3589
	Log CFU/mL	5.6232	5.6990	5.0792	5.2041	5.0414	5.0792	
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	4.6E+05	5.0E+05	4.9E+05	1.5E+05	8.4E+04	1.5E+05	0.5918
	Log CFU/mL	5.6628	5.6990	5.6902	5.1761	4.9243	5.1761	
10 Ounce Square Cast Iron Mini Server	CFU/mL	2.7E+05	3.0E+05	2.8E+05	7.4E+04	1.2E+05	1.3E+05	0.4311
	Log CFU/mL	5.4314	5.4771	5.4472	4.8692	5.0792	5.1139	

Table 3: *Escherichia coli* ATCC 8739 Recovery Comparison
Reported in CFU/mL recovered.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
14 Ounce Round Cast Iron Mini Server	CFU/mL	1.2E+04	1.7E+04	6.0E+03	5.0E+03	1.6E+04	5.6E+03	0.1455
	Log CFU/mL	4.0792	4.2304	3.7782	3.6990	4.2041	3.7482	
12 Ounce Cast Iron Mini Serving Bowl	CFU/mL	6.6E+03	3.0E+03	9.2E+03	4.4E+03	6.6E+03	7.0E+03	-0.0159
	Log CFU/mL	3.8195	3.4771	3.9638	3.6435	3.8195	3.8451	
16 Ounce Oval Cast Iron Mini Server	CFU/mL	5.4E+03	1.0E+04	5.8E+03	2.6E+04	2.6E+04	3.0E+04	-0.6038
	Log CFU/mL	3.7324	4.0000	3.7634	4.4150	4.4150	4.4771	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	6.4E+03	8.0E+03	8.4E+03	1.7E+04	2.7E+04	3.6E+04	-0.5282
	Log CFU/mL	3.8062	3.9031	3.9243	4.2304	4.4314	4.5563	
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	4.7E+03	4.1E+03	4.2E+03	4.0E+03	5.6E+03	4.6E+03	-0.0350
	Log CFU/mL	3.6721	3.6128	3.6232	3.6021	3.7482	3.6628	
10 Ounce Square Cast Iron Mini Server	CFU/mL	5.4E+03	6.0E+03	1.0E+04	3.1E+03	9.2E+03	8.3E+03	0.0454
	Log CFU/mL	3.7324	3.7782	4.0000	3.4914	3.9638	3.9191	

Table 4: *Salmonella* Enteritidis ATCC 13076 Recovery Comparison
Reported in CFU/mL recovered.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
14 Ounce Round Cast Iron Mini Server	CFU/mL	7.0E+04	7.2E+04	3.9E+04	1.4E+04	3.6E+04	3.8E+04	0.3371
	Log CFU/mL	4.8451	4.8573	4.5911	4.1461	4.5563	4.5798	
12 Ounce Cast Iron Mini Serving Bowl	CFU/mL	2.6E+04	1.3E+04	1.4E+04	8.9E+03	5.2E+04	4.6E+04	-0.2177
	Log CFU/mL	4.4150	4.1139	4.1461	3.9494	4.7160	4.6628	
16 Ounce Oval Cast Iron Mini Server	CFU/mL	9.9E+03	8.7E+03	2.8E+04	4.6E+03	1.3E+04	8.8E+03	0.2204
	Log CFU/mL	3.9956	3.9395	4.4472	3.6628	4.1139	3.9445	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	3.2E+04	4.2E+04	3.4E+04	2.8E+04	1.2E+04	1.4E+04	0.3291
	Log CFU/mL	4.5051	4.6232	4.5315	4.4472	4.0792	4.1461	
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	4.3E+04	3.4E+04	3.8E+04	1.2E+04	1.4E+04	2.7E+04	0.3627
	Log CFU/mL	4.6335	4.5315	4.5798	4.0792	4.1461	4.4314	
10 Ounce Square Cast Iron Mini Server	CFU/mL	6.3E+04	4.9E+04	5.8E+04	1.1E+04	1.7E+04	2.0E+04	0.5600
	Log CFU/mL	4.7993	4.6902	4.7634	4.0414	4.2304	4.3010	

Table 5: *Listeria monocytogenes* ATCC 7644 Recovery Comparison
Reported in CFU/mL recovered.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
14 Ounce Round Cast Iron Mini Server	CFU/mL	1.1E+04	5.6E+03	1.6E+04	4.6E+03	1.3E+04	6.8E+03	0.1282
	Log CFU/mL	4.0414	3.7482	4.2041	3.6628	4.1139	3.8325	
12 Ounce Cast Iron Mini Serving Bowl	CFU/mL	1.5E+04	5.8E+03	1.0E+03	6.3E+03	1.0E+03	6.4E+03	0.1133
	Log CFU/mL	4.1761	3.7634	3.0000	3.7993	3.0000	3.8062	
16 Ounce Oval Cast Iron Mini Server	CFU/mL	1.1E+04	8.2E+03	1.3E+04	7.0E+02	3.2E+03	2.6E+03	0.7680
	Log CFU/mL	4.0414	3.9138	4.1139	2.8451	3.5051	3.4150	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	2.6E+04	3.0E+04	2.6E+04	1.2E+03	2.1E+03	3.4E+03	1.1247
	Log CFU/mL	4.4150	4.4771	4.4150	3.0792	3.3222	3.5315	
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	1.2E+04	5.4E+03	5.5E+03	3.8E+03	3.0E+03	2.8E+03	0.3493
	Log CFU/mL	4.0792	3.7324	3.7404	3.5798	3.4771	3.4472	
10 Ounce Square Cast Iron Mini Server	CFU/mL	2.4E+03	1.7E+03	4.3E+03	1.8E+03	9.6E+02	1.7E+03	0.2587
	Log CFU/mL	3.3802	3.2304	3.6335	3.2553	2.9823	3.2304	

Table 6: *Clostridium perfringens* ATCC 12915 Recovery Comparison
Reported in CFU/mL recovered.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
14 Ounce Round Cast Iron Mini Server	CFU/mL	2.3E+05	2.7E+05	3.9E+05	1.0E+05	1.3E+05	1.6E+05	0.3554
	Log CFU/mL	5.3617	5.4314	5.5911	5.000	5.1139	5.2041	
12 Ounce Cast Iron Mini Serving Bowl	CFU/mL	2.9E+05	4.5E+04	2.9E+05	9.0E+04	1.0E+05	1.2E+05	0.1815
	Log CFU/mL	5.4624	4.6532	5.4624	4.9542	5.0000	5.0792	
16 Ounce Oval Cast Iron Mini Server	CFU/mL	2.5E+05	2.7E+05	1.5E+05	1.6E+05	1.9E+05	1.6E+05	0.1061
	Log CFU/mL	5.3979	5.4314	5.1761	5.2041	5.2788	5.2041	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	3.7E+05	4.7E+05	2.6E+05	1.1E+05	1.8E+05	1.7E+05	0.3761
	Log CFU/mL	5.5682	5.6721	5.4150	5.0414	5.2553	5.2304	
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	5.2E+05	3.8E+05	3.9E+05	1.7E+05	1.0E+05	2.6E+05	0.4138
	Log CFU/mL	5.7160	5.5798	5.5911	5.2304	5.0000	5.4150	
10 Ounce Square Cast Iron Mini Server	CFU/mL	1.9E+05	3.2E+05	2.6E+05	1.1E+05	8.0E+04	1.9E+05	0.3252
	Log CFU/mL	5.2788	5.5051	5.4150	5.0414	4.9031	5.2788	

Table 7: *Staphylococcus aureus* ATCC 6538 Recovery Comparison
Reported in CFU/mL recovered – Retested.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	2.1E+05	2.9E+05	4.5E+05	5.3E+05	4.1E+05	3.9E+05	-0.1635
	Log CFU/mL	5.3222	5.4624	5.6532	5.7243	5.6128	5.5911	

Table 8: *Escherichia coli* ATCC 8739 Recovery Comparison
Reported in CFU/mL recovered - Retested.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
16 Ounce Oval Cast Iron Mini Server	CFU/mL	1.3E+04	1.8E+04	2.4E+04	1.2E+04	3.4E+04	2.6E+04	-0.0921
	Log CFU/mL	4.1139	4.2553	4.3802	4.0792	4.5315	4.4150	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	1.5E+04	2.3E+04	2.7E+04	3.3E+04	2.9E+04	2.4E+04	-0.1306
	Log CFU/mL	4.1761	4.3617	4.4314	4.5185	4.4624	4.3802	

Table 9: *Salmonella* Enteritidis ATCC 13076 Recovery Comparison
Reported in CFU/mL recovered - Retested.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
10 Ounce Square Cast Iron Mini Server	CFU/mL	5.5E+04	3.2E+04	6.2E+04	2.2E+04	2.5E+04	3.4E+04	0.2554
	Log CFU/mL	4.7404	4.5051	4.7924	4.3424	4.3979	4.5315	

Table 10: *Listeria monocytogenes* ATCC 7644 Recovery Comparison
Reported in CFU/mL recovered - Retested.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
16 Ounce Oval Cast Iron Mini Server	CFU/mL	1.8E+04	2.6E+04	1.1E+04	3.4E+04	2.3E+04	3.8E+04	-0.2538
	Log CFU/mL	4.2553	4.4150	4.0414	4.5315	4.3617	4.5798	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	2.8E+04	3.9E+04	1.7E+04	2.0E+04	1.4E+04	4.5E+05	-0.2772
	Log CFU/mL	4.4472	4.5911	4.2304	4.3010	4.1461	5.6532	

Conclusion

Based on the results presented in this study report, the microorganism recovery equivalence from cast iron products and food grade stainless met the performance criteria for 2 of the 6 test articles. The performance criteria states that for equivalent recovery, the cast iron test articles must be within 0.5 Log of the stainless-steel carrier controls. Both 14 Ounce Round Cast Iron Mini Server and 12 Ounce Cast Iron Mini Serving Bowl met the performance criteria for each inoculum. The 9 Ounce Oval Cast Iron and 16 Ounce Oval Cast Iron did not meet the performance criteria for *Listeria monocytogenes,* and *Escherichia coli.* The 14 Ounce Rectangle Cast Iron Mini Server did not meet the performance criteria for *Staphylococcus aureus.* The 10 Ounce Square Cast Iron Mini server did not meet the performance criteria for *Salmonella* Enteritidis.

Since failure to meet the performance criteria could have been caused by variable inoculum levels due to homogenization of the test culture or by variable die off rate during the overnight drying, any test articles that did not meet the performance criteria were retested. Upon retesting all test articles met the performance criteria. The performance criteria states that for equivalent recovery, the cast iron test articles must be within 0.5 Log of the stainless-steel carrier controls.

Appendix 1

Signed Protocol

Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel

Protocol # QL19269-2B

Version 2

Prepared for:

Lodge Manufacturing (Study Sponsor)
204 East 5th Street
South Pittsburgh, TN 37380

Prepared by:

Q Laboratories (Testing Facility)
1930 Radcliff Drive
Cincinnati, OH 45204
(513) 471-1300

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1.0 **Title:** Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel

2.0 **Sponsor:** Lodge Manufacturing
204 East 5th Street
South Pittsburgh, TN 37380

3.0 **Testing Facility:** Q Laboratories
1930 Radcliff Drive
Cincinnati, OH 45204

4.0 **Study Director:** Benjamin J. Bastin

5.0 **Purpose:**

This study is designed to demonstrate that microorganisms can be removed from cast iron cookware with similar effectiveness as from stainless steel surfaces.

6.0 **Scope:**

The equivalence of recovery will be demonstrated by inoculating both materials with equivalent numbers of each microorganism. For this study the following microorganisms will be used: *Staphylococcus aureus, Escherichia coli, Salmonella* Enteritidis, *Listeria monocytogenes,* and *Clostridium perfringens*. Following inoculation, surfaces will be sampled.

7.0 **Test Articles:**

The test articles to be evaluated will be provided to the testing facility by the study sponsor, complete with appropriate documentation. Test articles will be sterilized via autoclave upon receipt.

7.1 Cast Iron Cookware
- 7.1.1 14 Ounce Round Cast Iron Mini Server (SKU: HMSRD)
- 7.1.2 12 Ounce Cast Iron Mini Serving Bowl (SKU: HMSB)
- 7.1.3 16 Ounce Oval Cast Iron Mini Server (SKU: HM16OS)
- 7.1.4 9 Ounce Oval Cast Iron Mini Server (SKU: HMSOV)
- 7.1.5 14 Ounce Rectangular Cast Iron Mini Server (SKU: HMS14RC)
- 7.1.6 10 Ounce Square Cast Iron Mini Server (SKU: HMSS)

7.2 Food Grade Stainless Steel Carriers (18 GA 300 series, brush finish)

8.0 **Testing Conditions:**

8.1 The evaluation will be conducted at ambient temperature (20 - 25 °C).

9.0 Test Microorganisms:

9.1 *Staphylococcus aureus* American Type Culture Collection (ATCC) 6538
9.2 *Escherichia coli* ATCC 8739
9.3 *Salmonella* Enteritidis ATCC 13076
9.4 *Listeria monocytogenes* ATCC 7644
9.5 *Clostridium perfringens* ATCC 12915

Note: Appropriate laboratory safety conditions will be employed while working with enriched culture suspensions. These conditions will include, but are not limited to, the use of appropriate PPE (including disposable gloves, beard nets, hair nets, and lab coats), Biological Safety Cabinets, and protective eyewear.

10.0 Media/Reagents:

10.1 Tryptic Soy Agar with 5% Sheep Blood (SBA) Commercially available from BD 221261 or equivalent
10.2 Microbial Content Test (MCT) agar MP107
10.3 Tryptic Soy Broth (TSB) MP058
10.4 Phosphate Buffered Saline (PBS) MP416
10.5 Columbia Blood Agar (CBA) with 5% Sheep Blood MP086
10.6 Reinforced Clostridial Medium (RCM) MP158

11.0 Equipment/Supplies:

11.1 Incubator, temperature range 35 ± 1 °C
11.2 Incubator thermometers, NIST traceable
11.3 Sterile containers
11.4 Steam autoclave
11.5 Vortex mixer
11.6 Calibrated, traceable minute/second timer
11.7 Refrigerator, temperature range 2 - 8 °C
11.8 Refrigerator thermometer, NIST traceable
11.9 Traceable thermometer/clock/humidity monitor
11.10 Adjustable pipettor, 1 µL - 200 µL capacity
11.11 Adjustable pipettor, 100 µL - 1000 µL capacity
11.12 Sterile serological pipettes
11.13 Sterile 100 µL and 1000 µL micropipette tips
11.14 Reichert Quebec® Colony Counter, or equivalent
11.15 Hand tally
11.16 Test tubes, sterilized
11.17 Sterile disposable Petri dishes, 100 x 15 mm
11.18 Sterile polyurethane tip swabs
11.19 Sterile disposable loops
11.20 Rotator/shaker
11.21 Anaerobic Sachets, BBL GasPaks or equivalent

12.0 Test Microorganism Preparation:

12.1 *Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 8739, *Salmonella* Enteritidis ATCC 13076, and *Listeria monocytogenes* ATCC 7644 will be propagated on Tryptic Soy Agar with 5% Sheep Blood (SBA) from a Q Laboratories frozen stock culture stored at -70 °C. SBA plates will be incubated aerobically at 35 ± 1 °C for 24 ± 2 hours. After incubation, an isolated colony will be picked to Tryptic Soy Broth (TSB) and incubated at 35 ± 1 °C for 24 ± 2 hours.

12.2 *Clostridium perfringens* ATCC 12915 will be propagated on SBA from a Q Laboratories frozen stock culture stored at -70 °C. The SBA plate will be incubated anaerobically at 35 ± 1 °C for 24 ± 2 hours. After incubation, an isolated colony will be transferred to pre-reduced Reinforced Clostridial Medium (RCM) and incubated anaerobically at 35 ± 1 °C for 24 ± 2 hours.

13.0 Microorganism Recovery Study Parameters:

13.1 Three (3) total replicates of the test articles will be evaluated for each microorganism. A summary of the recovery study parameters is presented in Table 1.

13.2 Three (3) total replicates using food grade stainless steel carries will be evaluated for each microorganism as controls. A summary of the antimicrobial activity study parameters is presented in Table 1.

Table 1. Summary of Recovery Study Parameters.

Test Organisms	Test Article	No. of Test Replicates	No. of Stainless-Steel Control Replicates
S. aureus, *E. coli*, *S.* Enteritidis, *L. monocytogenes*, *C. perfringens*	14 Ounce Round Cast Iron Mini Server	3	3
	12 Ounce Cast Iron Mini Serving Bowl	3	3
	16 Ounce Oval Cast Iron Mini Server	3	3
	9 Ounce Oval Cast Iron Mini Server	3	3
	14 Ounce Rectangular Cast Iron Mini Server	3	3
	10 Ounce Square Cast Iron Mini Server	3	3

14.0 Test Procedure:

Preconditioning:

14.1 The study sponsor reported that the test articles were pre-cleaned using one cycle in an industrial dishwasher prior to shipping.

14.2 Test articles and stainless-steel control carriers will be placed in a sterile container and autoclaved after receipt by the testing facility. This step will be done to ensure there is no residual bioburden prior to inoculation.

Inoculation:

14.3 Using sterile gloves, place the test article on a disinfected flat surface. One (1) 1" x 1" location on the test article will be marked for evaluation as depicted in Figures 1 - 4.

14.4 Apply 100 µL of each test culture to the 1" x 1" marked areas. The culture will be uniformly spread over the sample area using 100 - 1000 µL micropipette tip to prevent areas of pooling.

14.5 After inoculation, the test articles will be allowed to dry for 18 - 24 hours at ambient temperature (20 - 25 °C). After 18-24 hours, the test article will be visually inspected to ensure the test culture suspension is uniformly dried and testing will be initiated.

14.6 Repeat inoculation steps 14.2 to 14.4 for the stainless-steel control carriers.

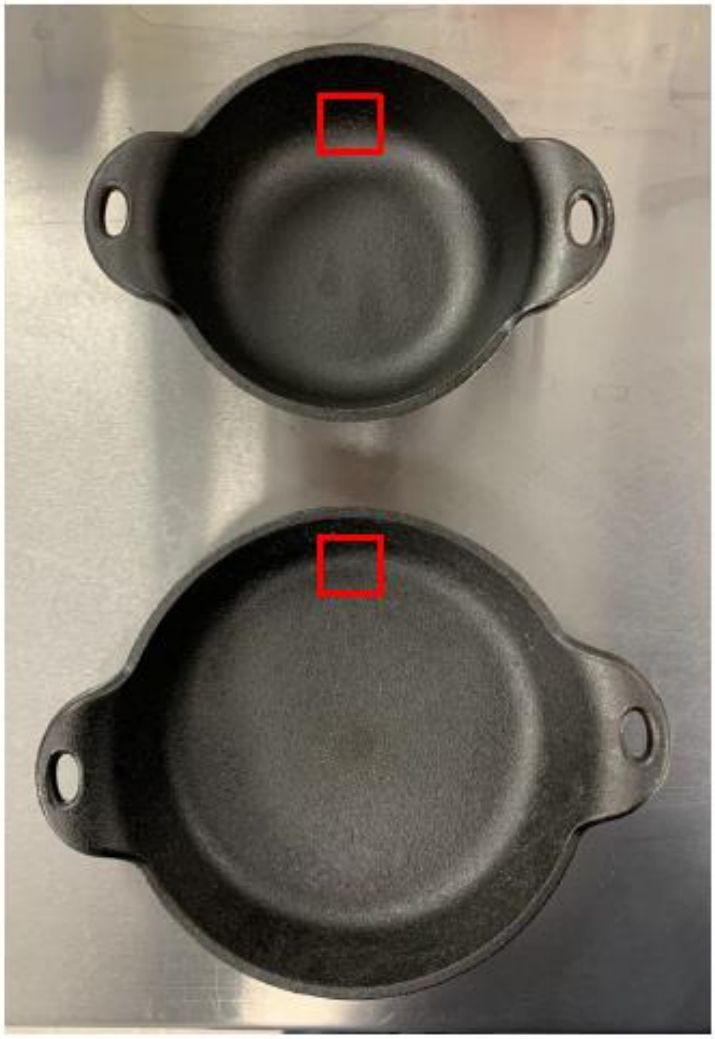

Figure 1. 12 Ounce Cast Iron Mini Serving Bowl and 14 Ounce Round Cast Iron Mini Server Sample Areas.

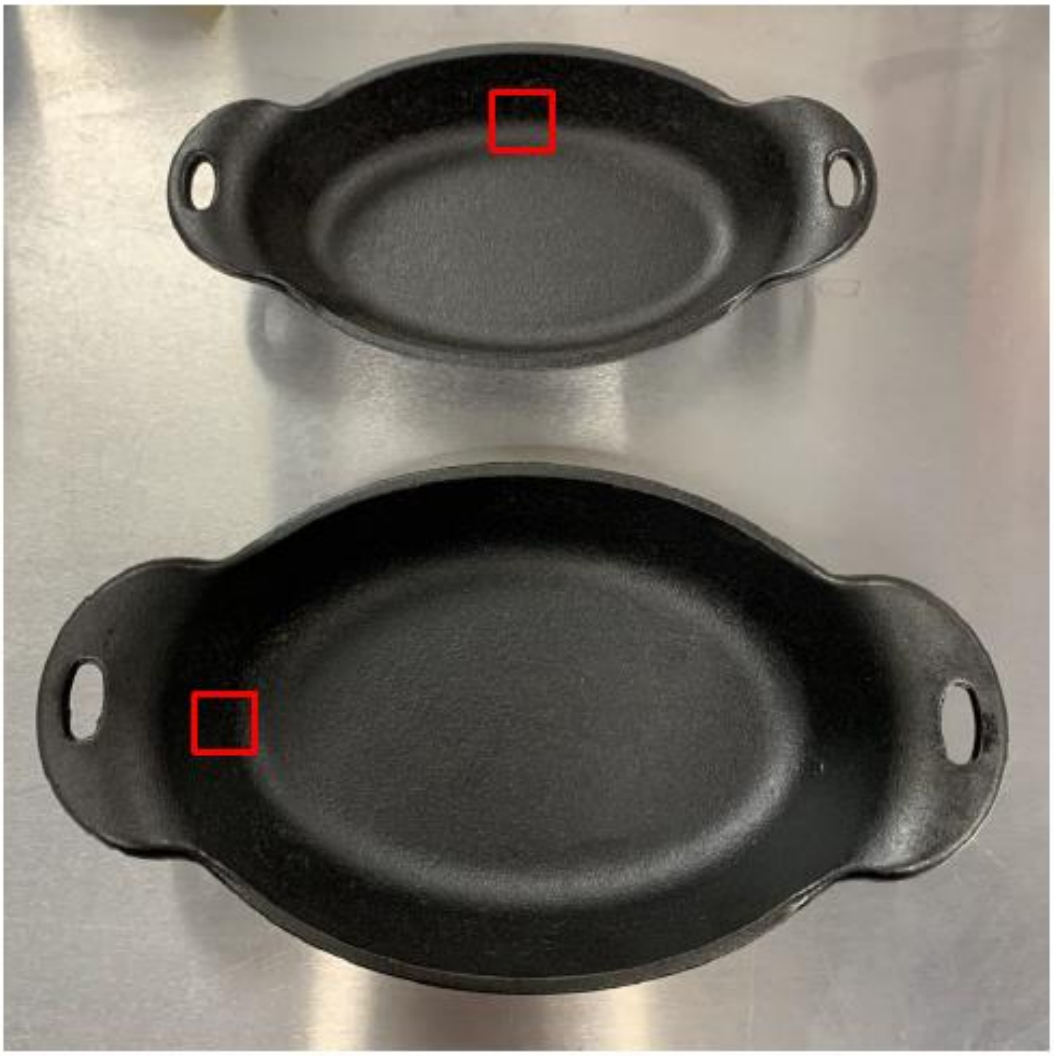

Figure 2. 9 Ounce Oval Cast Iron Mini Server and 16 Ounce Oval Cast Iron Mini Server Sample Areas.

Figure 3. 14 Ounce Rectangular Cast Iron Mini Server Sample Area.

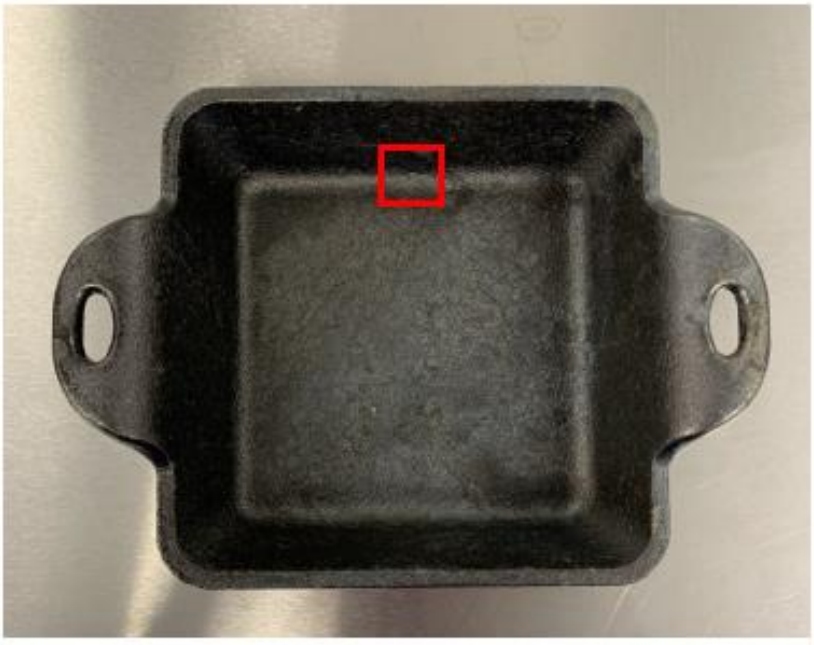

Figure 4. 10 Ounce Square Cast Iron Mini Server Sample Area.

15.0 Recovery and Enumeration Procedure:

15.1 Add 1.0 mL of PBS to a sterile swab. Thoroughly swab the 1" x 1" sample area in a both an up and down vertical motion and in a left and right horizontal motion. This process is designed to remove viable microorganisms from the surface of the test article for enumeration.

15.2 Place the swab in a test tube containing 9.0 mL of PBS. Express the swab into the test tube and thoroughly vortex. Prepare ten-fold serial dilutions of the sample by transferring 1.0 mL from the initial dilution into 9.0 mL of PBS.

15.3 For *S. aureus, E. coli, S.* Enteritidis and *L. monocytogenes*, plate each dilution into duplicate sterile Petri dishes and add 12 - 15 mL of tempered MCT to the Petri dishes. Mix thoroughly and allow the plates to solidify. Invert plates and incubate at 35 ± 1 °C for 48 ± 2 hours.

15.4 For *C. perfringens* spread plate each dilution on duplicate pre-poured plates of CBA. Spread inoculum with a sterile L-shaped spreader or sterile plating beads. Invert plates and incubate anaerobically at 35 ± 1 °C for 48 ± 2 hours.

15.5 After incubation, typical colonies will be enumerated and raw data recorded as CFU/plate. Duplicate plates will be averaged and multiplied by the dilution factor to arrive at CFU/test article. Raw values will be recorded and used for the calculations in section 18.0.

16.0 Study Controls:

16.1 Food Grade Stainless Steel Controls – Three (3) 4" x 4" food grade stainless steel test articles will be inoculated according to the procedures outlined in Section 14.0. The recovered microorganisms will be determined following the procedures in Section 15.0. In order for the testing to be considered acceptable, recovery data comparable to the cast iron test articles much be achieved.

17.0 Statistical Analysis:

17.1 A logarithmic transformation measuring surviving microbial populations of the positive control article and test replicates for each microorganism will be performed.

17.2 Equivalence of Recovery will be calculated as follows:

ΔLog10 = Equivalence Recovery
TR1 = Test Article Replicate 1
TR2 = Test Article Replicate 2
TR3 = Test Article Replicate 3
SS1 = Stainless Steel 1
SS2 = Stainless Steel 2
SS3 = Stainless Steel 3

$$\left(\frac{TR1 + TR2 + TR3}{3}\right) - \left(\frac{SS1 + SS2 + SS3}{3}\right) = \Delta\text{Log10}$$

18.0 Media Quality Controls:

18.1 The MCT plating media will be inoculated with an aliquot of each *S. aureus, E. coli, S.* Enteritidis, and *L. monocytogenes* suspension. The MCT plates will be incubated at 35 ± 1 °C for 48 ± 2 hours. These plates will serve as positive growth controls for the media.

18.2 The CBA and RCM media will be inoculated with an aliquot of the *C. perfringens* suspension. The CBA and RCM will be incubated anaerobically at 35 ± 1 °C for 48 ± 2 hours. These will serve as positive growth controls for the media.

18.3 The acceptance criterion for these bacterial media controls is "typical growth" of the organisms.

18.4 For negative sterility controls, two tubes each of TSB, PBS, and three plates of MCT will be incubated at 35 ± 2 °C for 48 ± 2 hours.

The acceptance criterion for these uninoculated media controls is "negative for growth".

19.0 Performance Criteria:

19.1 In order to demonstrate equivalent recovery the cast iron test articles must be within 0.5 Log of the stainless-steel carrier controls.

20.0 Acceptance Criteria:

20.1 The study controls below must perform according to the criteria detailed for the data to be considered acceptable.

20.1.1 Comparable growth acceptance will be within 50 - 200 % between the media. Sterility acceptance is no growth.

20.1.2 The acceptance criteria are growth from inoculated streaks and no growth from the sterility controls.

21.0 References:

21.1 U. S. Food and Drug Administration *Bacteriological Analytical Manual*, Chapter 3 *Aerobic Plate Count (*January 2001). (Accessed October 2019) http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm063346.htm

22.0 Final Report:

A final validation report will be prepared upon completion of the study, including a tabularized summary of data and a description of results of the study.

23.0 Documentation and Record-Keeping:

All documentation and records will be compiled, analyzed, and retained by Q Laboratories at its facility in Cincinnati, Ohio. All raw data for this study, as well as the final report, will be sent to the study sponsor and retained in safe storage by the testing facility for a period of at least seven (7) years (20 –ADMN-ISO-008D, Control of Records).

24.0 Quality Compliance:

Q Laboratories has developed and implemented a quality management system that enhances our ability to provide testing services that consistently meet client expectations and regulatory requirements. Q Laboratories quality documentation requirements are defined by ISO 17025, FDA Quality System Regulations (QSR), FDA Current Good Manufacturing Practices (cGMPs), FDA Good Laboratory Practices (GLP), and EPA Good Laboratory Practices standards (GLPs).
Q Laboratories applies the following standards as applicable:

- ISO 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories
- FDA 21 CFR Part 820 Quality System Regulation
- FDA 21 CFR Part 58 Good Laboratory Practice for Non Clinical Laboratory Studies
- FDA 21 CFR Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals
- FDA 21 CFR Part 210 Current Good Manufacturing Practice in Manufacturing Processing, Packing or Holding of Drugs; General
- EPA 40 CFR Part 160 FIFRA Good Laboratory Practice Standards

25.0 Protocol Modifications:

During the testing phase, changes to the protocol may be required. The study sponsor will be notified immediately of any modifications to the protocol. Approval of the modifications is required before any additional analysis is conducted. The modifications will be added to the protocol as an amendment and approved by both the study director and study sponsor.

26.0 Test Article Disposition:

All unused test material will be offered for return to the Study Sponsor at expense of Study Sponsor. If not desired by Study Sponsor, all unused test material to be disposed of within 90 days following the study completion.

27.0 Acceptance of Study Protocol:

Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel

Q Laboratories (Testing Facility)
1930 Radcliff Drive
Cincinnati, OH 45204

Laboratory Supervisor: _____ 10/31/19
Benjamin J. Bastin — Date
Microbiology R&D Laboratory Supervisor

Lodge Manufacturing (Study Sponsor)
204 East 5th Street
South Pittsburgh, TN 37380

David Fletcher — 10/31/19
Representative — Date

QA Supervisor
Title

Literature Demonstrating Microbial Growth in Cut Fruits/Vegetables

TYPE OF FOOD	PATHOGEN	TITLE	MICROBIAL GROWTH (≥ 1 log @RT)	REFERENCES
Cantaloupe flesh / Avocado pulp	*Listeria monocytogenes*	Growth kinetics of *Listeria monocytogenes* in cut produce.	Avocado pulp reached 1 log growth in 5.2-7.7 hrs. at 25°C and Cantaloupe reached 1 log growth in 7.3-10.7 hrs. at 25°C	(Salazar et al., 2017)
Avocado pulp and processed Guacamole	*Listeria monocytogenes*	Behavior of *Listeria monocytogenes* in Avocado Pulp and Processed Guacamole	1 log growth at approximately 8 hours at 22°C	(Iturriaga et al., 2002)
Cantaloupe flesh and Avocado pulp, green Olives, and Broccoli	*Listeria monocytogenes*	Growth kinetics of *Listeria monocytogenes* in cut produce.	At 25°C storage temp., growth rates of *L.* monocytogenes in Cantaloupe flesh and Avocado pulp were ≥ 0.1 log CFU/g/h	(Salazar et al., 2017)
Fresh-cut Celery	*Escherichia coli* O157:H7	Fate of *Escherichia coli* O157: H7, *Listeria monocytogenes*, and *Salmonella* on fresh-cut celery.	*E. coli* O157:H7 populations on fresh cut celery increased by 1.0 log CFU/g over the 2-day storage period at 22° C. The most growth occurred over the first 17 hours.	(Vandamm et al., 2013)
	Listeria monocytogenes		*L. monocytogenes* populations on fresh cut celery increased by 0.5 log CFU/g over the 2-day storage period at 22°C	
	Salmonella		*Salmonella* populations on fresh cut celery increased by 2.0 log CFU/g over the 2-day storage period at 22°C. The most growth occurred over the first 17 hours.	
Highbush blueberries	*Listeria monocytogenes*	Survival of *Listeria monocytogenes* on Fresh Blueberries (Vaccinium corymbosum) Stored under Controlled Atmosphere and Ozone.	Estimated initial inoculum per sample was approximately 10^7 CFU/mL. Blueberries inoculated with *L. monocytogenes* and stored in regular air conditions at 12°C for 10 days had bacterial recovery of 5.15 CFU/mL.	(Concha-Meyer et al., 2014)
Cut red round tomatoes	*Salmonella* (Includes four serotypes, Typhimurium, Newport, Javiana, and Braenderup)	Modeling the Growth of *Salmonella* in Cut Red Round Tomatoes as a Function of Temperature	Starting concentration on cut tomato was 10^2 CFU/g. Cut tomato was inoculated at 10, 12.5, 15, 17.5, 20, 22.5, 25, 27.5, 30, and 35°C for five to twelve hours. Concentration increased throughout incubation time to a final concentration of 10^7 to 10^8 CFU/g of tomato. Growth has little to no lag time which is in contrast to FDA research that indicates that *Salmonella* will	(Pan and Schaffner, 2010)

			have a growth lag time between 3 to 7 hours at 22.2˚C depending on tomato variety.	
Peaches	*Escherichia coli* O157:H7	Fate of *Escherichia coli* O157:H7, *Salmonella* and *Listeria innocua* on minimally processed peaches under different storage conditions	Initial population was 5.2 $\log_{10}$ cfu $plug^{-1}$. Population after 6 days at 20˚C was approximately 6.0 $\log_{10}$ cfu $plug^{-1}$. Peak growth was 8.0 $\log_{10}$ cfu $plug^{-1}$ after 2 days at 20˚C. Population after 6 days at 25˚C was 7.7 $\log_{10}$ cfu $plug^{-1}$. Peak growth was 8.0 $\log_{10}$ cfu $plug^{-1}$ after 24 hours at 25˚C.	(Alegre et al., 2010)
	Salmonella choleraesuis		Initial population was approximately 5.3 $\log_{10}$ cfu $plug^{-1}$ Population after 6 days at 20˚C was approximately 7.5 $\log_{10}$ cfu $plug^{-1}$. Peak growth was 7.7 $\log_{10}$ cfu $plug^{-1}$ after 3 days at 20˚C. Population after 6 days at 25˚C was approximately 7.7 $\log_{10}$ cfu $plug^{-1}$. Peak growth was 8.2 $\log_{10}$ cfu $plug^{-1}$ after 3 days at 25˚C.	
	Listeria innocua		Initial population was 5.3 $\log_{10}$ cfu $plug^{-1}$. Population after 6 days at 20˚C was approximately 7.5 $\log_{10}$ cfu $plug^{-1}$. Peak growth was 7.9 $\log_{10}$ cfu $plug^{-1}$ after 3 days at 20˚C. Peak growth was 8.1 $\log_{10}$ cfu $plug^{-1}$ after 6 days at 25˚C.	
Fresh cut mangoes and papayas	*Escherichia coli* O157:H7	Fate of *Escherichia coli* O157:H7 and *Salmonella* spp. on fresh and frozen cut mangoes and papayas	**Mangoes:** Initial population of 2.9 log CFU/g on day 0 at 23˚C. Peak growth was 4.7 log CFU/g on day 1 at 23˚C. Population after 7 days at 23˚C was 4.0 log CFU/g. Cut mango was visually determined to be spoiled on day 3 at 23˚C.	(Strawn and Danyluk, 2010)
			Papayas: Initial population was 2.6 log CFU/g on day 0 at 23˚C. Peak growth was 7.1 log CFU/g on day 3 at 23˚C. Population after 7 days at 23˚C was 6.3 log CFU/g. Initial population was 3.9 log CFU/g on day 0 at 12˚C. Peak growth was 6.9 log CFU/g on day 5 at	

			12˚C. Population after 7 days at 12˚C was 6.8 log CFU/g.	
	Salmonella spp.		**Mangoes:** Initial population was 2.9 CFU/g on day 0 at 23˚C. Peak growth was 6.2 CFU/g on day 3 at 23˚C. Population after 7 days at 23˚C was 2.4 CFU/g. Initial population was 4.5 CFU/g on day 0 at 12˚C. Peak growth was 5.9 CFU/g on day 1 at 12˚C. Population after 7 days at 12˚C was 4.5 CFU/g.	
			Papayas: Initial population was 2.6 CFU/g on day 0 at 23˚C. Peak growth was 7.4 CFU/g on day 3 at 23˚C. Population after 7 days at 23˚C was 6.6 CFU/g. Initial population was 4.1 CFU/g on day 0 at 12˚C. Peak growth was 7.7 CFU/g on day 5 at 12˚C. Population after 7 days at 12˚C was 7.6 CFU/g.	
Fresh cut Golden Delicious apple plugs	*Listeria monocytogenes*	Biocontrol of the Food-Borne Pathogens *Listeria monocytogenes* and *Salmonella enterica* Serovar Poona on Fresh-Cut Apples with Naturally Occurring Bacterial and Yeast Antagonists	Initial population was 2.8 log CFU/plug. Without antagonistic treatment, population increased to 5.3 log CFU/plug when stored at 10˚C for 5 days. Without antagonistic treatment, population increased to 6.0 log CFU/plug when stored at 25˚C for 7 days.	(Leverentz et al., 2006)
	Salmonella enterica		Initial population was 2.3 log CFU/plug. Without antagonistic treatment, population increased to 5.3 log CFU/plug when stored at 25˚C for 7 days.	
Sliced cucumbers	*Listeria monocytogenes*	Growth and Survival of *Listeria monocytogenes* and *Salmonella* on Whole and Sliced Cucumbers	**Non-selective Media:** Initial population was 4.3 log CFU/g on hour/day 0. Population after 24 hours at 23˚C was 6.0 log CFU/g (increase of 1.7 log CFU/g). Peak population growth was 6.5 log CFU/g at 23˚C on day 2. After day 2 populations declined. **Selective Media:** Initial population was 4.1 log CFU/g on hour/day 0. Population after 24 hours at 23˚C was 5.8 log CFU/g (increase of 1.7 log CFU/g). Peak population growth was 6.4 log CFU/g at 23˚C on day 2. After day 2 populations declined.	(Bardsley et al., 2019)
	Salmonella		**Non-selective Media:** Initial population was 2.8 log CFU/g on hour/day 0. Population after 8 hours at	

			23˚C was 5.9 log CFU/g (increase of 3.1 log CFU/g). Peak population growth was 6.3 log CFU/g at 23˚C at hour 17. After day 1 populations declined. **Selective Media:** Initial population was 2.7 log CFU/g on hour/day 0. Population after 8 hours at 23˚C was 5.7 log CFU/g (increase of 3.0 log CFU/g). Peak population growth was 6.1 log CFU/g at 23˚C at hour 17. After day 1 populations declined.	
Rocha fresh-cut pears	*Escherichia coli*	Growth of *Escherichia coli*, *Salmonella enterica* and *Listeria* spp., and their inactivation using ultraviolet energy and electrolyzed water, on 'Rocha' fresh-cut pears	At 12˚C maximum growth rate was 1.9±0.193 day^{-1} At 20˚C maximum growth rate was 2.98±0.258 day^{-1}	(Graça et al., 2017)
	Salmonella enterica		At 12˚C maximum growth rate was 2.2±0.23 day^{-1} At 20˚C maximum growth rate was 2.7±0.322 day^{-1}	
	Listeria spp.		At 12˚C maximum growth rate was 2.6± 0.636 day^{-1} At 20˚C maximum growth rate was 3.1±0.296 day^{-1}	
Various fresh cut produce items (summary of early literature findings)	*Shigella*	Outbreaks Fresh Produce Incidence, Growth, and Survival of Pathogens in Fresh and Fresh- Cut Produce	Populations of *S. sonnei, S. flexneri, and S. dysenteriae* inoculated on fresh cut cubes of papaya, jicama, and watermelon increased substantially within 4 to 6 hours at 22˚C - 27˚C. (Table G/S2, G/S4. GS1)	(Harris et al., 2003)
	Listeria monocytogenes		Chopped tomato stored at 21˚C with initial population of 5 log_{10} CFU/g. After 8 days, population was between 1.0 to 3.5 log_{10} CFU/g with survival slightly better in chlorine treated samples. Butternut squash cubes stored in a sealed bag at 10˚C had an initial concentration of 3.0 log_{10} CFU/g. After 9 days of storage at 10˚C population increased to approximately 8.5 log_{10} CFU/g. Shredded cabbage stored in plastic impermeable bags with ambient air had an initial concentration of 4.1 log_{10} CFU/g. For the first 24 hours, package was stored in refrigerator, afterwards stored at 25˚C. After 2 days at 25˚C, population increased to approximately 6.0 log_{10} CFU/g. Shredded cabbage stored in plastic impermeable bag with 70% CO_2 and 30% N_2 at 25˚C had an initial	

			concentration of 4.0 log_{10} CFU/g. After 2 days at 25˚C population increased to approximately 4.5 log_{10} CFU/g. Shredded carrots held at 15˚C had initial concentration of <1.0 log_{10} CFU/g. After 7 days of storage at 15˚C population increased to 3.4 - 5.8 log_{10} CFU/g. Sliced onion stored at 10˚C had initial concentration of 3.5 log_{10} CFU/g. After 9 days of storage at 10˚C population increased to approximately 4.8 log_{10} CFU/g. Rutabaga sticks stored at 10˚C had initial concentration of 3.0 log_{10} CFU/g. After 9 days of storage at 10˚C population increased to approximately 6.0 log_{10} CFU/g.	
	Salmonella		Cut tomato was stored at 22˚C with initial population of 1.1 log_{10} CFU/g. After 24 hours population increased to 6.3-6.9 log_{10} CFU/g.	
	Salmonella Typhi		Papaya cubes stored between 25-27˚C with initial population of 2.9 log_{10} CFU/cube (pH 5.69) and 3.0 log_{10} CFU/cube (pH 3.59). After 6 hours of incubation, population increased to 4.3 log_{10} CFU/cube (pH 5.69) and 3.8 log_{10} CFU/cube (pH 3.59). Jicama cubes stored between 25-27˚C with initial population of 3.1 log_{10} CFU/cube (pH 3.30) and 3.2 log_{10} CFU/cube (pH 5.97). After 6 hours of incubation, population increased to 3.4 log_{10} CFU/cube (pH 3.30) and 4.7 log_{10} CFU/cube (pH 5.97).	
	Salmonella Baildon		Diced tomatoes stored at 21˚C with initial population of 3.4 log_{10} CFU/g. After 72 hours, population was 8.1 log_{10} CFU/g.	

	Salmonella Montevideo		Slices of tomato stored at 25˚C with initial counts of 3.4 $\log_{10}$ CFU/slice and 4.4 $\log_{10}$ CFU/slice. After 12 hours, population was approximately 7.5 and 8.0 $\log_{10}$ CFU/slice respectively.	
	Clostridium botulinum		Butternut squash cubes inoculated with 2.0 $\log_{10}$ spores/g of 10 strains of proteolytic *C. botulinum* stored at 15˚C and 25˚C for 14 days and 3 days respectively. Toxin was detected at for both temperatures after storage for 14 days and 3 days respectively.	
	Escherichia coli O157:H7		Shredded carrot stored in 3% O_2 97% N_2 polyolefin L-bags with initial concentration of 2.5 $\log_{10}$ CFU/g at 21˚C. After 7 days population increased to 4.2 $\log_{10}$ CFU/g. Shredded carrot stored in air in polyolefin L-bags with initial concentration of 5.3 $\log_{10}$ CFU/g at 12˚C and 21˚C. After 14 days at 12˚C population increased to 6.3 $\log_{10}$ CFU/g. After 7 days at 21˚C population increased to 6.0 $\log_{10}$ CFU/g. Shredded carrot stored in polyolefin L-bags with initial concentration of 2.5 $\log_{10}$ CFU/g at 21˚C. After 7 days population increased to 3.8 $\log_{10}$ CFU/g. Sliced cucumber stored in 3% O_2 97% N_2 in polyolefin L-bags with initial concentration of 2.3 $\log_{10}$ CFU/g at 21˚C. After 7 days at 21˚C population increased to 2.6 $\log_{10}$ CFU/g. Sliced cucumber stored in air in polyolefin L-bags with initial concentration of 5.1 $\log_{10}$ CFU/g at 12˚C. After 10 days at 12˚C population increased to 5.7 $\log_{10}$ CFU/g. Sliced cucumber stored in air in polyolefin L-bags with initial concentration of 2.3 $\log_{10}$ CFU/g at 21˚C.	

			After 7 days at 21°C population increased to 3.1 log_{10} CFU/g.	
Cut turnips	*Listeria monocytogenes*	Growth of *Listeria monocytogenes* Inoculated on Packaged Fresh-Cut Turnips Stored at 4 and 10°C	Initial population was 3.40 log CFU/g (LOT 1) and 3.51 log CFU/g (LOT 2) on day 0 at 10°C. Peak growth was 4.7 log CFU/g (LOT 1) and 5.10 log CFU/g (LOT 2) on day 10 at 10°C.	(Brierley et al., 2020)
Cut red cabbage	*Listeria monocytogenes*	Growth Kinetics of *Listeria monocytogenes* on Cut Red Cabbage	Initial population on cut red cabbage was 3.67 log CFU/g. After 3 days of storage at 10°C, population increased to 4.25 log CFU/g. Maximum growth rate was 0.27 log CFU/g/day. After 3 days of storage at 25°C, population increased to 4.74 log CFU/g. Maximum growth rate was 1.15 log CFU/g/day.	(Salazar et al., 2022)
Sliced zucchini squash	*Salmonella* Typhimurium, Gaminara, Typhi, Montevideo	Incidence and Behavior of *Salmonella* and *Escherichia coli* on Whole and Sliced Zucchini Squash (Cucurbita pepo) Fruit	Initial populations were approximately 2.5 log CFU/slice. After two days at 25°C, populations increased to approximately 6.0 log CFU/slice.	(Castro-Rosas et al., 2010)
	Escherichia coli		Initial population was approximately 2.5 log CFU per slice. After two days at 25°C, population increased to approximately 7.0 log CFU/slice.	
Tomato and cucumber salad without lemon juice or salt (Arabic salad)	*Listeria monocytogenes*	Survival and growth of *Listeria monocytogenes* and *Staphylococcus aureus* in ready-to-eat Mediterranean vegetable salads: Impact of storage temperature and food matrix	Initial population was approximately 5.5 log CFU/g. After 1 day stored at 24°C, population increased to 7.2 log CFU/g. After 5 days stored at 10°C, population increased to 7.5 log CFU/g.	(Olaimat et al., 2021)
	Staphylococcus aureus		Initial population was approximately 5.7 log CFU/g. After 2 days stored at 24°C, population increased to 7.5 log CFU/g. After 5 days stored at 10°C, population increased to 6.7 log CFU/g.	

Fresh-cut canary melon and papaya	*Listeria monocytogenes*	Effect of citral nanoemulsion on the inactivation of *Listeria monocytogenes* and sensory properties of fresh-cut melon and papaya during storage	Initial population was 5.0 log CFU/g. After 7 days stored at 12˚C, population on cut melon increased to approximately 7.5 log CFU/g. After 7 days stored at 16˚C, population on cut melon increased to approximately 8.7 log CFU/g. After 7 days stored at 12˚C, population on cut papaya increased to approximately 7.3 log CFU/g. After 7 days stored at 16˚C, population on cut papaya increased to approximately 7.8 log CFU/g.	(Luciano et al., 2023)
Cut grapes, tomato, white cabbage, red cabbage	*Listeria monocytogenes*	Evaluating the growth potential of *Listeria monocytogenes* in Ready to Eat Vegetables	All cut produce was inoculated and stored at 5˚C for two days then 10˚C until a few days after shelf-life. Initial population on grapes was 4.2 log CFU/g. Two days after shelf life (9 days total), population on cut grapes increased to 4.9 log CFU/g. Initial population on tomatoes was 4.0 log CFU/g. Two days after shelf life (8 days total), population on cut tomatoes increased to 4.1 log CFU/g. Initial population on white cabbage was 4.1 log CFU/g. Two days after shelf life (9 days total), population on cut white cabbage increased to 4.2 log CFU/g. Initial population on red cabbage was 3.6 log CFU/g. Two days after shelf life (9 days total), population on cut red cabbage increased to 4.0 log CFU/g.	(Shoja Gharehbagh et al., 2023)

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Chapter 1. Purpose and Definitions

- Page 20 *(page 49 in PDF)* –
  - "Time/temperature control for safety food" included:
    a. An animal FOOD that is raw or heat-treated; a plant FOOD that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation

Annex 2. References

- Page 281 *(page 313 in PDF)* –
  - N. Retail Food Protection Program Information Manual: Storage and Handling of Tomatoes, 2007.

    This document can be found at the web site: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm

    The Retail Food Protection Program Information Manual, Storage and Handling of Tomatoes provides safe storage and handling practices for cut tomatoes and additional rationale for including cut tomatoes in the definition of time/temperature control for safety food in the 2005 Food Code. Historically, uncooked fruits and vegetables have been considered non-TCS food unless they were epidemiologically implicated in foodborne illness outbreaks and are capable of supporting the growth of pathogenic bacteria in the absence of temperature control. Since 1990, at least 12 multi-state foodborne illness outbreaks have been associated with different varieties of tomatoes. From 1998 – 2006, outbreaks associated with tomatoes made up 17% of the produce-related outbreaks reported to FDA. Salmonella has been the pathogen of concern most often associated with tomato outbreaks. Recommendations are being offered to prevent contamination in food service facilities and retail food stores and to reduce the growth of pathogenic bacteria when contamination of fresh tomatoes may have already occurred (regardless of the location where the contamination occurred).

- Page 281-282 *(page 313-314 in PDF)* –
  - O. Retail Food Protection Program Information Manual: Recommendations to Food Establishments for Serving or Selling Cut Leafy Greens.

    This document can be found at: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm.

    Following 24 multi-state outbreaks between 1998 and 2008, cut leafy greens was added to the definition of time/temperature for safety food requiring time-temperature control for safety (TCS). The term used in the definition includes a variety of cut lettuces and leafy greens. Raw agricultural commodities (RACs) that are not processed or cut on-site are excluded from the definition of cut leafy greens. Herbs such as cilantro or parsley are also not considered cut leafy greens. The pH, water activity, available

moisture and nutrients of cut leafy greens supports the growth of foodborne pathogens and refrigeration at 41ºF (5ºC) or less inhibits growth and promotes general die off in some pathogens such as E. coli O157:H7. Salmonella, E. coli O157:H7 and Listeria monocytogenes, once attached to the surface or internalized into cut surfaces of leafy greens, are only marginally affected by chemical sanitizers. Recommended handling instructions for leafy greens during purchasing and receiving, storage, food employee handling fresh produce, washing fresh produce, preparation for sale or service and display for sale or service are attached to the document.

Annex 3. Public Health Reasons/Administrative Guidelines

- Page 295-297 *(page 327-329 in PDF)* –
    - **Time/Temperature Control for Safety Food**

      Time Temperature Control for Safety Food (TCS) is defined in terms of whether or not it requires time/temperature control for safety to limit pathogen growth or toxin formation. The term does not include foods that do not support growth but may contain a pathogenic microorganism or chemical or physical food safety hazard at a level sufficient to cause foodborne illness or injury. The progressive growth of all foodborne pathogens is considered whether slow or rapid.

      The definition of TCS food takes into consideration pH, aw, pH and aw interaction, heat treatment, and packaging for a relatively simple determination of whether the food requires time/temperature control for safety. If the food is heat-treated to eliminate vegetative cells, it needs to be addressed differently than a raw product with no, or inadequate, heat treatment. In addition, if the food is packaged after heat treatment to destroy vegetative cells and subsequently packaged to prevent re-contamination, higher ranges of pH and/or aw can be tolerated because remaining spore-forming bacteria are the only microbial hazards of concern. While foods will need to be cooled slightly to prevent condensation inside the package, they must be protected from contamination in an area with limited access and packaged before temperatures drop below 57°C (135°F). In some foods, it is possible that neither the pH value nor the aw value is low enough by itself to control or eliminate pathogen growth; however, the interaction of pH and aw may be able to accomplish it. This is an example of a hurdle technology. Hurdle technology involves several inhibitory factors being used together to control or eliminate pathogen growth, when they would otherwise be ineffective if used alone. When no other inhibitory factors are present and the pH and/or aw values are unable to control or eliminate bacterial pathogens which may be present, growth may occur and foodborne outbreaks result. Cut melons, cut tomatoes, and cut leafy greens are examples where intrinsic factors are unable to control bacterial growth once pathogens are exposed to the cellular fluids and nutrients after cutting.

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      The Food Code definition designates certain raw plant foods as TCS food because they have been shown to support the growth of foodborne pathogens in the absence of temperature control and to lack intrinsic factors that would inhibit pathogen growth. Unless product assessment shows otherwise, these designations are supported by Tables A and B. For example:

For cut cantaloupe (pH 6.2-7.1, aw > 0.99, not heat-treated),. fresh sprouts (pH > 6.5, aw > 0.99, not heat-treated), and cut tomatoes (pH 4.23 – 5.04, aw > 0.99, not heat-treated), Table B indicates that they are considered TCS Foods unless a product assessment shows otherwise. Maintaining these products under the temperature control requirements prescribed in this code for TCS food will limit the growth of pathogens that may be present in or on the food and may help prevent foodborne illness.

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More information can be found in the Institute of Food Technologists (IFT) Report, "Evaluation and Definition of Potentially Hazardous Foods" at http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm094141.htm

- Page 389 *(page 421 in PDF)* –
  - 3-302.15 Washing Fruits and Vegetables

    After being cut, certain produce such as melons, leafy greens and tomatoes are considered time/temperature control for safety food (TCS) requiring time/temperature control for safety and should be refrigerated at 41°F or lower to prevent any pathogens that may be present from multiplying. For more retail food guidance on the storage and handling of tomatoes, leafy greens, and other produce, you may consult the FDA Program Information Manual, Retail Food Protection Storage and Handling of Tomatoes, dated October 5, 2007, available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm, the document, Time as a Public Health Control for Cut Tomatoes, dated June 8, 2010 available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm215053.htm and the FDA Program Information Manual, Recommendations for the Temperature Control of Cut Leafy Greens during Storage and Display in Retail Food Establishments dated July 7, 2010 available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm218750.htm

- Page 427 (*page 459 in PDF)* –
  - At the 2018 meeting of the CFP it was recommended that Section 3-501.19 be amended to allow raw agricultural commodities (RACs) that are cut on-site (such as tomatoes, melons, or leafy greens) or shelf-stable hermetically sealed containers (such as canned tuna) opened on-site have an initial temperature of 21°C (70°F) or less when time without temperature control is used as a public health control for a maximum of 4 hours. Peer-reviewed scientific literature and the above-mentioned pathogen modeling has shown Salmonella spp. and L. monocytogenes will not exceed a 1-log increase in growth when started and maintained at 21°C (70°F) or less for up to 4 hours.

STATE OF COLORADO

Warwick - CDPHE, Robert <robert.warwick@state.co.us>

Fwd: Issue Edited | Conference for Food Protection

1 message

Warwick - CDPHE, Robert <robert.warwick@state.co.us> Wed, Feb 22, 2023 at 8:46 AM
To: Robert Warwick - CDPHE <robert.warwick@state.co.us>

From: **Patrick Guzzle** <pguzzle@restaurant.org>
Date: Tue, Feb 21, 2023 at 2:43 PM
Subject: RE: Issue Edited | Conference for Food Protection
To: Huffman - CDPHE, Troy <troy.huffman@state.co.us>
Cc: Kate Piche <KPiche@restaurant.org>

Let me know if this doesn't work and I'll edit as appropriate. I've copied Kate Piche from my team as a heads up.

The National Restaurant Association Food Safety/Compliance team supports this Issue. With continually decreasing time and resources in the face of increasing demands, the recommended solution reduces the regulatory burden without jeopardizing public health and food safety. As indicated in the Issue, several States are now relying on the more recent technology of culture independent diagnostic tests to help determine an appropriate time frame to allow a restricted or excluded food employee to return to work. We add our voice to those asking FDA to consider this change to the Food Code.

Patrick L. Guzzle | Vice President, Food Science

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Research Paper

Influence of Soap Characteristics and Food Service Facility Type on the Degree of Bacterial Contamination of Open, Refillable Bulk Soaps

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ABSTRACT

Concern has been raised regarding the public health risks from refillable bulk-soap dispensers because they provide an environment for potentially pathogenic bacteria to grow. This study surveyed the microbial quality of open refillable bulk soap in four different food establishment types in three states. Two hundred ninety-six samples of bulk soap were collected from food service establishments in Arizona, New Jersey, and Ohio. Samples were tested for total heterotrophic viable bacteria, *Pseudomonas,* coliforms and *Escherichia coli,* and *Salmonella*. Bacteria were screened for antibiotic resistance. The pH, solids content, and water activity of all soap samples were measured. Samples were assayed for the presence of the common antibacterial agents triclosan and parachlorometaxylenol. More than 85% of the soap samples tested contained no detectable microorganisms, but when a sample contained any detectable microorganisms, it was most likely contaminated at a very high level (~7 log CFU/mL). Microorganisms detected in contaminated soap included *Klebsiella oxytoca, Serratia liquefaciens, Shigella sonnei, Enterobacter gergoviae, Serratia odorifera,* and *Enterobacter cloacae*. Twenty-three samples contained antibiotic-resistant organisms, some of which were resistant to two or more antibiotics. Every sample containing less than 4% solids had some detectable level of bacteria, whereas no samples with greater than 14% solids had detectable bacteria. This finding suggests the use of dilution and/or low-cost formulations as a cause of bacterial growth. There was a statistically significant difference ($P = 0.0035$) between the fraction of bacteria-positive samples with no detected antimicrobial agent (17%) and those containing an antimicrobial agent (7%). Fast food operations and grocery stores were more likely to have detectable bacteria in bulk-soap samples compared with convenience stores ($P < 0.05$). Our findings underscore the risk to public health from use of refillable bulk-soap dispensers in food service establishments.

Key words: Bulk soap; Coliforms; Contamination; Hand washing

Washing hands with soap and water is a universally accepted practice to reduce cross-contamination and the incidence of nosocomial infections *(9, 12–14, 16, 18, 20, 26, 29, 33)*. The U.S. Food and Drug Administration (FDA), the U.S. Centers for Disease Control and Prevention (CDC), and the World Health Organization (WHO) suggest proper hand hygiene with soap and water and/or an alcohol-based hand sanitizer in health care and food preparation settings *(3, 35, 39)*. The CDC and WHO recommend alcohol-based hand sanitizer as the primary means for hand hygiene at key moments in health care settings *(3, 31, 39),* whereas food handling guidance from FDA *(35)* supports gloving or hand washing for primary prevention. The respective hand hygiene guidance documents from these three public health agencies all have language that indicates that a hand wash is not complete without the use of soap *(3, 35, 39)*. However, concern has been raised that the use of refillable bulk-soap dispensers is a public health risk because they provide an environment for potentially pathogenic bacteria to grow, especially if the bulk soap is diluted with water to reduce cost *(8, 21, 25, 30, 40)*.

Outbreaks associated with contaminated soap have been extensively documented in health care settings *(1, 2, 5, 24, 27, 30, 38),* but none to date have been connected to food service settings. Organisms found in bulk soaps are primarily gram-negative bacteria *(8),* and these bacteria include microorganisms that are commonly associated with nosocomial infection in hospitals *(3, 19)*. *Klebsiella pneumonia,* a bacterium associated with contaminated bulk soaps, can cause community-acquired pneumonia; proper hand hygiene is a good way of preventing cross-contamination by these bacteria because health care workers' hands can be vectors for these organisms *(7)*. Outbreaks of *Serratia marcescens* have also been traced to contaminated soap *(2, 5, 27, 30, 37)*. Although no outbreaks in food service have been directly linked to contaminated bulk-soap dispensers, roughly 50% of food service–linked outbreaks can be traced to food workers' hands as the source of pathogens *(16)*. Whereas soaps and other cosmetics are not required to be

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sterile, good manufacturing practices for soaps and cosmetics require that any bacteria present should not constitute a hazard to consumers during regular use *(32)*.

Several factors contribute to bulk-soap contamination, including design of dispenser, soap formulation, and economically motivated dilution of soap *(5, 25)*. To refill sealed dispensers, new cartridges, which contain soap sealed inside with a new nozzle, are placed into the dispenser; in contrast, open refillable bulk-soap dispensers reuse a permanent nozzle and are refilled with soap from a larger bottle. A top-fill reservoir design allows for "topping-off" the soap. Although this potentially reduces soap waste, it also allows mixing of multiple soap lots and types and exposes the soap to an open-air environment, which increases the risk of contamination *(3, 25, 40)*. Furthermore, top-fill design dispensers may never thoroughly be rinsed out, as commonly recommended by dispenser manufacturers. The CDC recommends that bulk liquid soap dispensers be thoroughly cleaned every time before fresh soap is added *(3, 8, 14)*. However, as pointed out by Lorenz et al. *(21)*, no data exist to show that cleanings in between soap refills actually prevent contamination of soap. Regardless, bulk soap can quickly become contaminated due to biofilm formation inside the dispenser (up to 9 log CFU/mL) and can support growth in as little as 24 h *(25)*. Once pump mechanisms are colonized with bacteria, cells from the biofilm continue to contaminate soap, even if completely new bacteria-free soap is used to fill the container *(15)*. Soap formulations will often include preservatives to prevent growth, but because these preservatives are concentration dependent, dilution (as a cost savings measure) can render them ineffective. There has been no evidence of contamination in soap samples collected from dispensers in sealed disposable refills to date.

Potentially harmful bacteria will remain on hands after using contaminated soap *(8, 30, 40)*. Although the bacteria may not be a health concern for the hand washer, these bacteria can transfer from hands to food, objects, and surfaces *(6, 9, 12, 13, 16, 17, 22, 29)*. Hands are one of the main sources of cross-contamination in both health care and food service *(12, 20)*.

The purpose of this study was to survey the microbial quality of open refillable bulk soap sampled in four different food establishment types, within three different states, and to determine the influence of formulation factors on the degree of contamination.

MATERIALS AND METHODS

Sample collection. Samples were acquired from food service establishments around New Brunswick, NJ; Tucson, AZ; and Akron, OH. The categories of merchants from which soap samples were collected were convenience stores, grocery stores, "sit-down" restaurants, and fast food (quick-service) restaurants. Categories were sampled based on the prevalence of the types of establishment in each area and on the likelihood of finding bulk soap in the establishment. Soap was collected from the bathrooms of these establishments. Men's and women's restrooms were sampled in approximately equal frequency. Although soap color was noted, no attempt was made to sample specific colors.

Samples were shipped to the University of Arizona for microbiological analysis, and to GOJO Industries, Inc. (Akron, OH) for physical and chemical analysis. One hundred samples each were collected from Arizona and New Jersey, and 96 samples were collected from Ohio.

Soap samples were collected in a 50-mL sterile conical tube (Corning, Union City, CA), with a minimum volume goal of 45 mL. Two tubes of soap were collected from most establishments, except in a few instances in which a facility only had enough soap for one tube. Soap was collected in the tube by catching the soap released when the dispenser lever was pressed. We used this method to ensure that the soap collected was representative of what would be dispensed onto a customer's hands. Foaming soap was not sampled because bulk refillable foam soap dispensers are uncommon, and challenges in collecting an adequate mass of foaming soap made sampling impractical. Samples were sealed using parafilm (Bemis NA, Neenah, WI) and were placed in an ice pack–chilled cooler after collection.

Microbiological analysis. Total heterotrophic viable bacteria were assayed on Reasoner's 2A agar (R2A; EMD Chemicals, Inc., Gibbstown, NJ), using serial dilutions of 10^{-1} through 10^{-3} of the soap samples, with colonies counted after 5 days of incubation at 22 ± 2°C. R2A agar was originally developed as a rapid method for fecal coliforms in water *(28)*; however, since its development, it has been used in a wide variety of applications, including screening of bulk soap for contaminants *(8)* because it may be especially suitable for culturing slower growing organisms from stressed environments *(36)*. Colonies of the three most predominant morphologies were streaked onto plates of Trypticase soy agar (TSA; EMD Chemicals, Inc.) for isolation and identification. R2A plates were also examined for the presence of *Pseudomonas,* which was then isolated and confirmed.

Coliforms and *E. coli* were quantified using the IDEXX Quanti-Tray/2000 system (IDEXX Laboratories, Westbrook, MA). A 10-mL aliquot of the sample was added to 90 mL of sterile water containing the Quanti-Tray reagent, poured into the Quanti-Tray, and then sealed and incubated at 35°C for 24 h. Coliforms were identified by yellow pigmentation and *E. coli* by fluorescence under UV light. The number of positive yellow and fluorescing wells were quantified, and the IDEXX most-probable-number (MPN) generator program was used for quantification.

Randomly selected coliform-positive wells from the IDEXX Colilert Quanti-Tray/2000 (IDEXX Laboratories) were spread plated on MacConkey agar (EMD Chemicals, Inc.) to select for lactose fermenters. These isolates were then spread plated to TSA (EMD Chemicals, Inc.) and subjected to an oxidase test (BD, Sparks, MD) and API 20E identification biochemical test strips (bioMérieux, Durham, NC) for confirmation as coliforms. Twenty-eight isolates were identified as coliforms and tested for antibiotic resistance by placing antibiotic disks for vancomycin, ampicillin, gentamicin, and ciprofloxacin (Sigma Chemical, St. Louis, MO) onto bacterial lawns of the individual bacteria.

Salmonella preenrichment started by placing a 5-mL aliquot of the soap sample into a tube that contained 10 mL of tryptic soy broth (TSB; EMD), followed by incubation at 35°C for 24 h. After 24 h, 1 mL of the TSB was transferred to a tube that contained 10 mL of Rappaport-Vassiliadis broth (Hardy Diagnostics, Santa Maria, CA), followed by incubation at 41.5°C for 24 h. One milliliter of TSB was also added to a tube that contained 10 mL of selenite cystine broth (EMD Chemicals, Inc.) and was incubated at 35.0°C for 24 h. Each tube showing turbidity was streaked onto plates of Hektoen (EMD Chemicals, Inc.) and xylose lysine desoxycholate (XLD; EMD Chemicals, Inc.) agars and incubated

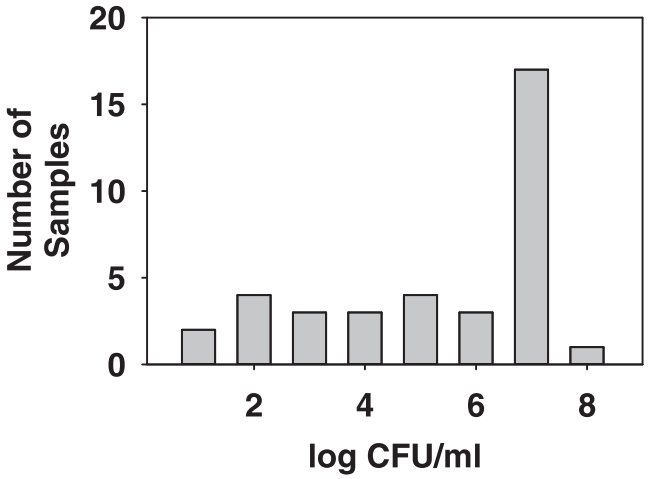

FIGURE 1. *The distribution of microbial counts in contaminated soap samples.*

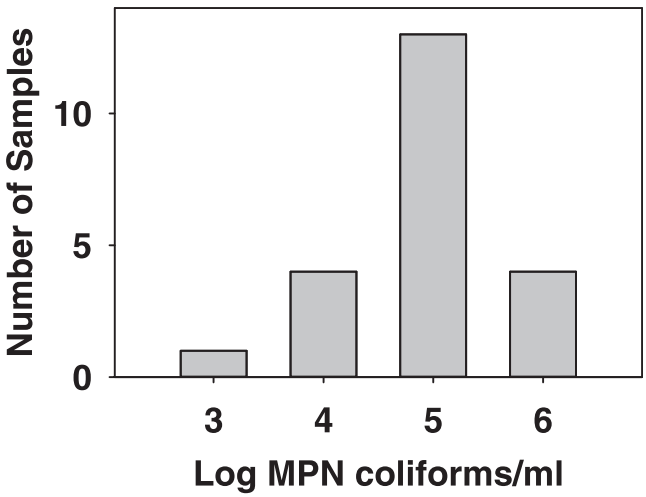

FIGURE 2. *The distribution of coliform counts in contaminated soap samples.*

at 35°C for 24 h. Presumptive *Salmonella* isolates were transferred to TSA for biochemical identification using the API 20E (bioMérieux). If the isolate was presumptively identified as *Salmonella,* the isolated colonies were sent to the National Veterinary Services Laboratories (Ames, IA) for serotyping.

pH and water activity. The pH of all samples was evaluated using a Thermo Orion 720A+ pH with the Thermo Scientific Orion ROSS Sure-Flow pH electrode (Thermo Fisher Scientific, Pittsburgh, PA). Five grams of each test sample was evaluated using the Ohaus standard moisture analyzer (model MB45, Ohaus, Pine Brook, NJ).

A water activity meter (Rotronic Instrument Corp., Hauppauge, NY) was used to measure the water activity of soap samples. Distilled water and glycerol solutions were used as standards. Each sample cup was filled with about 10 mL of soap sample, and after 4 to 5 min the temperature and water activity were recorded. The sample cup was rinsed using distilled water and was dried completely using a Kimwipe (Kimberly-Clark, New York, NY) after each test.

Antimicrobial analysis. All samples were evaluated for the presence and quantity of triclosan using the Waters (Milford, MA) e2695 Alliance high-performance liquid chromatography system with a UV/Visible Detector (Waters 2489) and a Waters μBondapak C18 column (125Å, 10 μm, 3.9 by 150 mm; Waters no. WAT086684). All samples that tested negative for the presence of triclosan were evaluated for the presence and quantity of parachlorometaxylenol, using the same system, detector, and column as used for triclosan.

RESULTS

Most of the soap samples tested (>85%) contained no detectable microorganisms (10 CFU/mL detection limit). The distribution of microbial counts found in contaminated soap samples is shown in Figure 1. Samples containing detectable microorganisms were most often contaminated at a very high level (~7 log CFU/mL), with counts on the remaining samples ranging uniformly from 1 to 6 log CFU/mL. Although not all bacteria recovered were identified, microorganisms detected in contaminated soap included *Klebsiella oxytoca, Serratia liquefaciens, Shigella sonnei, Enterobacter gergoviae, Serratia odorifera,* and *Enterobacter cloacae*. Four of the soap samples were positive for *Salmonella* by API 20E, but were not confirmed as *Salmonella* by the National Veterinary Services Laboratories. Twenty-three samples contained vancomycin-resistant organisms. Seven of these were also resistant to ampicillin, and two of those, in turn, were resistant to gentamicin. One sample contained an organism resistant to vancomycin, ampicillin, gentamicin, and ciprofloxacin (antibiotic resistance data not shown).

When a sample contained detectable coliforms, similarly, the population was likely to be high, as shown in Figure 2. The distribution of coliforms is likely higher than what is shown in Figure 2, because the two highest populations were at the upper limit of quantification (i.e., >241,960 MPN/mL or >24,196 MPN/mL).

Figure 3 shows that higher coliform counts tended to be associated with samples that contained higher bacterial counts overall. Coliform counts at the upper limits of the MPN method are especially associated with high total bacterial counts.

Figure 4 shows the relationship between sample pH and the population of detectable microorganisms. Of samples with a pH less than 7.0, 18% had detectable contamination, whereas only 10% of samples with a pH of 7 and above had detectable contamination. Note, however, that contaminated soap samples with a pH ≥7.0 are more likely to result in contamination at a relatively higher level (i.e., >1,000 CFU/mL), perhaps because pH influences bacterial growth or survival.

Figure 5 shows the relationship between the measured percent solids (top panel) or water activity (bottom panel) of a sample and the bacterial count. Note that every sample containing less than 4% solids had some detectable level of bacteria, whereas only two samples with greater than 14% solids had detectable bacteria. A similar pattern is shown with water activity (Fig. 5, bottom panel), and samples with water activities between 0.99 and 1.0 were associated with a range of bacterial populations, including the highest populations observed. As the measured water activity

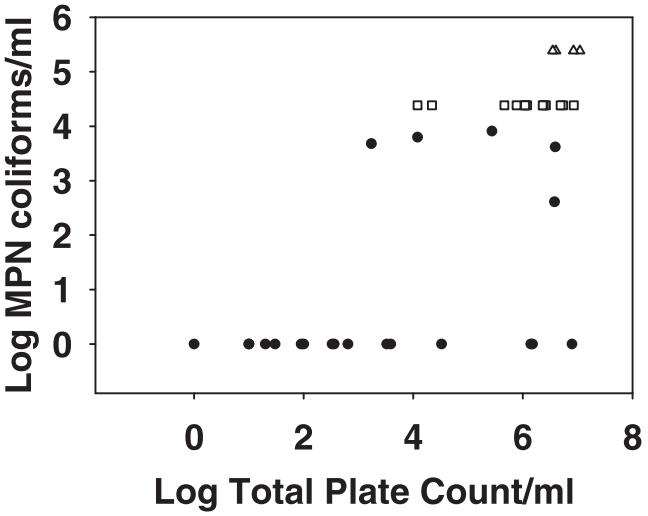

FIGURE 3. *Relationship between coliform counts and total plate counts in contaminated soap samples. Coliform counts above 4.4 log MPN or above 5.4 log MPN are shown using open squares and open triangles, respectively. Counts below the detection limit (10 CFU/mL) are plotted as 0 log CFU or MPN.*

decreased, the occurrence of higher bacterial populations declined, although there was a low population of bacteria in the soap with the lowest water activity measured. There was no clear relationship between the solids content and the water activity (data not shown).

Figure 6 expands upon the analysis of the relationships between percent solids (top panel) or water activity (bottom panel) and bacterial count. As percent solids increases, the fraction of samples with a bacterial count above the detection limit (10 CFU/mL) decreases (Fig. 6, top panel). Note that the two leftmost bars in the figure are associated with very few observations (three and six observations, respectively), whereas all other points are always associated with 30 or more observations. The bottom panel of Figure 6 shows the number of samples associated with different water

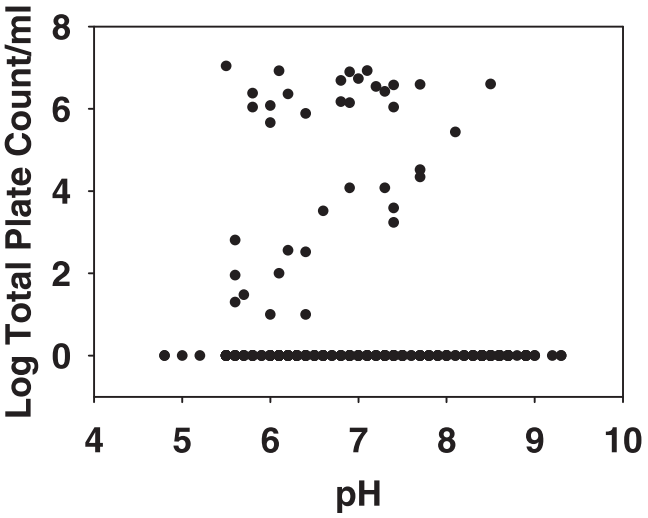

FIGURE 4. *Relationship between sample pH and the population of detectable microorganisms. Counts below the detection limit (10 CFU/mL) are plotted as 0 log CFU.*

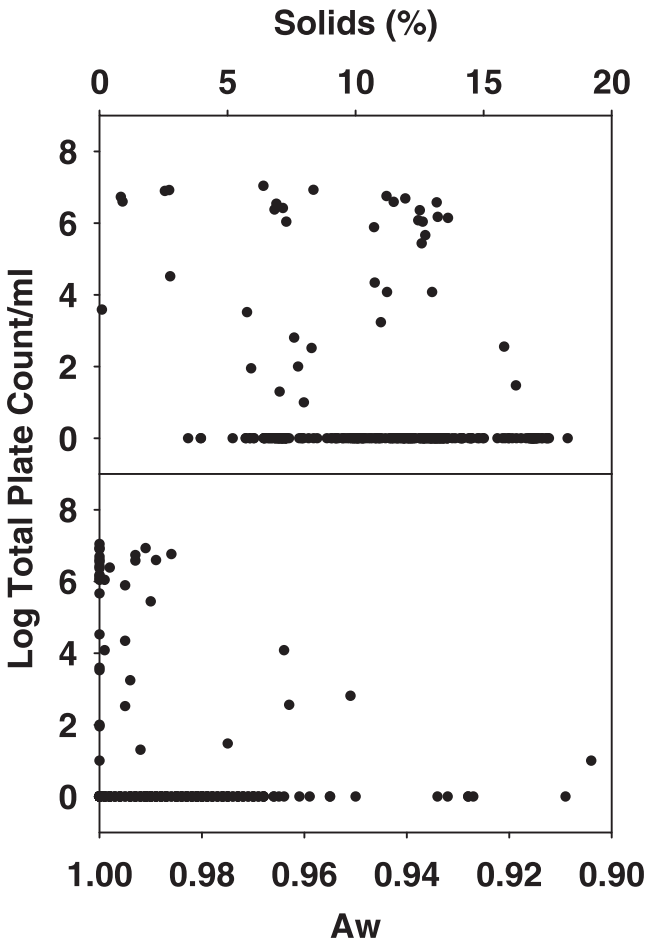

FIGURE 5. *Relationship between soap sample percent solids (top panel) or water activity (bottom panel) and bacterial count. Counts below the detection limit (10 CFU/mL) are plotted as 0 log CFU.*

activities, with the number of samples generally decreasing as water activity increases. The number of contaminated (gray) versus uncontaminated (black) samples are shown by shading on the bars. Clearly the greatest number, as well as the greatest fraction, of samples containing detectable bacteria is associated with higher (0.99 to 1.00) water activities, although even soaps with lower water activity can also contain detectable bacteria.

Figure 7 shows the relationship between the measured population of antimicrobial agent in the soap and the bacterial count. Samples containing no detected antimicrobial agent have widely distributed contamination levels. Although samples containing triclosan were contaminated regardless of the triclosan level (~0.15 to 0.65%), only one sample containing parachlorometaxylenol was contaminated, and that was at a relatively low level (0.15%).

Table 1 shows a summary of these antimicrobial data. Most of the samples tested contained no detected antimicrobial, and these samples contained the greatest fraction with countable microorganisms, almost 17%. There was a statistically significant difference between the fraction of bacteria-positive samples with no detected antimicrobial agent and those containing an antimicrobial agent ($P = 0.0035$). There was not a statistically significant difference between the fractions of bacteria-positive samples for the two types of

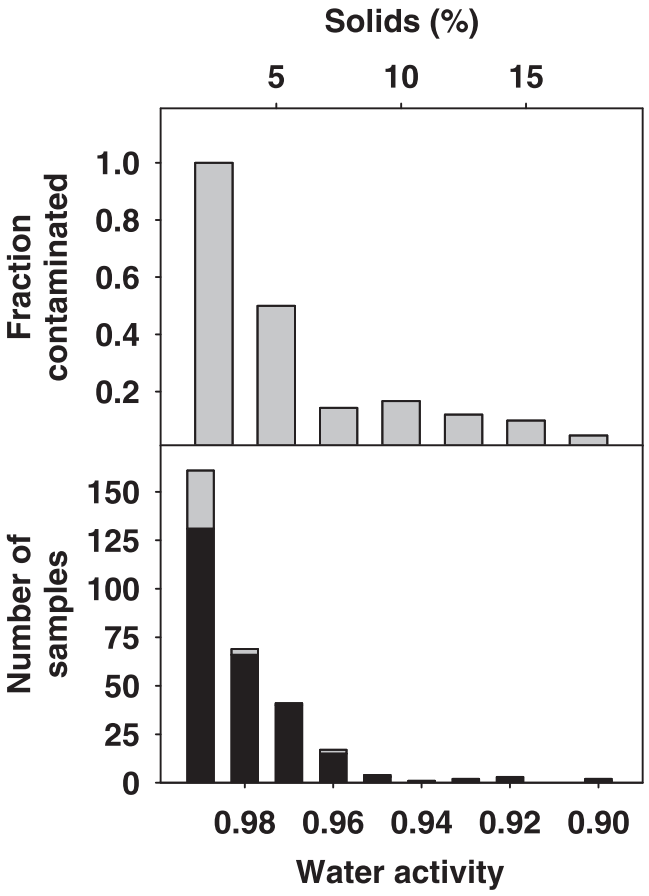

FIGURE 6. *Relationship between fraction of soap samples with bacterial counts above the detection limit (10 CFU/mL) and percent solids (top panel) or number of soap samples contaminated (gray) or uncontaminated (black) and soap water activity (bottom panel).*

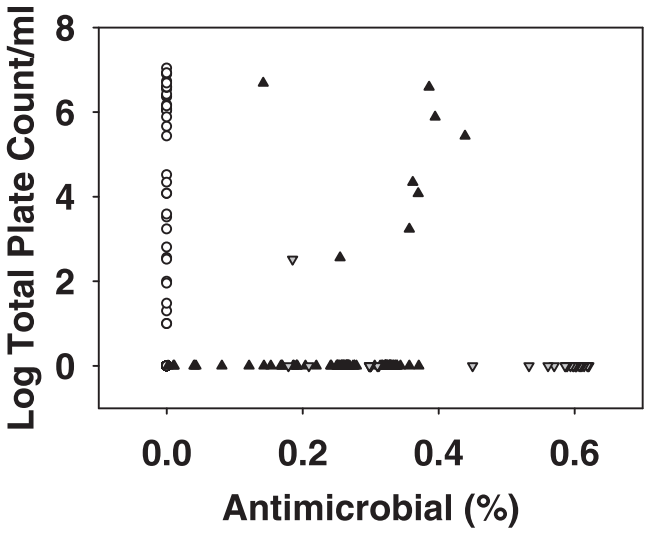

FIGURE 7. *Relationship between the measured concentration of the antimicrobial agent triclosan (black triangle) or parachlorometaxylenol (gray downward triangle) or no detectable antimicrobial agent (open circles) and total bacterial count. Counts below the detection limit (10 CFU/mL) are plotted as 0 log CFU.*

TABLE 1. *Comparison of the fraction of samples containing detectable bacteria for soap samples with detectable antimicrobial agents*[a]

	No. sampled	No. countable	% total samples	% countable
None	166	28	56.1	16.9 A
Triclosan	97	8	32.8	8.2 B
Parachlorometaxylenol	33	1	11.1	3.0 B
Total	296	37	100.0	12.5

[a] Percent countable values followed by a different letter are significantly different ($P < 0.05$).

antimicrobial agents ($P = 0.1022$). The fraction contaminated in total for all soap samples collected was 12.5%.

The relationship between the type of location sampled and the fraction of the time that samples contained detectable microorganisms is shown in Table 2. Grocery stores and fast food operations each had more than 10% bulk-soap samples positive. Grocery stores, fast food restaurants, and sit-down restaurants did not have significantly different fractions of contaminated samples from one another ($P > 0.05$), but grocery stores and fast food restaurants had significantly more ($P < 0.05$) contaminated bulk-soap samples than convenience stores.

The breakdown of bulk-soap samples in Table 3 shows that both men's and women's bathrooms have contaminated soap >10% of the time. Although samples collected from men's restrooms have a slightly higher frequency of detectable bacteria, the difference was not significant ($P = 0.29$).

The relationship between soap color and the presence of detectable bacteria is shown in Table 4. There are differences in the fraction of samples containing detectable bacteria, by soap color. However, given the wide array of soap colors observed, and the small number of samples containing detectable microorganisms, no differences were statistically significant.

Table 5 shows the fraction of samples containing detectable microorganisms by state, with >10% of soap contaminated in all three states. There were not statistically significant differences among the three states where soap samples were collected ($P > 0.05$).

DISCUSSION

This study identified gram-negative organisms as the primary organisms that colonize bulk-soap dispensers,

TABLE 2. *Fraction of samples containing detectable bacteria by store type*[a]

Type	No. sampled	No. of times bacteria detected	% detected
Grocery	30	5	16.7 A
Fast food	122	19	15.6 A
Sit down	113	11	9.7 AB
Convenience	28	1	3.6 B

[a] Percent detected values followed by a different letter are significantly different ($P < 0.05$).

TABLE 3. *Fraction of samples containing detectable bacteria by restroom gender type*

Type	No. sampled	No. of times bacteria detected	% detected
Men	169	23	13.6
Women	114	13	11.4
Other[a]	13	1	7.7

[a] Includes unknown, not recorded, and unisex bathrooms.

consistent with past outbreaks *(1, 2, 24, 38)* and screening studies *(8, 25)*. We identified gram-negative organisms at a broad range of populations (1 to 7 log CFU/mL), as reported by Momeni et al. (2 to 9 log CFU/mL *(25)*). Whereas Momeni et al. found detectable bacteria in ~60% of their samples, we found detectable bacteria in 15% of samples. This may be owing to differences in sample size (our 296 versus their 14), locations (three states versus two institutes), and type of facility (food service versus dental institute). Chattman et al. *(8)* collected 541 bulk-soap samples from five U.S. cities (Boston, Atlanta, Columbus, Los Angeles, Dallas), from liquid soap dispensers in a wide variety of public settings: offices, health clubs, restaurants, and retail stores. These authors found heterotrophic and coliform populations greater than ~2 log CFU/mL in ~19% of the sink area dispensers, similar to what we found (>2 log CFU/mL in ~15% of dispensers).

Specifically relevant to the food industry was the identification of *S. sonnei* from a contaminated soap dispenser in Arizona. According to the CDC, *S. sonnei* is the predominant cause of shigellosis in industrialized countries (and is the most common species in the United States). Consumption of ready-to-eat food contaminated due to handling by an infected worker could be a significant contributor to the spread of *S. sonnei (4)*.

The published literature reports that bacteria are more commonly isolated from plain soaps *(1, 5, 27, 30)* and are less frequently isolated from antimicrobial soaps *(1, 2, 24)*, which is consistent with the findings from our study. Although fewer bacteria are generally isolated from antimicrobial soaps (as they were in our study), it is a major technical challenge to maintain the activity of active ingredients, such as triclosan, so that they are not bound by the surfactant micelles *(11, 34)*. Our research clearly shows that the presence of an antimicrobial agent is not a safeguard

TABLE 4. *Fraction of samples containing detectable bacteria by soap color*

Color	No. sampled	No. of times bacteria detected	% detected
Green	11	5	45.5
Clear	24	7	29.2
Orange	37	8	21.6
Pink	120	12	10.0
White	41	3	7.3
Blue	42	3	7.1
Yellow	16	0	0.0
Unknown	6	0	0.0

TABLE 5. *Fraction of samples containing detectable bacteria by state*

State	No. of samples	No. of times bacteria detected	% detected
AZ	100	14	14.0
NJ	100	11	11.0
OH	96	12	12.5

against the colonization of bulk soap by bacteria. This is consistent with Archibald et al. *(1)*, who detected *S. marcescens* in 1% chloroxylenol soap (parachlorometaxylenol), and with Barry et al. *(2)* and McNaughton et al. *(24)*, who isolated bacteria from soap that contained triclosan.

It is well understood by chemists that formulation affects the performance of hand hygiene products *(10, 23)*. Our study is a reminder that quality also matters in soap development. For example, high water–low solids formulations may be less expensive to manufacture, but they are more likely to be contaminated. Soap delivery systems designed to allow mixing (or dilution of soaps to save money) promote colonization and lead to less-stable formulations. We also observed differences among types of food establishments. Fast food and grocery stores are more likely to be contaminated than convenience stores; this may be because, in the former, there is less maintenance and management oversight of the bathrooms, whereas convenience stores typically have small bathrooms that are cleaned frequently. Fast food restaurants should be of the greatest concern because food handlers often use the bathrooms we sampled that were located in the "front of the house" and then often return directly from the bathroom into the kitchen. This finding warrants strong consideration of Food Code restrictions on the use of bulk soap in restaurants, analogous to rules that discourage their use in health care *(3, 31, 39)*.

We believe this work is generalizable across the United States. Samples were obtained from a variety of food handling environments in three states spread across the country, with a wide range of weather (temperature and humidity); we found no significant differences in level of microbial contamination among states. Our findings show that the design of open refillable systems for dispensing bulk soap is fundamentally flawed and creates opportunities for contamination and biofilm development, independent of geographic location. Future needs and opportunities include better understanding the relationship of bathroom design (e.g., toilet proximity to the soap dispenser, size of bathroom) and further assessment of the risk of antibiotic-resistant bacteria in bulk soaps. Alternative approaches to achieve a lower or acceptable cost to the food service provider are also important, because low cost is the primary attraction to bulk-soap systems. Changing this practice will require good policy development, analogous to what happened in health care *(3)*.

Use of refillable bulk-soap dispensers is a clear public health concern because they provide an environment for bacteria to grow, often to high populations *(8, 21, 25, 30, 40)*, and their use has led to non–foodborne disease outbreaks *(1, 2, 5, 24, 27, 30, 38)*. In our study, most soap

samples had no detectable bacteria; however, those soap samples that did have detectable bacteria (12.5%) had populations that would be considered highly risky if the bacteria present were pathogenic (~7 log CFU/mL). Whereas the CDC recommends that bulk liquid soap dispensers be thoroughly cleaned before adding fresh soap *(3, 8, 14),* cleanings in between soap refills might not prevent recontamination *(21),* and difficult-to-clean biofilms may develop. Bulk soap has been proven to cause infection outbreaks in health care settings. It has been difficult to document outbreaks in food service settings to date; however, our findings show that the use of bulk soap presents a clear risk in food service facilities.

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Original Article

A survey of public restrooms microbial contamination in Tehran city, capital of Iran, during 2019

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Abstract

Introduction: Daily use of public restrooms may have a significant impact on spreading infectious diseases. Human society could be affected by spreading of transitional infectious diseases through feces, urinary tract infection and poor personal hygiene. According to the World Health Organization reports, plenty of people's developed diseases caused by contaminated public restrooms that may result in severe health problems. **Methods:** This descriptive cross-sectional study was conducted on 7,482 samples that were collected randomly in 6 months (spring and summer 2019) in different regions of Tehran. The Data were obtained by analyzing 804 restroom's indoor and outdoor handles, 1062 toilet faucet, 826 washbasin taps, 1,062 toilet hoses, 804 flush tank levers, 643 soap dispenser bottoms, 643 liquid soaps, 99 bar soaps, 169 toilet papers and paper towels, and 50 hand dryer machines. Samples which were tested, based on bacteriology standard methods. **Result:** 7,482 samples were gathered of which 6,678 contaminated cases (89.25%) were observed and 804 cases (10.75%) were found non-contaminated. *Escherichia coli* with 28.48% and *Pseudomonas* with 0.39% were the most and the least common bacteria, respectively, in this study. **Conclusion:** The required tests to identify the bacteria that cause contamination through the use of public restrooms have been done. It is essential to inform the public of the mentioned items and teach how to prevent infectious diseases.

Keywords: Bacterial contamination, hand dryer soaps, public restrooms

Introduction

Using public restrooms on a regular basis could have a significant effect on the transmission and diffusion of infectious diseases and other bacterial contamination. Due to many people using public toilets or washbasins and touching doorknobs several times a day, it can cause transmission of such contamination and pathogenic infectious disease. Therefore, the importance of toilets and washbasins as a source of transmission of bacterial contamination becomes more evident. It's obvious that if people's awareness of transitional contamination and related diseases enhances, it can be good for better social health and prevention of various infections. The purpose of this research is to boost health care in public services. In this study, by the

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survey of bacteriology and sampling of every facility that exist in restrooms and public services, we have measured the kind and amount of contamination that may be transferred by one to another people while they are using this places.

It seems that public services and home services must be more sanitized; absolutely in order to use public services and preventing problem for public health, more care of these services are recommended. Public services such as cinemas, hotels, hospitals, libraries, parks, etc., are more intended to be polluted because of severe public usage this should be done repeatedly to prevent transmission of disease and not to establish various illnesses such as skin disease, digestive disease, genital and venereal disease to the public. Such diseases are commonly transferable to public services because of sharing the same spaces of usage. All the points that are touchable for publics such as door handles, toilet paper, flush tanks, water hoses, valve handles, sink, liquid and solid soap, tissues, electrical driers, etc., subjects to be cleaned properly. The ventilation of public services areas is a very important factor to keep health care for public services.[1] Per annum, many cases of disease from public places occur to the people who are using these services, because of lack of sanitizing procedure; furthermore, by being infected with multidrug-resistant (MDR) bacteria or a harmful one, the process of recovery will become more complicated; this causes many economic and mental consequences to these people. Knowing the variety of contamination and checking infected facilities (such as an important one, toilet papers) that are existing in such services and have an important role in publishing the infection, McCusky *et al.*[2] and Robinton *et al.*[3] can help us to find means of preventing or diminishing infectious diffusion.

Recognizing the transmittal ways of"germs" and the means, help us to prevent establishing of contamination and to decrease the prevalence rate of disease that we expect to come after use of these facilities. . Also, making people aware of the bad consequences of poor health services and encouraging them to keep their personal belongings clean will cause social behavior more confident in their health. This study examines whether electric driers, liquid or solid soaps, toilet paper and toilet valves, outdoor, and indoor handles etc., and whether they can play a positive or negative role in the transmission of diseases. In this article, we tried to answer this question by determining the type of microorganisms that we presume to exist. By the 7,482 samples we had taken from different points of many services, we get rich to achieve the trustful answer to the question. Definitely, by the numerous numbers of samples taken, its precision, accuracy, and reliability would be also higher.

Materials and Methods

This descriptive cross-sectional study was conducted in different areas of Tehran during 2019. The subjects which were sampled are indoor and outdoor handles, taps, flush tank bottoms and levers, liquid and bar soaps. For bacterial type detecting, we have used of principals scientific sources and standard methods of bacteriology.

For a bacterial sampling of cases mentioned above, first provided wet sterile swabs which after sampling, transported on transport culture media and then as soon as possible it was transferred to the laboratory for passaging them on culture medias such as nutrient agar (HIMEDIA, LOT45114591), blood agar (HIMEDIA, LOT45114591), MacConkey agar (HIMEDIA, LOTWe215), and EMB (HIMEDIA, LOT00000015320) which had been prepared before and were keeping on the refrigerator. Before passaging the samples on culture media, the prepared media were brought out from the refrigerator in order to reach room temperature. After passage, in order to bacterial growth, the culture media which were passaged on were put into the incubator on 37 centigrade degrees (for 24–48 h). Finally, in order to assess the bacterial growth and colony-formation, the preserved culture media were examined precisely. When it manifested that the bacterial colonies had been grown on culture media, the Gram-staining method used to determine Gram-positive and Gram-negative bacteria.

Generally, all the species with their bacterial load of up to 100,000 CFU/g were designated detrimental even though those between 50,000 and 100,000 CFU/g were repeated for sampling and reassessed. Although, less than 50,000 colonies of bacteria/g are also considered normal and were excluded from the samples.

We realized that all the bacteria (whether Gram-positive and Gram-negative) could be able to grow on Nutrient agar media; also Gram-positive bacteria were grown on blood agar media and Gram-negative bacteria were grown on EMB and MacConkey agar media. For determining the specious of bacteria, these biochemical tests had been done; as mentioned below: For detecting the specious of Gram-negative bacilli such as *Shigella*, *Salmonella*, *Pseudomonas*, etc., Catalase, oxidase, urease test and triple sugar iron agar (TSI) (HIMEDIA, LOT00000015312) culture media were used. For detecting the specious of Gram-positive bacteria such as *Enterococcus faecalis*, *Staphylococcus aureus*, etc., Catalase, coagulase, and MSA culture media (HIMEDIA, LOT0000287212) were used, too.

Result

In the above study, we sampled 1,062 restrooms that in this survey: 2,124 restroom indoor and outdoor handles, 1,062 toilet faucet, 826 washbasin taps, 1,062 toilet hoses, 804 flush bottoms, 643 soap dispenser bottoms, 643 liquid soaps, 99 bar soaps, 169 toilet papers and paper towels, and 50 hand dryer machines. In total 7482 samples were tested from which 6,678 samples (89.25%) were contaminated and 804 samples (10.75%) uncontaminated.

Discussion

In this study, 7,482 samples were taken from various cases. According to Table 1, there were 6,678 contaminated specimens, of which the highest rate was found in toilet hoses and taps with 99.72% (Out of 1,062 samples, 1,058 specimens were contaminated), followed by toilet outdoor handles with 99.62% (out of 1,062 samples, 1,058 specimens were

contaminated). Flush tank levers with 99.14% (out of 804 samples, 781 samples were contaminated), toilet indoor handles with 95.52%, soap dispenser bottoms with 97.82%, washbasin taps with 95.52%, bar soaps with 91.92%, hand dryer with 56% and towel papers with 20.12% were placed in terms of the amount of contamination.

According to results of Table 2. *E. coli* (28.5%) and Klebsiella (1.51%) were the most and least present bacteria in toilet indoor handles, respectively. On toilet outdoor handles, *E. coli* was the most (28.54%) and *Pseudomonas* was the least (1.32%). On flush tank levers, maximum bacteria was *E. coli* (35.08%) and *Pseudomonas* (0.26%) was the minimum. *E. coli* (30.6%) and *Salmonella* (1.52%) were the most and the least bacteria on

Table 1: Absolute and relative frequency table of contaminated and non-contaminated public restrooms

Sample items	Contaminated items		Non-contaminated items		Total
	n.	Percentage	*n*	Percentage	
Restroom indoor handles	1042	98.12	20	1.88	1062
Restroom outdoor handles	1058	99.62	4	0.38	1062
Toilet faucet	1059	99.72	3	0.28	1062
Toilet hose	1059	99.72	3	0.28	1062
Flush bottoms and levers	781	99.14	23	2.86	804
Washbasin tap	789	95.52	37	4.48	826
Liquid Soap dispenser bottoms	629	97.82	14	2.18	643
Liquid soaps	108	16.80	535	83.2	643
Solid soaps and bar soaps	91	91.92	8	8.08	99
Toilet paper and paper towels	34	20.12	135	79.88	169
Hand dryer machines	28	56	22	44	50
Total	6678	89.25	804	10.75	7482

* *n.*=number * %=Percent

Table 2: Absolute and relative frequency table of microorganisms isolated from public restrooms

Microorganisms / Sampl items	S.epidermidis	S.aureus	salmonella	Entrococcus faecalis	Basillus subtilis	E.coli	Klebsiella	Citrobacter	Entrobacter	Pseudomonas	Proteus vulgaris	Shigella	Mix	Contaminating cases	
	N. (%)	N. (%)	N.(%)	N.(%)	N.(%)	N.(%)	N.(%)	N.(%)	N.(%)	N.(%)	N.(%)	N.(%)	N.(%)	N.(%)	
Restroom indoor handles	138 (13.24%)	105 (10.08%)		16 (1.54%)	186 (17.85%)	297 (28.5%)	12 (1.15%)	18 (1.73%)	14 (1.34%)		128 (12.28%)	14 (1.44%)	114 (10.94%)	1042	
Restroom outdoor handles	130 (12.29%)	98 (9.26%)	24 (2.27%)	38 (3.59%)	191 (18.05%)	302 (28.54%)	14(1.32%)	21 (1.98%)	28 (2.65%)		80 (7.56%)	14 (1.44%)	112 (10.59%)	1058	
Toilet faucet	61 (5.76%)	59 (5.57%)	26 (2.46%)	40 (3.78%)	189 (17.85%)	365 (34.47%)	16 (1.51%)	30 (2.83%)	35 (3.31%)		98 (9.25%)	20 (1.89%)	108 (10.2%)	1059	
Toilet hose	107 (10.1%)	101 (9.54%)	18 (1.7%)	81 (7.65%)	197 (18.6%)	217 (20.49%)	22 (2.08%)	34 (3.21%)	38 (3.59%)	4 (0.38%)	109 (10.29%)	32 (3.02%)	110 (10.39%)	1059	
Flush bottom and levers	90 (11.52%)	62 (7.94%)	24 (3.07%)	73 (9.35%)	60 (7.68%)	274 (35.08%)	67 (8.57%)	29 (3.71%)	22 (2.82%)	2 (0.26%)	45 (5.76%)	21 (1.98%)	8 (1.21%)	781	
Whashbasin tap	76 (9.63%)	94 (11.91%)	12 (1.52%)	49 (6.21%)	128 (16.22%)	238 (30.6%)			46 (5.83%)		86 (10.9%)	25 (3.2%)	48 (6.08%)	789	
Liquid soap dispenser bottoms	48 (7.63%)	38 (6.04%)	10 (1.59%)	92 (14.63%)	111 (17.65%)	187 (29.73%)		12 (1.91%)	9 (1.43%)	2 (0.32%)	63 (10.02%)	12 (1.52%)	40 (6.36%)	629	
Liquid soaps				2 (1.85%)	22 (20.27%)			10 (9.26%)		18 (16.67%)	30 (27.78%)	17 (2.7%)	26 (24.07%)	108	
Solid soaps and bar soaps	14 (15.83%)	10 (10.99%)	10 (10.99%)		10 (10.99%)	16 (17.58%)	1 (1.1%)	2 (2.2%)			14 (15.38%)		14 (15.38%)	91	
Toilet paper and paper towels	10 (29.41%)				4 (11.76%)	6 (17.65%)					4 (11.76%)		10 (29.41%)	34	
Hand dryer	10 (35.71%)	2 (7.14%)			2 (7.14%)						6 (21.43%)		8 (28.57%)	28	
Total	684 (10.24%)	569 (8.52%)	124 (1.86%)	391 (5.86%)	1100 (16.47%)	1902 (28.84%)	132 (1.98%)	156 (2.34%)	192 (2.86)	26 (0.39%)	663 (9.93%)	141 (2.11%)	598 (8.95%)	6678	c

washbasin taps, respectively. In soap dispenser bottoms, *E. coli* was the most (29.73%) and *Pseudomonas* was the least (0.32%). The most and the least bacteria that were found in liquid soaps were *Proteus vulgaris* (27.78%) and *Enterococcus* (1.85%). The most bacteria in bar soaps was *E. coli* (17.58%) and the least was *Klebsiella (1.1%)*. On toilet papers, *Staphylococcus epidermidis* and mix bacteria were the most with (29.41%) and *Proteus spp.* and *Bacillus spp.* with (11.76%) were the least and finally in hand dryer machines *S. epidermidis* (35.71%) was the most and *S. aureus* and *Bacillus spp.* (7.14%) were the least.

In general, *E. coli* is the highest rate of contamination related to flush tank levers or bottoms and *Pseudomonas* is the lowest rate of contamination. It seems that after using the bathroom, flush tank levers can be effective in transmitting bacterial infectious diseases due to non-adherence in health care. It seems that *E. coli*, which is an intestinal bacteria, causes various parts of restroom contamination during the use of toilets, which is a sign of non-adherence in health care. Also, *E. coli* bacteria are very sensitive to drying on the contaminated hands; so the high potential of this bacteria for cross-contamination is expected due to soppy hands.[4] *Pseudomonas* in liquid soap and the other parts of restrooms, which were contaminated by these bacteria, is a sign that subjects and materials are not used correctly. People are infected, and they transmit diseases.

A study performed by Buffet-Bataillon *et al.*,[5] has questioned the outbreak of *Serratia marcescens* and its investigation and control in the neonatal intensive care unit (NICU). In this study, during 3 months period, five infants were colonized by a single strain of *Serratia marcescens*. The researchers of this study achieved that a bottle soap dispenser can be a reservoir of this nosocomial pathogenic bacteria. So, these microorganisms can be easily transferred to newborns by healthcare workers. Conversely, *P. vulgaris* (27.78%) were the most bacteria sampled from liquid soaps as well as *E. coli* (29.73%), *Bacillus subtilis* (17.65%), and *Entrococcus faecalis* (14.63%) liquid soap dispenser bottoms. Although some researchers have proved that washing hands with non-antibacterial soaps and water are more effective than with water alone, Burton *et al.*,[6] basically by regarding the contamination of soap dispensers, we suggest using of alcoholic hand antiseptic instead of liquid or solid soaps.

In the study of microbial biogeography of public restroom surfaces which have been done by Flores *et al.*,[7] the communities were clustered into three general categories: those found on surfaces associated with toilets, those on the restroom floor, and those found on the surface routinely touched with hands. However, by comparison to our study, the sample items and bacterial diversity were almost alike, also vagina-associated *Lactobacillaceae* were wildly distributed in female restrooms.

In the study of Kanayama *et al.*,[8] 252 samples were contaminated from 292 specimens, taken from toilets and warm water taps. *S. aureus*, *Streptococcus spp*, *Enterococcus spp*, *Enterobacteriaceae* and other negative bacteria had been found. From the above items, *Enterobacteriaceae* were isolated as 84 (%28.8) bidets and *E. coli*, *Enterobacter spp. Klebsiella, Citrobacter spp, and Enterobacteriaceae* by 38 (13.0%), 22 (7.5%), 13 (4.5%), 5 (1.7%) and 6 (2.1%) were isolated in toilet bidets warm water, respectively.

In the study of McCusky *et al.*, *Bacillus licheniformis* was the most isolated bacteria with 20.2% that shows a remarkable difference to compare with our study.[2] Also, in the study of Harrison *et al.*, *Micrococcus luteus* and some strains of *Serratia marcescens* were the two specious of bacteria found in paper towel specimens.[9] In addition, Robinton *et al.*,[3] showed that paper towels have substantially fewer viable bacteria on them than cloth towels, although in the opposite of cloth towels, the number of bacteria found on paper towels does not seem to be a variable appreciably influenced by geographic and/or climatic differences. In the above study, *Bacillus spp* were the most bacterial species found in both kinds of towels. This is in contrast to our results in which *S. epidermidis* was common. There is no difference in the type of infectious bacteria in the above study compared with our study, but there is a significant difference in the percentage of contamination.[10] In a study by Sabra in Egypt in 2011,[11] the contamination of the women's public toilets were examined. 71.9% of the samples being positively infected. Toilets door handles (91.3%), toilet doors (73.8%), toilet sinks (63.3%), and flush tank levers (50%) were contaminated. *S. aureus* (40.6%) and *E. coli* (22.5%) were the most isolated bacteria from positive samples and *P. vulgaris* was the least one. There is no significant difference to compare with our study.

In the study of Alharbi *et al.*,[12] five different bacterial isolations were sampled from the airflow of 15 warm air dryers used in washrooms; including *Staphylococcus haemolyticus*, *Micrococcus luteus*, *Pseudomonas alcaligenes*, *Bacillus cereus,* and *Brevandimonad diminuta (vascularis)*. In this survey, the most bacterial isolates were due to *S. haemolyticus* with 95% pathogenicity; however, in our study, hand dryer machines were highly contaminated by *S. epidermidis* (35.71%). It is obvious that hot air dryers can deposit the pathogenic bacteria onto the hands and body of users as well as distributing them into the general environment whenever dryers are running. Also, some microorganisms could be inhaled by users and nonusers alike. So, it is imperative to recommend the sanitization of this machines several times a day. It is notable that in some studies it's manifested by which using warm air dryers or some jet dryers, we actually have augmented the aerosolization of bacteria and facilitating the microbial cross-contamination via airborne dissemination to the environment.[1] Best *et al.* reported that higher levels of contamination were due to washrooms using a jet air dryers compared with those using paper towels.[13] The hand-drying method can affect the risk of (airborne) dissemination of bacteria in real-world settings. JADs may not be suitable for settings where microbial cross-contamination risks are high, including hospitals.

The study that was conducted by Zapka *et al.*, in 2011,[14] the *K. pneumoniae* was isolated from samples after the bacteria were recovered and transferred by hand after washing with liquid soap which had been spontaneously infused and liquid soaps which were contaminated without control.

A study of bacteriological assessment of door handles/knobs of toilets and washrooms was conducted by Frank Ngonda in a hospital setting in 2017,[15] which revealed some bacteriological similar results. Among the total of 442 samples, 184 cases (41.6%) were contaminated and also *S. aureus* was the most bacteria had isolated. The male toilet handles were most contaminated than the females (35.5% beside 19.4%), followed by general sets (9.7%). Whilst the washroom was less contaminated in general, the highest contamination being observed in the male washroom 19.4% as compared to the female washroom at 9.7%.

In the study of Ogba *et al.*,[16] the researchers have checked on 151 samples of public toilet seats. Out of the 151 samples examined, *E. coli* 70 (46.4%) was the most prevalent isolate followed by *Salmonella spp.* 45 (29.8%) while *Staphylococcus aureus* 15 (9.9%) was the least encountered isolate. Nevertheless, most of the samples and isolates were from hostels 41 (44.0%). This study demonstrates that public toilet seats that have been washed still harbor a high number of bacterial organisms and may serve as a potential source of infections.

Conclusion

The results of this study and other similar related studies, that have been presented, demonstrate that illnesses such as genitourinary tract infections as well as gastrointestinal diseases can be found in children and adults by using contaminated services. In females, some genitourinary tract disorders such as vulvovaginocistitis, acute and chronic pregnancy, premature rupture of membrane (PROM), and acute pyelonephritis would arise mostly due to *E. coli*. In males, acute and chronic urethritis, cystitis, and prostatitis are most likely. Also, *E. coli* contamination is principally qualified to lead on Infertility in males and females. Acute cystitis, urethritis, and vaginal discharges are the main problems that occur in children are affected by this bacteria, therefore, enhancing personal hygiene, sanitizing public restrooms regularly and correctly, and using public toilets safely can prevent the transmission, diffusion, and spread of bacterial infections.

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Conflicts of interest

There are no conflicts of interest.

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Bacterial Hand Contamination and Transfer after Use of Contaminated Bulk-Soap-Refillable Dispensers▽†

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Bulk-soap-refillable dispensers are prone to extrinsic bacterial contamination, and recent studies demonstrated that approximately one in four dispensers in public restrooms are contaminated. The purpose of this study was to quantify bacterial hand contamination and transfer after use of contaminated soap under controlled laboratory and in-use conditions in a community setting. Under laboratory conditions using liquid soap experimentally contaminated with 7.51 $\log_{10}$ CFU/ml of *Serratia marcescens*, an average of 5.28 $\log_{10}$ CFU remained on each hand after washing, and 2.23 $\log_{10}$ CFU was transferred to an agar surface. In an elementary-school-based field study, Gram-negative bacteria on the hands of students and staff increased by 1.42 $\log_{10}$ CFU per hand (26-fold) after washing with soap from contaminated bulk-soap-refillable dispensers. In contrast, washing with soap from dispensers with sealed refills significantly reduced bacteria on hands by 0.30 $\log_{10}$ CFU per hand (2-fold). Additionally, the mean number of Gram-negative bacteria transferred to surfaces after washing with soap from dispensers with sealed-soap refills (0.06 $\log_{10}$ CFU) was significantly lower than the mean number after washing with contaminated bulk-soap-refillable dispensers (0.74 $\log_{10}$ CFU; $P < 0.01$). Finally, significantly higher levels of Gram-negative bacteria were recovered from students (2.82 $\log_{10}$ CFU per hand) than were recovered from staff (2.22 $\log_{10}$ CFU per hand) after washing with contaminated bulk soap ($P < 0.01$). These results demonstrate that washing with contaminated soap from bulk-soap-refillable dispensers can increase the number of opportunistic pathogens on the hands and may play a role in the transmission of bacteria in public settings.

Hand washing with soap and water is a universally accepted practice for reducing the transmission of potentially pathogenic microorganisms. However, liquid soap can become contaminated with bacteria and poses a recognized health risk in health care settings. In particular, bulk-soap-refillable dispensers (ones in which new soap is poured into a dispenser) are prone to bacterial contamination, and several outbreaks linked to the use of contaminated soap in health care settings have been reported (2, 3, 5, 15, 18, 22–24). The Centers for Disease Control and Prevention (CDC) "Guideline for Hand Hygiene in Health-Care Settings" addresses this risk in a recommendation: "Do not add soap to a partially empty soap dispenser. This practice of 'topping off' dispensers can lead to bacterial contamination of soap" (4). This "category IA recommendation" was "strongly supported by well-designed experimental, clinical, and epidemiologic studies." (4) Sealed-soap-dispensing systems, in contrast, are typically refilled by inserting into the dispenser a new bag or cartridge of soap that usually includes a new nozzle.

Bulk-soap-refillable dispensers are the predominant dispenser type in community settings, such as public restrooms. However, few studies have been conducted to evaluate the occurrence of microbial soap contamination in community settings. One study, conducted in Japan, examined bacterial contamination of hand washing soaps obtained from restrooms of various public use facilities. The authors found 17 different species of bacteria, many of which were opportunistic pathogens, including *Klebsiella pneumoniae*, *Serratia marcescens*, *Enterobacter* species, and *Pseudomonas* species (1). Recent studies conducted in the United States demonstrated that 25% of bulk-soap-refillable dispensers in public restrooms were excessively contaminated (8). Bacterial loads averaged more than 10^6 CFU/ml of soap, and 16% of the samples contained coliform bacteria. Interestingly, of the 15 different species isolated in this study, 7 were identical to those found in the Japanese study, including both *K. pneumoniae* and *S. marcescens.* Both *S. marcescens* and *K. pneumoniae* are opportunistic pathogens known to transmit via the hands (7, 17, 21).

Despite these findings, the public health risk associated with the use of contaminated bulk-soap-refillable dispensers in community settings is unclear. It would be very difficult if not impossible to trace the source of a community-acquired infection back to contaminated soap in a public restroom. Therefore, to better understand this risk, a greater understanding of the potential for bacteria from contaminated soap to remain on the hands and to be transferred to secondary surfaces after washing with contaminated soap is needed. The objectives of this study were to (i) quantify the levels of bacteria remaining on hands after washing with contaminated soap; (ii) quantify the transfer of contaminating bacteria from the hands to a secondary surface; and (iii) collect microbiological data in a field setting under actual use conditions. To our knowledge this is the first study of its kind in any setting.

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MATERIALS AND METHODS

Controlled hand washing studies. (i) Test articles. The liquid test soap contained a surfactant system representative of soaps found in public restrooms but did not contain preservatives. Soap was prepared by mixing 1,648 g of soft water, 17 g of ammonium chloride, 330 g of surfactant blends (Lubrizol Advanced Materials, Cleveland, OH; and Rhodia, Inc., Mississauga, Ontario, Canada), 2 g of fragrance (Flavorchem Orchidia, Downers Grove, IL), and 2 g of citric acid. Contaminated-soap samples were prepared by 8 successive inoculations with 300-μl to 10-ml aliquots of overnight tryptic soy broth (TSB) cultures of the marker organism *S. marcescens* ATCC 14756 or *K. pneumoniae* ATCC 13883 over the 3-week period prior to the hand wash test date. Populations of marker organisms were determined by standard plating on tryptic soy agar (TSA) and monitored over time to achieve the target contamination level.

(ii) Subjects. Eighteen subjects participated in controlled study I, and 16 participated in study II. Subjects recruited from the Bozeman, MT, area were at least 18 years of age, and the study demographics were mixed for age, sex, and race. Exclusion criteria included dermatoses or other injuries to the skin of the hands or forearms or any other conditions that would have compromised the subjects and the study.

(iii) Study design. Two controlled studies (study I and study II) assessed bacterial hand contamination and transfer post-hand washing with contaminated or uncontaminated soap. Protocols were approved by the Gallatin Institutional Review Board (Bozeman, MT). In study I, 6 subjects washed with uncontaminated test soap, 6 subjects washed with soap contaminated with *K. pneumoniae* (5.85 $\log_{10}$ CFU/ml), and 6 subjects washed with soap contaminated with *S. marcescens* (3.72 $\log_{10}$ CFU/ml). Following the hand wash, hands were sampled for residual *S. marcescens* and/or *K. pneumoniae* as described below. In study II, 8 subjects washed with soap contaminated with a low level of *S. marcescens* (4.51 $\log_{10}$ CFU/ml), and 8 subjects washed with soap contaminated with a high level of *S. marcescens* (7.51 $\log_{10}$ CFU/ml). Following the hand wash, the hands of 6 random subjects per test soap were sampled for residual *S. marcescens*. Two subjects per test soap touched agar plates to create hand imprints of bacteria transferred to the agar surfaces.

(iv) Hand washing procedure. Water used for wetting and rinsing the hands was maintained at a temperature of 40°C ± 2°C. In study I, subjects washed with 5 ml of test soap for 30 s, followed by a 30-s water rinse. In study II, subjects washed with 1.5 ml of test soap for 10 s followed by a 10-s rinse.

(v) Bacterial recovery and enumeration. To recover bacteria from the hands, powder-free, sterile, latex gloves were placed on subjects' hands, 75 ml of a recovery solution (0.4 g KH_2PO_4, 10.1 g Na_2HPO_4, and 1.0 g isooctylphenoxypolyethoxyethanol [Triton X-100] in 1 liter distilled water [pH adjusted to 7.8]) was transferred into each glove, and gloves were secured above the wrist. Technicians massaged the hands through the gloves for 60 s. Within 1 min of completing the massage, a 5-ml aliquot of the "glove juice" sample was removed and serially diluted in Butterfield's phosphate buffer solution containing lecithin and polysorbate 80 (BPB+). Dilutions were plated in duplicate onto appropriate agar plates by spread plating 1.0 ml of the recovery solution manually and spiral plating 50-μl aliquots of all dilutions (Spiral Biotech Autoplate; Advanced Instruments, Inc., Norwood, MA). *S. marcescens* was recovered on TSA with lecithin and polysorbate 80 (TSA+) and incubated for 24 to 48 h at 25°C. *K. pneumoniae* was recovered on MacConkey agar and incubated for 24 to 48 h at 35°C (7). Colonies with a morphology qualitatively similar to that of the marker organism were counted (i.e., red pigment on TSA+ for *S. marcescens* and pink mucoid on MacConkey agar for *K. pneumoniae*) with a plate-counting system (QCount model 510; Advanced Instruments, Inc., Norwood, MA). For the hand-stamp sampling procedure, subjects pressed the palms of the hands onto TSA+-containing polystyrene bioassay trays for 15 s. Trays were placed in laminar flow hoods to remove residual moisture and then incubated for 24 to 48 h at 25°C.

Field hand washing study. (i) Study site and test site. The field study was conducted in the restrooms of an elementary school in Ohio. Twenty-two subjects participated, including 12 adult staff members (teachers, administration, and janitorial staff) and 10 students (fourth and fifth grades). Exclusion criteria included cuts, rashes, or other skin conditions that would have compromised the subjects and the study. All adult subjects signed an informed consent form preapproved by Chesapeake Research Review, Inc. (Columbia, MD). All students participated only after signed parental consent, which was also preapproved by Chesapeake Research Review, Inc.

(ii) Test articles and assessment of microbial contamination. The contaminated soap used in the field study was a commercially available antimicrobial soap formulation that had been in use in the school for years prior to this study. Samples were obtained from all 14 bulk-soap-refillable soap dispensers used in the school restrooms. Approximately 10 ml of soap was aseptically collected from the dispenser nozzle into sterile 50-ml conical centrifuge tubes. The sealed-soap dispensers contained a foam soap which was sampled by filling a 120-ml sterile cup with foam. Samples were vortexed for at least 30 s and placed at rest until all bubbles dissipated. An aliquot of soap was removed with a positive displacement pipette and serially diluted in BPB+. One hundred microliters of each dilution was spiral plated onto R2A agar plates in duplicate. R2A agar is a nonselective medium designed for heterotrophic plate counts from potable water and has been previously used to quantify levels of bacteria in contaminated soap (8). Plates were incubated for 96 h at 37°C, and colonies were enumerated by hand by the standard spiral plate count methodology. The number of CFU/ml of bacteria in the original soap sample was determined based on the average colony count and the dilution factor. Soaps were considered to be contaminated if the level exceeded 1,000 CFU/ml, which is the level typically considered acceptable in nonsterile cosmetic products (13). Representatives of each dominant colony type were streak purified by multiple passages on TSA. Bacterial species were identified by using AP120E strips (bioMérieux, Marcy-l'Etoile, France). Contamination levels were monitored in the bulk-soap dispensers for 3 months prior to the hand washing trials (data not shown). All soap samples used in hand washing trials were also collected and tested for the presence of contaminating bacteria on the same days that the hand washing trials were conducted.

(iii) Study design. The study protocol was approved by Chesapeake Research Review, Inc., and was conducted in compliance with procedures approved under this protocol. Hand wash trials were conducted in 14 different restroom locations throughout the school. Technicians executing the study were of the gender indicated by the restroom. In phase I of the study, the contaminated bulk soap and uncontaminated bulk soap trials were conducted over a 4-day period. The bulk dispensers were then replaced with sealed-system dispensers. Phase II of the study, which evaluated the sealed system, was conducted 6 months later and was completed in 1 day. Each subject participated in up to 6 hand washes total for the entire study. No subject participated in more than 2 hand washes on a single day, and a minimum of 30 min was required between each hand wash. Each subject's visit consisted of a pre-hand wash (baseline) sampling, a hand wash, and a post-hand wash sampling. Right and left hands were randomized for glove juice or hand-stamp sampling at the first wash for each participant and alternated at each subsequent wash.

(iv) Hand washing and decontamination procedures. Subjects were asked to wash their hands with soap as they normally would do when washing after using the restroom facilities. The amount of soap and the length and technique of washing, rinsing, and towel drying were at the discretion of each test subject. The temperature of the water used was not controlled. The participants' hands were decontaminated at the end of each visit by washing with soap from a bottle of commercially available uncontaminated soap and then sanitizing with an ethanol-based hand sanitizer.

(v) Bacterial recovery and enumeration. The glove juice sampling method was performed similarly to the controlled study method, except for a few modifications designed to improve the detection limit of the method. Fifty milliliters of recovery solution was added to each glove, and all of the solution recovered from each hand sample was transferred to a sterile 50-ml centrifuge tube. The solution was centrifuged (10 min at 5,000 × *g*) to concentrate the bacteria. Pilot testing verified the effectiveness of the concentration method. All but 5 ml of recovery solution supernatant was removed, and the pellet was vortexed for 1 min to resuspend the cells back into the remaining 5 ml. One milliliter of the concentrated recovery solution was pour plated in duplicate, and 0.1 ml of 10-fold dilutions prepared in BPB+ was spiral plated. All plating was conducted in duplicate on both MacConkey and Chromagar orientation agar (BD, Franklin Lakes, NJ). MacConkey agar was used to select for Gram-negative bacteria. Chromagar orientation results are not presented here, but were used to qualitatively verify that MacConkey plates were adequately selective for contaminants in the soap (versus normal skin microbiota). For the hand-stamp method, subjects placed the palms of their hands and fingers onto MacConkey agar plates for 10 s. All agar plates were incubated for 96 h at 37°C and photographed for archiving. Colonies present on the MacConkey plates were counted.

Data analysis and statistical considerations. For the controlled studies, the estimated $\log_{10}$ number of viable *S. marcescens* or *K. pneumoniae* cells recovered from each hand (the "*R* value") was determined with the formula $R = \log_{10}(75 \times C_i \times 10^D)$, where 75 is the amount (ml) of recovery solution instilled in each glove, C_i is the arithmetic average colony count of the 2 plate counts at a particular dilution, and D is dilution factor. The limit of detection for the controlled studies was 1.57 $\log^{10}$ CFU/hand. For the field study, the total number of Gram-negative bacteria recovered from each hand was determined by the

TABLE 1. Bacteria recovered from hands after washing with contaminated liquid soap

Bacterial contaminant (marker organism)	Bacterial load		Postwash bacterial recovery (mean $\log_{10}$ CFU/hand ± SD [n = 12])
	Test soap ($\log_{10}$ CFU/ml)	Applied ($\log_{10}$ CFU/hand)	
None	0.00	0.00	<1.57[a]
Klebsiella pneumoniae	5.85	6.25	2.74 ± 0.5
Serratia marcescens	3.72	4.12	3.60 ± 0.2[b]

[a] Limit of detection.
[b] Greater bacterial recovery per hand after washing with soap contaminated with *Serratia marcescens* versus washing with soap contaminated with *Klebsiella pneumoniae.* $P < 0.0001$ by unpaired two-sample t test.

TABLE 2. Bacteria recovered and transferred from hands after washing with soap contaminated with *S. marcescens*

Bacterial load in test soap ($\log_{10}$ CFU/ml)	Bacterial load applied ($\log_{10}$ CFU/hand)	Postwash bacterial recovery (n = 12)		Postwash bacterial transfer (n = 4)	
		Mean $\log_{10}$ CFU/hand ± SD	P value	Mean $\log_{10}$ CFU/hand ± SD	P value
4.51	4.39	1.70 ± 0.27		0.30 ± 0.42	
7.51	7.39	5.28 ± 0.47	<0.0001[a]	2.23 ± 0.49	0.001[a]

[a] Unpaired two-sample t test.

formula $R = \log_{10}(5 \times C_i \times 10^D)$. The limit of detection for the field studies was 0.40 $\log_{10}$ CFU/hand. The total numbers of bacteria transferred to MacConkey agar hand-stamp plates were counted directly from the agar plates. Results were obtained by analysis of 91 hand wash trials that yielded usable results for all four measurements taken (CFU recovered before, CFU recovered after, CFU transferred before, and CFU transferred after). Raw CFU values were converted to $\log_{10}$ CFU values, and statistical comparisons were performed by using paired and unpaired t tests on GraphPad Prism version 5.04 for Windows (GraphPad Software, San Diego, CA).

RESULTS

Recovery and transfer of bacteria from hands after washing with experimentally contaminated liquid soap. Human subjects washed for 30 s with 5 ml of soap experimentally contaminated with either *K. pneumoniae* (5.85 $\log_{10}$ CFU/ml) or *S. marcescens* (3.72 $\log_{10}$ CFU/ml) followed by a 30-s rinse. Neither test organism was recovered from the hands of subjects prior to washing hands or from the subjects that washed with uncontaminated control soap. In contrast, for *K. pneumoniae*, a mean of 2.74 $\log_{10}$ CFU/hand was recovered from subjects after washing with *K. pneumoniae*-contaminated soap, and for *S. marcescens*, a mean of 3.60 $\log_{10}$ CFU/hand was recovered from subjects after washing with *S. marcescens*-contaminated soap (Table 1). Interestingly, more bacteria were recovered from hands washed with *S. marcescens*-contaminated soap than from those washed with *K. pneumoniae*-contaminated soap ($P < 0.0001$), even though the level of *K. pneumoniae* contamination was 100-fold higher.

In a second experiment, subjects performed a 10-s hand wash with 1.5 ml of liquid soap experimentally contaminated with either a high level of *S. marcescens* (7.51 $\log_{10}$ CFU/ml) or with a low level of *S. marcescens* (4.51 $\log_{10}$ CFU/ml) followed by a 10-s rinse. It is known that when soap that is not contaminated is used for hand washing, it is more effective at removing transient bacteria when greater volumes of soap and longer wash times are used (11). Therefore, the second controlled study was conducted under conditions chosen to be more representative of the hand washing behaviors typically observed (6, 12, 14, 16, 19). The mean numbers of *S. marcescens* cells recovered after washing with high- and low-level-contaminated soap were 5.28 $\log_{10}$ CFU and 1.70 $\log_{10}$ CFU per hand, respectively (Table 2) ($P < 0.0001$). The number of bacteria transferred to an agar surface after washing were 2.23 $\log_{10}$ CFU and 0.30 $\log_{10}$ CFU per hand for the high- and low-level-contaminated soap, respectively (Table 2 and Fig. 1) ($P = 0.001$).

Recovery and transfer of bacteria from hands after washing with contaminated liquid soap in an elementary school. An elementary school was identified in which all (14/14) of the bulk-soap-refillable dispensers being used in the restrooms were found to be contaminated with bacteria at levels ranging from 6.0 to 7.0 $\log_{10}$ CFU/ml of soap (Table 3). A variety of Gram-negative species from the *Citrobacter*, *Providencia*, *Pseudomonas*, and *Serratia* genera were identified among the recovered contaminants. All of the contaminated dispensers were replaced with sealed-soap-dispensing systems after the first phase of the field hand washing study. After 1 year postinstallation, all of the soap dispensed from the sealed-soap dispensers was confirmed to be contamination free.

A study was conducted with students and staff to assess the levels of Gram-negative bacteria remaining on or transferred from hands after washing with contaminated soap from these dispensers or with uncontaminated control soaps (Table 4). Prior to washing with contaminated bulk soap, uncontaminated bulk soap, and uncontaminated soap from sealed refills, the mean numbers of bacteria recovered from hands of subjects were 1.17, 0.99, and 1.67 $\log_{10}$ CFU per hand, respectively. The mean number of bacteria recovered from the hands after hand washing with the contaminated soap (2.59 $\log_{10}$ CFU per hand) was significantly higher than the pre-hand-washing value ($P < 0.0001$). Gram-negative bacteria were detected in 97% (60/62) of hands tested after washing with bulk soap compared to 52% (32/62) before washing. In contrast, the mean number of bacteria recovered from hands after washing with uncontaminated bulk soap (0.82 $\log_{10}$ CFU per hand) was reduced compared to the prewashing numbers. When hands were washed with uncontaminated soap from the new replacement sealed-system dispensers, the mean numbers of bacteria recovered from hands after washing (1.37 $\log_{10}$ CFU per hand) were also reduced compared to the prewashing numbers and were statistically lower than those recovered from hands washed with contaminated soap ($P < 0.0001$). The mean number of Gram-negative bacteria recovered from the hands after washing with contaminated soap was significantly higher for students (2.82 $\log_{10}$ CFU per hand) than that for staff (2.22 $\log_{10}$ CFU per hand; $P = 0.008$) (Table 5).

Figure 2 compiles $\log_{10}$ CFU changes after individual hand washes into a histogram in which the bars represent the number of times each reduction or increase was observed. When contaminated soap was used, an increase was observed for 55 of 62 hand washes (89%), and the mean change was a 1.42-$\log_{10}$ CFU increase. In contrast, when uncontaminated soap (bulk or sealed) was used, an increase was observed for only 3

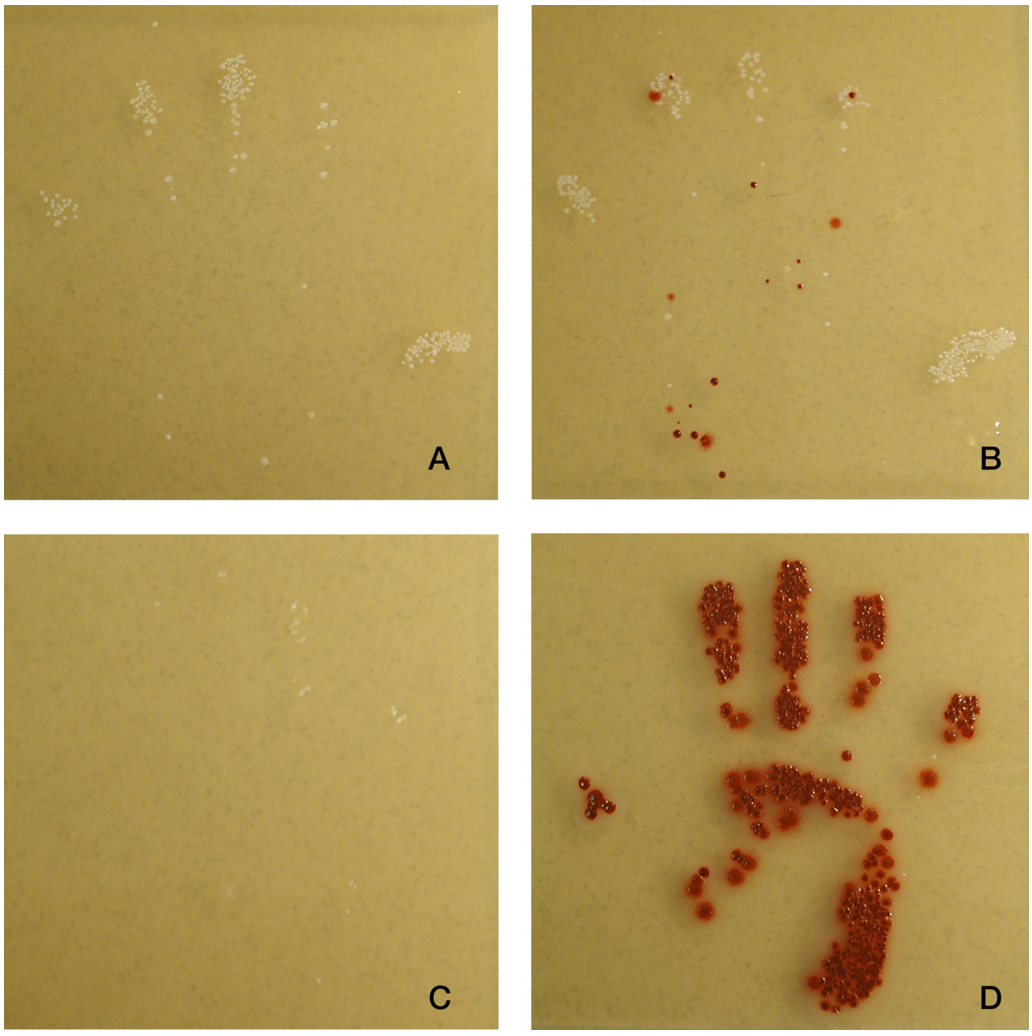

FIG. 1. Sample images from a controlled study (Table 2) to determine the number of bacteria from contaminated hands transferred to an agar surface before (A and C) and after (B and D) hand washing with soap containing 4.51 $\log_{10}$ CFU/ml (A and B) or 7.51 $\log_{10}$ CFU/ml (C and D) of *S. marcescens*.

of 29 hand washes (10%), and the mean change was a 0.26-$\log_{10}$ CFU decrease.

Prior to washing, subjects transferred on average 0.10, 0.10, and 0.18 $\log_{10}$ CFU/hand of Gram-negative bacteria to touched agar surfaces. This number increased significantly after washing with soap from the contaminated dispensers (0.74 $\log_{10}$ CFU/hand; $P < 0.0001$) (Table 4). Washing with uncontaminated-soap controls did not significantly change the mean number of transferred Gram-negative bacteria ($P = 0.945$, uncontaminated bulk soap; $P = 0.100$, uncontaminated sealed soap). Furthermore, fewer bacteria were transferred from subjects' hands after washing with uncontaminated sealed soap (0.06 versus 0.74 $\log_{10}$ CFU; $P = 0.0004$) or uncontaminated bulk soap (0.09 versus 0.74 $\log_{10}$ CFU; $P = 0.012$), compared to bacteria that were transferred from subjects' hands after washing with contaminated soap. Transfer of at least 1 CFU of Gram-negative bacteria after washing was observed in 61% (38/62) of hands washed with contaminated soap versus 21% (4/19) of hands washed with uncontaminated sealed soap. In addition, significantly more Gram-negative bacteria were transferred to agar surfaces touched by students (0.98 $\log_{10}$ CFU per hand) after using contaminated soap than by the adult staff (0.37 $\log_{10}$ CFU per hand; $P = 0.003$) (Table 5).

A comparison of the pre- and postwash recoveries of bacteria for the individual bulk-soap-refillable dispensers tested in the field study is shown in Fig. 3. The number of bacteria recovered from hands postwash increased significantly relative to the prewash recoveries for all of the contaminated dispensers, and the increase was significant for 8 of the 14 contaminated dispensers (P values ranging from 0.0003 to 0.03). In contrast, the number of bacteria recovered from hands after washing with the uncontaminated control soaps decreased relative to the prewash recoveries, but was not significant ($P = 0.199$ for control 1, and $P = 0.324$ for control 2).

DISCUSSION

The purpose of hand washing is to remove soil and to reduce the level of potentially pathogenic transient microorganisms. This is the first study to quantitatively demonstrate that wash-

TABLE 3. Identification of bacteria isolated from bulk-soap-refillable soap dispensers in an elementary school

Soap dispenser tested	Total bacterial contamination in soap (log_{10} CFU/ml)	Presence of:							
		Unknown species	*Citrobacter freundii*	*Citrobacter youngae*	*Providencia rettgeri*	*Providencia stuartii*	*Pseudomonas aeruginosa*	*Pseudomonas fluorescens*	*Serratia rubidaea*
1	6.9				+				+
2	6.8				+				
3	6.3		+				+		
4	6.4				+		+		
5	6.0		+				+		
6	6.4		+			+			
7	6.0						+		
8	6.7			+	+				
9	6.2				+				
10	6.2		+		+				
11	6.4						+		
12	6.2	+						+	
13	7.0				+		+		
14	6.0		+		+				

ing hands with contaminated liquid soap actually increases the number of Gram-negative bacteria on hands. Furthermore, the results directly demonstrate that bacteria from contaminated hands can be transferred to secondary surfaces. We therefore conclude that washing with contaminated soap not only defeats the purpose of hand washing but may contribute to the transmission of potentially harmful bacteria. The results of the two laboratory hand washing studies were corroborated by the elementary school field study, which demonstrated a 26-fold increase in the number of Gram-negative bacteria present on the hands (Table 4) after washing with contaminated soap from bulk-soap-refillable dispensers, demonstrating a potential public health risk in public, non-health-care settings. Importantly, when the contaminated dispensers in the school were replaced with dispensers containing sealed-soap refills, none were found to be contaminated after 12 months of use. Furthermore, washing hands with soap from the sealed-soap system reduced the number of bacteria on hands of the study participants (Table 4). Taken together, these results indicate that use of dispensers with sealed refills instead of open bulk-soap-refillable dispensers can lower the risk of extrinsic microbial contamination and can reduce the spread of potentially pathogenic bacteria.

Previous studies have demonstrated an association between the use of bulk-soap-refillable dispensers and bacterial contamination of the liquid soap. Contamination rates in these studies ranged from 20% to 25% (8; C. A. Zapka, M. Chattman, S. L. Maxwell, D. R. Macinga, M. J. Dolan, and C. P. Gerba, unpublished data). In the present study, we found that 100% (Table 3) of bulk soap dispensers in one elementary school were contaminated. A single soap formulation was used in the school and was dispensed from two similar bulk-soap dispensers. In previous studies, multiple sites using different soap formulations and different dispensers were surveyed. These differences may account for the higher rate of contamination in this facility. Further analysis of the factors contributing to the unusually high prevalence of contaminated soap in this school will be presented elsewhere (C. A. Zapka, unpublished data). Many of the bacteria isolated from the bulk soap in the elementary school are considered to be opportunistic pathogens and can cause infections in compromised populations (10, 15). In fact, use of a shampoo contaminated with *Pseudomonas aeruginosa*, an organism found in 43% (6/14) of the dispensers in this elementary school (Table 3), has been reported to have led to a fatality (9).

The levels of bacteria in the soaps tested in the two laboratory hand washing studies (3.72 to 7.51 log_{10} CFU/ml) were representative of those encountered in this and our previous field studies (2.77 to 7.81 log_{10} CFU/ml) (8; C.A. Zapka, unpublished data). Significantly higher levels of *S. marcescens* were recovered from the hands despite a lower level of contamination in the test soap compared to *K. pneumoniae* (Table 1). These results suggest that the two organisms may interact with human skin in qualitatively different ways. Both organisms have been reported to contaminate soaps and lead to infections in health care settings (5, 18, 20, 22). Even a brief contact

TABLE 4. Gram-negative bacteria recovered and transferred from the hands of students and staff in an elementary school before and after hand washing

Test soap type	No. of hand washes	Bacteria recovered/hand			Bacteria transferred/hand		
		Mean log_{10} CFU ± SD		*P* value[a]	Mean log_{10} CFU ± SD		*P* value[a]
		Before hand wash	After hand wash		Before hand wash	After hand wash	
Contaminated bulk soap	62	1.17 ± 0.70	2.59 ± 0.89	<0.0001	0.10 ± 0.31	0.74 ± 0.81	<0.0001
Uncontaminated bulk soap	10	0.99 ± 0.39	0.82 ± 0.19	0.084	0.10 ± 0.32	0.09 ± 0.28	0.945
Uncontaminated sealed soap	19	1.67 ± 0.98	1.37 ± 0.81	0.025	0.18 ± 0.37	0.06 ± 0.20	0.100

[a] Log_{10} CFU before versus after by paired two-sample *t* test.

TABLE 5. Influence of gender and age on Gram-negative bacteria recovered and transferred from hands washed with contaminated bulk soap in an elementary school

Participant type	No. of hand washes	Bacteria recovered/hand				Bacteria transferred/hand			
		Before hand wash (mean $\log_{10}$ CFU ± SD)	*P* value[a]	After hand wash (mean $\log_{10}$ CFU ± SD)	*P* value[a]	Before hand wash (mean $\log_{10}$ CFU ± SD)	*P* value[a]	After hand wash (mean $\log_{10}$ CFU ± SD)	*P* value[a]
Students									
Male	19	0.95 ± 0.52	0.222	2.49 ± 1.01	0.024	0.10 ± 0.37	0.575	0.71 ± 0.89	0.047
Female	19	1.22 ± 0.78		3.15 ± 0.69		0.17 ± 0.37		1.25 ± 0.71	
Staff									
Male	13	1.53 ± 0.91	0.134	2.37 ± 0.72	0.253	0.08 ± 0.23	0.450	0.42 ± 0.61	0.688
Female	11	1.06 ± 0.44		2.03 ± 0.70		0.03 ± 0.09		0.32 ± 0.61	
All									
Students	38	1.09 ± 0.66	0.218	2.82 ± 0.91	0.008	0.13 ± 0.37	0.344	0.98 ± 0.84	0.003
Staff	24	1.31 ± 0.76		2.22 ± 0.71		0.06 ± 0.18		0.37 ± 0.60	

[a] Male versus female or students versus staff by unpaired two-sample *t* test.

(10 s) with contaminated soap resulted in detectable levels of bacteria on hands (Table 2). Significantly higher levels of *S. marcescens* were recovered from the hands and were transferrable to a secondary surface when the liquid soap was contaminated with a higher bacterial load. These results demonstrate that both the identity of the microbial contaminant and the level of contamination are important factors influencing the public health risk associated with the use of contaminated soap.

The elementary school field study revealed that students retained more bacteria on the hands and transferred significantly more after washing with contaminated bulk soap than the adult staff (Table 4). Although the reasons for these observed differences are not clear, we hypothesize that differences in hand size, skin condition, and/or hand washing technique (e.g., thoroughness of water rinsing and paper towel drying) may be contributing factors. Children represent a vulnerable population with potentially a greater susceptibility to bacterial infections due to their less developed immune systems. Hence, further studies to identify these factors are warranted.

The number of bacteria transferred to agar surfaces was directly proportional to the number of bacteria recovered from subjects' hands post-hand washing in both laboratory studies and in the field study. Analysis of the combined data set showed the concentration of bacteria in contaminated soap correlated positively with both the number of CFU recovered from the hands ($P < 0.0001$) and the number of CFU transferred from the hands ($P < 0.0001$) post-hand washing (data not shown). Based on the observed correlations, washing with soap containing less than 3.7 $\log_{10}$ CFU of bacteria/ml would not lead to detectable bacteria on the hands, and washing with soap with less than 5.4 $\log_{10}$ CFU/ml would not result in detectable transfer of the bacteria to touched surfaces. Coincidentally, this observation confirms the appropriateness of a current industry guideline that recommends that cosmetic products contain less than 3.0 $\log_{10}$ CFU of bacteria/g (13).

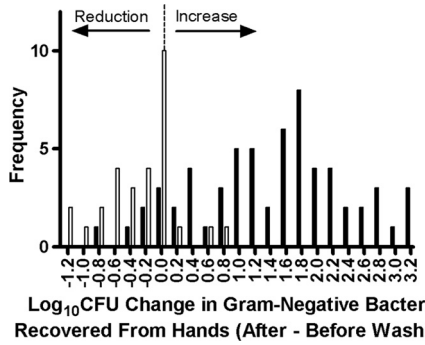

FIG. 2. $\log_{10}$ CFU change in Gram-negative bacteria recovered from hands of elementary school students and staff as a result of hand washing with contaminated soap (solid bars) versus uncontaminated control soaps (open bars).

In summary, this study is the first to quantify the levels of bacteria remaining on hands after washing with contaminated soap and to quantify the transfer of contaminating bacteria from the hands to a secondary surface. This research confirms previous work demonstrating a strong association between open bulk-soap-refillable soap dispensers and extrinsic bacterial soap contamination and demonstrates that washing with contaminated soap poses a potential public health risk in community settings. Our findings further show that extrinsic contamination of hand soap can be eliminated or considerably reduced through the use of sealed-soap-dispensing systems.

Limitations of our study that future studies should be designed to address include species identification of the entire microbial communities present on the hands before and after washing, comparison of results between dominant and nondominant hands, and correlation of hand washing techniques (volume of soap used, length of washing and rinsing, paper towel use behaviors, etc.) employed by participants with the observed results. Further studies to confirm these preliminary findings and to develop accurate risk models should be considered. Epidemiological studies of the causal relationship between contaminated soap and disease would be very useful to quantify the risk; however, they may be impractical to execute. The lack of such study data, however, should not preclude proactive efforts to reduce the

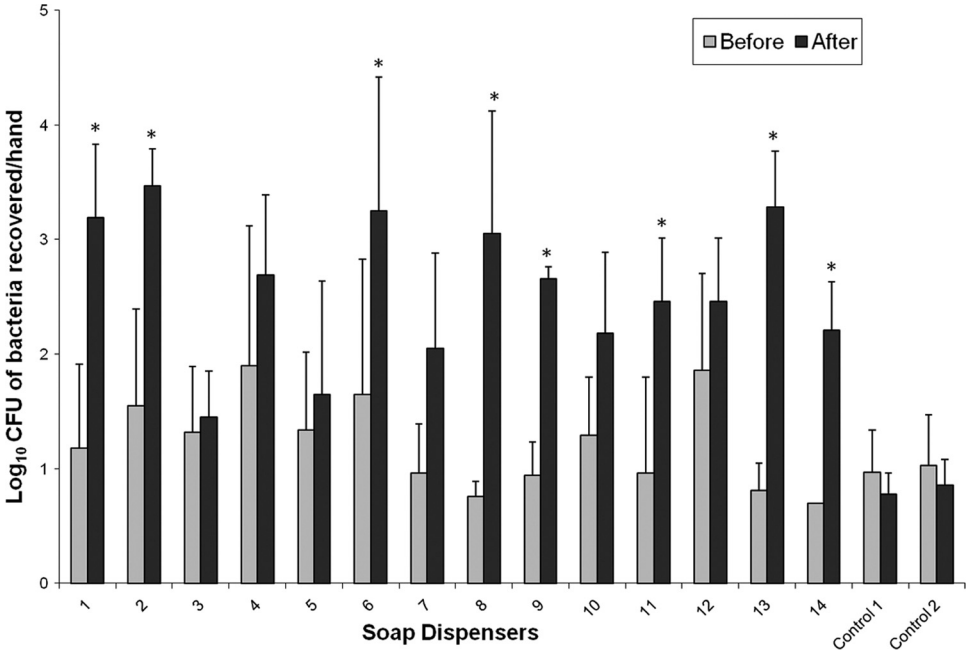

FIG. 3. Gram-negative bacteria recovered from the hands of elementary school students and staff before and after washing with contaminated bulk soap. Fourteen contaminated soap dispensers and 2 uncontaminated soap controls were used by students and staff. $n = 4$ for dispensers 2 to 5 and 12, and $n = 2$ for dispenser 10; $n = 5$ for all other dispensers. *, $P < 0.05$ for bacteria recovered per hand before versus after hand washing by paired two-sample t test.

unnecessary public health risks posed by open bulk-soap-refillable dispensers.

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Evaluation and remediation of bulk soap dispensers for biofilm

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Recent studies evaluating bulk soap in public restroom soap dispensers have demonstrated up to 25% of open refillable bulk-soap dispensers were contaminated with * 6 $\log_{10}$(CFU ml^{71}) heterotrophic bacteria. In this study, plastic counter-mounted, plastic wall-mounted and stainless steel wall-mounted dispensers were analyzed for suspended and biofilm bacteria using total cell and viable plate counts. Independent of dispenser type or construction material, the bulk soap was contaminated with 4–7 $\log_{10}$(CFU ml^{71}) bacteria, while 4–6 $\log_{10}$(CFU cm^{72}) biofilm bacteria were isolated from the inside surfaces of the dispensers (n ¼ 6). Dispenser remediation studies, including a 10 min soak with 5000 mg l^{71} sodium hypochlorite, were then conducted to determine the efficacy of cleaning and disinfectant procedures against established biofilms. The testing showed that contamination of the bulk soap returned to pre-test levels within 7–14 days. These results demonstrate biofilm is present in contaminated bulk-soap dispensers and remediation studies to clean and sanitize the dispensers are temporary.

Keywords: biofilm; bulk soap; soap dispensers; efficacy testing

Introduction

Hand washing has long been recognized to play an important role in public health (Garner and Favero 1986), and is generally accepted as an important practice to help prevent the spread of infectious microorganisms, which is especially significant in the healthcare industry. Hand washing sinks and liquid soap are generally provided to patrons of public restrooms to encourage good hand hygiene. Shared public bathrooms, however, can be a vector, con-tributing to the spread of pathogenic microorganisms (Mokhtari and Jaykus 2009). As early as the 1960s, studies were published regarding significant surface contamination of bar soap (Bannan and Judge 1965; Kabara and Brady 1983). Liquid soap was eventually recommended to be a more hygienic solution, and dispensers were developed to distribute liquid soaps (Graf et al. 1988; Chattman et al. 2011).

Like bar soaps, liquid soap dispensers have been associated with microbial contamination issues. Reports dating back to the 1960s have linked bulk liquid hand soap and hand lotion contamination to nosocomial infections in hospital operating rooms and neonatal units (Morse et al. 1967; Archibald et al. 1997; Sartor et al. 2000; Rabier et al. 2008; Buffet-Bataillon et al. 2009). Washing with contaminated soap can leave more bacteria present on the hands after the washing event than before, which undermines the effectiveness of hand washing (Sartor et al. 2000; Zapka et al. 2011). In 1986, the healthcare industry hand hygiene guidelines recognized that 'since liquid-soap containers can become contaminated and might serve as reservoirs of microorganisms, reusable liquid containers need to be cleaned when empty and refilled with fresh soap. Completely disposable containers obviate the need to empty and clean dispensers.' (Garner and Favero 1986). In response to this guideline, the use of bulk hand soap dispensers is now rare in US healthcare settings. How-ever, these types of dispensers are still common in public restrooms. Recent research has demonstrated that up to 25% of bulk hand soap dispensers from office buildings, health clubs, schools, food service centers, retail spaces and other locations are contaminated. Heterotrophic bacteria in contaminated soap averages 6 $\log_{10}$(CFU ml^{71}), which is approximately 1000 times in excess of what industry guidelines recommend (Krowka and Bailey 2007; Chattman et al. 2011).

There are numerous unique dispenser designs but all include a reservoir area to store the soap, a mechanism to pump the soap out of the reservoir onto hands, and a way to refill the dispenser with new soap. Dispensers are constructed of metal or plastic and are typically semi-permanently mounted to the wall or under the counter near the sink. Dispensers are

designed to be refilled by one of two methods: bulk refill and sealed soap refill. Bulk refill dispensers are manually refilled by pouring soap through an opening in the top from a separate bulk soap refill bottle, commonly supplied in a 1 gallon volume. These bulk soap dispenser models typically have a built-in permanent nozzle through which soap is dispensed and is not replaced under normal circumstances. Sealed soap dispensing systems, in contrast, are typically refilled by inserting a new bag or cartridge of soap that contains a new built-in nozzle. As such, the nozzles in these systems are replaced regularly and the soap does not come into contact with the dispenser itself. Empty cartridges are then either disposed or recycled.

Personal care and cosmetic products, such as soap, are not expected to be sterile, but US manufacturers are required by law to ensure that their products do not present a hazard to consumers when they are used as directed (Steinberg 2006). The Federal Food, Drug, and Cosmetic Act 'requires that successful preservation can only be established if one considers all aspects of development from concept and design through manufacturing to the last consumer use before disposal' (Geis 2006). Industry guidelines suggest that to be safe, a product should not contain any pathogens and that the bacterial load should not exceed 1000 total bacteria per gram or milliliter of product (Krowka and Bailey 2007). In order to protect products from contamination during use, soap manufacturers include preservatives in their formulations and verify their performance by testing that each newly-developed formulation effectively inhibits the growth of a range of microorganisms (Sutton 2006). Liquid hand soaps, however, are perishable and can become contaminated with microorganisms under certain adverse circumstances, particularly when consumers use or store the product in unintended ways that are hostile to preservative efficacy (Geis 2006). Occasionally, products are sold that are either already contaminated (intrinsic contamination) or that are inherently susceptible to becoming contaminated because of poor formulation design. However, the primary cause of failure of even a robust, well-preserved formulation is the introduction of contamination during use of the product when a consumer intentionally adds water, mixes products, or stores the product in inhospitable conditions, such as in warm or humid places (extrinsic contamination) (Geis 2006). The design of packaging and dispensing mechanisms used to store and deliver products affects the probability that a product will become contaminated. Systems that have an open design and that allow for increased opportunity for consumers to manipulate the product inside are inherently at greater risk of becoming contaminated as compared to products with a closed design (Garner and Favero 1986; Brannan and Dille 1990; Geis 2006).

Dispenser design and construction of soap packaging is a critical factor to both the occurrence of contamination and the challenge of contamination remediation. The likelihood of extrinsic contamination is greatest when products are packaged, stored, or used in a manner that allows for repeated introduction of microorganisms from the consumer or the surrounding environment (Brannan and Dille 1990; Geis 2006). Dispenser designs, particularly those for wall-mounted dispensers, do not take into consideration the potential for microbial contamination, thus, cleaning is impractical because the dispensers are often securely bolted into walls, making them difficult to remove. For this reason, the same dispensers often remain in facilities for many years. Some wall-mounted dispensers are designed with a nozzle that is located centimeters above the bottom of the dispenser, rather than dispensing the soap from the bottom of the dispenser. This design flaw ensures that the dispenser will never completely drain. Once the soap becomes contaminated, this serves to provide a reservoir of bacteria that are uniquely adapted to survive in the soap environment. Also, some counter-mounted dispensers are sold with one dispensing pump to be reused between bottles (Sartor et al. 2000). Once the pump becomes contaminated, it can transfer the bacteria between bottles (Graf et al. 1988).

Remediation of contaminated dispensers is one option for reducing potential health risks to the general public. There are no published research studies to date that have determined if there is an effective way to eliminate or reduce the contamination problem by washing and/or sanitizing the dispenser. Furthermore, even as far back as the late 1980s, biofilm was suspected of being present in bulk soap dispensers (Graf et al. 1988). Given that bacterial biofilm is known to be more tolerant to disinfectants (Stewart et al. 2000; Donlan and Costerton 2002; Smith and Hunter 2008; Peeters et al. 2008), biofilms likely survive on internal surfaces in contact with soap. While most published studies only tested the bulk soap coming out of the dispenser for bacterial contamination, the entire soap dispenser could be considered a microbial habitat and should be examined. This examination should include both the bulk soap for planktonic contamination and the inner dispenser surfaces to test for the presence of biofilm.

The objectives of this study were to test for the presence of biofilm within dispensers collected from public restrooms and to determine which organisms were present, to understand the efficacy of cleaning and disinfection procedures against established biofilm, and to examine the recurrence of bulk soap contamination following cleaning. Plastic counter-mounted, plastic wall-mounted, and stainless steel (SS) wall-mounted

dispensers were analyzed for planktonic and biofilm heterotrophic and coliform bacteria using viable plate counts (VPC) and total cell counts (TCC). Isolated bacterial colonies were identified using biochemical and molecular profiling. Once the presence of biofilm within dispensers was confirmed, several washing and sanitizing procedures were evaluated for their ability to remediate contamination using both plastic and SS wall-mounted dispensers.

Methods

Sampling dispensers for biofilm

Test dispenser information

Three counter-mounted plastic dispensers from a shopping complex, two plastic wall-mounted dispensers from an elementary school, and two SS wall-mounted dispensers from a middle school and high school, all located in Ohio, USA were evaluated. The dispensers were sampled in the field and determined to be contaminated prior to being sent to the Center for Biofilm Engineering (CBE) for analysis. The plastic dispensers tested were designed with a top lid that completely lifted open for refilling the dispenser with new soap. The SS dispensers were designed with a small, hinged lid that is lifted to refill the dispenser with soap.

Experimental design

A schematic of the process used to sample the refillable soap dispensers for viable and total cells is found in Figure 1. Dispensers were visually inspected and imaged after arrival from the collection site. Three samples were collected from each dispenser: bulk soap to enumerate viable, planktonic bacteria (CFU ml^{-1}); rinse water to enumerate loosely-attached, surface-associated bacteria (CFU cm^{-2}); and inner surface scrapings to determine the density of attached, biofilm bacteria (CFU cm^{-2}). In addition, TCC were determined for each sample type collected, as described below.

Determination of planktonic bacteria

For the plastic counter- and wall-mounted dispensers, the soap was drained through the nozzle into a sterile beaker containing 220 g of 3 mm glass beads. For the SS dispensers, the soap was drained into a sterile glass beaker, and after vigorous mixing, a 10 ml aliquot was added to a 50 ml conical vial containing 10 g of glass beads.

Determination of loosely-attached bacteria

After the soap was removed from the dispenser, 100 ml of sterile phosphate buffered water was added to the dispenser and swirled around to remove any loosely-attached bacteria. For the plastic dispensers, the rinse water was drained into a sterile beaker containing 60 g of glass beads. For the SS dispensers, the rinse water was drained into a beaker and a 10 ml aliquot was collected for culturing.

Determination of strongly-attached bacteria

For the plastic dispensers, the entire inside of the dispenser was scraped with a Teflon scraper and then rinsed with 100 ml of DeyEngley (D/E) Neutralizing Broth.

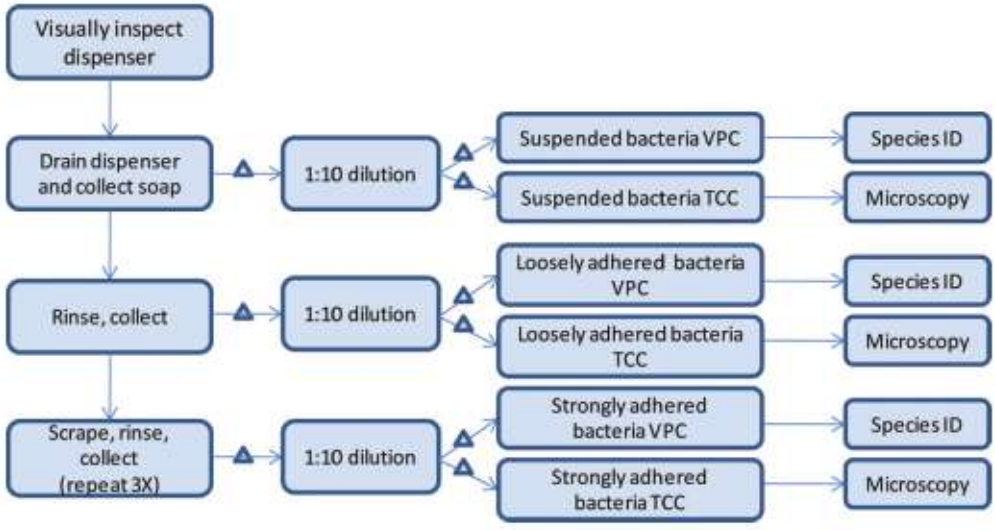

Figure 1. Schematic of the experimental design used to analyze bacteria suspended in the soap and loosely- or strongly-attached to the inside surfaces of contaminated bulk soap dispensers. Three samples were collected and analyzed for viable cells (VPC) and total cells (TCC). Δ = sample disaggregation steps.

The D/E broth was poured into a beaker containing 185 g of glass beads. The scrape and rinse procedure was completed three times and all rinses were combined.

For the SS dispensers, 150 ml of cold phosphate buffered water were added to the dispenser. The dispenser was shaken vigorously for 5 min and the inside surfaces of the dispenser that were accessible were scraped with a sterile Teflon scraper.

Disaggregation and plating methods

All samples were neutralized with D/E broth. Three cycles of sonication and vortexing (1 min each) followed to disaggregate the biofilm. Sterile glass beads were included to aid in biofilm disaggregation. The efficiency of this method was confirmed microscopically. Samples were serially diluted and 1 ml aliquots were plated on both R2A and MacConkey agar. The R2A plates were incubated at room temperature for 7 days and the MacConkey plates were incubated at 36°C for a period of 24–72 h. In addition, 1 ml of the disaggregated, undiluted soap was plated.

For TCC, an additional 1 ml aliquot from the diluted sample was pipetted onto a 0.2 μm membrane. LIVE/DEAD *Bac*Light Bacterial Viability Kit stain (Invitrogen #L7012, Carlsbad, CA) was added, incubated for 15 min in the dark, and after rinsing, the membrane was placed on a glass slide. The total cell count slides were imaged on a Nikon Eclipse E800 microscope with a FITC cube (ex 480/15, DM 505, em 535/20) for the green and a TRITC cube (ex 546/5, DM 575, em 590 LP) for the red. Images were analyzed for total cells regardless of the color the cell stained. A scan of 20 fields per slide was performed and this information was processed for total counts per sample dilution using Metamorph, v7.6.4 Software (MDS Analytical Technologies, Sunnyvale, CA).

Identification of bacterial isolates

Colonies collected from the three sample types that expressed a unique morphology were streaked for isolation and sent to an outside laboratory (Medical Laboratory Services, Inc., Bozeman, MT) for bacterial identification based upon biochemical profiling. Identification of bacterial isolates was confirmed by sequence determination of the V1–V3 region of the SSU rRNA gene. The SSU rRNA gene was amplified with previously described primers FD1 and 1540R and sequenced with 529R via capillary Sanger sequencing (Ye et al. 2004; Hwang et al. 2009). Sequences were identified using the BLASTn algorithm through NCBI (http://ncbi.nlm.nih.gov/blast).

For the plastic wall-mounted dispensers, the field identifications (from historical data) and laboratory identifications were determined using biochemical profiling and molecular analysis. For the SS wall-mounted dispensers, the laboratory identifications were determined biochemically and the isolated colonies used in the biochemical identifications were sent in for molecular testing to provide direct comparisons between the two methods.

Molecular analysis of whole biofilm community

Using separate dispensers from above, two plastic wall-mounted and two SS wall-mounted dispensers were sampled to determine microbial diversity of biofilm within the dispensers. For each dispenser tested, bulk soap was removed and 100 ml cold, sterile 1X PBS were added. The inside surfaces of the dispenser were scraped into the PBS and transferred to 50 ml conical centrifuge tubes. Biomass was collected *via* centrifugation and multiple pellets from the same dispenser were combined until all biomass was in a single pellet for each sample. Pellets were resuspended in 10 ml of PowerBead solution and transferred into sterile mortars with sand. Samples were flash frozen with liquid nitrogen and ground with pestles three times. The whole sample was collected into PowerBead tubes and nucleic acid extraction was done according to the manufacturer's instructions with the PowerMax Soil DNA Extraction Kit (MO BIO, Inc., Carlsbad, CA). The extracted DNA was amplified as above with primers FD1 and 1540R using PCR program 80°C 1:30, 94°C 2:00, 25 cycles of (94°C 0:30, 58°C 1:00, 72°C 1:00), 72°C 7:00 followed by 4°C hold. Appropriately-sized DNA was cloned into plasmid pCR2.1-TOPO (plastic) or pCR4-TOPO (SS), transformed into competent *E.coli* DH5α and plated on LB-Kan50 plates as per the manufacturer's instructions (Invitrogen, Inc., Carlsbad, CA). Transformants were screened for appropriately-sized inserts using primers M13F and M13R. Ninety-six M13 amplicons were submitted from each dispenser for Sanger sequencing using primer 529R. Sequence libraries were checked for chimeras and identified as described above.

Dispenser imaging

Prior to any sampling steps, the dispensers were visually inspected and various outside and/or removable dispenser pieces were imaged using a Nikon SMZ1500 stereo zoom microscope.

Experimental design of remediation study

Washing studies were conducted on plastic and SS wall-mounted dispensers. Five plastic wall-mounted dispensers from an elementary school in Ohio were used in the first set of experiments. Some of these

dispensers were previously used to investigate hand transfer of contaminants in a different study (Zapka et al. 2011). Eight SS wall-mounted dispensers from a school district in New Jersey were used in the second set of experiments. Each experiment included a positive control (randomly chosen dispenser that had tested positive for contamination in the bulk soap) and a negative control (a new dispenser that had never tested positive for bacteria in the bulk soap). The experiments were performed in triplicate and control dispensers remained the same for each of three experimental repeats. The remaining dispensers used in the studies had all tested positive for viable bacteria (at least 3 $\log_{10}$(CFU ml^{-1})) in the bulk soap prior to commencing each washing experiment. The washing procedure tested on each dispenser was randomly assigned before every experiment.

The washing procedures were designed to vary in difficulty and to utilize products that would be readily available to any cleaning personnel, including the use of tap water. Just prior to washing the dispenser, a sample of the bulk soap was collected and analyzed for heterotrophic bacteria. Samples from plastic dispensers were neutralized with D/E Neutralizing Broth and disaggregated and plated on R2A, while samples from SS dispensers were neutralized with a modified Butterfield's phosphate buffer solution containing lecithin, polysorbate 80, KH_2PO_4, K_2HPO_4, $Na_2S_2O_3 \cdot 5H_2O$, Tamol SN, and Triton X-100 (BPB^+ Neutralizer) (Beausoleil 1999), followed by disaggregation and plating on TSA. The control dispensers were then drained and refilled with an antibacterial soap labeled to contain triclosan (percent triclosan not listed on the label) for the plastic dispensers or a bland (non-antimicrobial) soap for the SS dispensers. The soap formulation used to fill each dispenser was consistent with the formulation used to fill that dispenser in the field. The test dispensers were washed with sodium hypochlorite (5000 mg l^{-1}), a quaternary ammonium compound-containing disinfectant (Ecolab Oasis 146 Multi-Quat Sanitizer, 8 ml l^{-1}), or a mildew remover (Tilex Mildew Root Penetrator & Remover, 24,000 mg l^{-1} sodium hypochlorite, active ingredient), as depicted in Figure 2. They were then filled with the appropriate soaps as described above. The bulk soap from all the dispensers was then sampled immediately after filling and for up to 2 weeks or until the population reached pre-test levels. Both the fresh soap and tap water were plated and tested on each experiment day for viable cells.

Results

Planktonic and biofilm contamination

Bulk soap from contaminated dispensers harbored between 3.7 to 6.7 $\log_{10}$(CFU ml^{-1}) of viable coliform and heterotrophic bacteria and between 6.9 to 8.0 $\log_{10}$(CFU ml^{-1}) total cells (Figure 3). Soap from plastic wall-mount dispensers had the highest density of viable planktonic bacteria (5.4 to 6.7 $\log_{10}$(CFU ml^{-1})) while plastic counter-mounted dispensers contained the lowest density (3.7 to 4.9 $\log_{10}$(CFU ml^{-1})) and SS wall-mounted dispensers contained an intermediate density (4.9 to 5.2 $\log_{10}$(CFU ml^{-1})). The TCC in the soap were $\sim$ 1 to 3 logs greater than the viable counts for all of the dispensers.

Loosely- and strongly-adhered viable coliform or heterotrophic cells were present at densities between 3.3 to 6.4 $\log_{10}$(CFU cm^{-2}) in all dispensers (Figure 4). The SS wall-mounted dispensers had the highest density of surface-associated viable bacteria (5.1 to 6.4 $\log_{10}$(CFU cm^{-2})) as compared to the plastic counter-mounted and wall-mounted (3.3-5.8 $\log_{10}$(CFU cm^{-2})) dispensers. The TCC from the loosely- and strongly adhered bacteria were generally greater than the loosely- and strongly-adhered viable bacteria, except for the strongly-adhered bacteria from the plastic wall-mounted dispenser. For the majority of dispensers, slightly more strongly-adhered and total cell count bacteria were recovered than loosely-adhered bacteria, except for the plastic counter-mounted dispensers, in which much higher densities of loosely-attached bacteria and TCC were recovered (6.3 to 6.9 as compared to the strongly-associated bacteria at 4.6 to 5.1).

Bacterial identification

The colonies recovered from the plastic counter-mounted dispensers were identified through biochemical profiles as *Klebsiella oxytoca* and *Kluyvera ascorbata*, both of which are Gram-negative opportunistic pathogens. The bacteria identified in the plastic wall-mounted dispensers were commonly Gram-negative, presumptive opportunistic pathogens (eg *Providencia, Citrobacter, Klebsiella, Serratia*, and *Pseudomonas*) (Table 1). Bacterial populations were also identified *via* clone libraries of SSU rRNA gene sequences. The isolates identified with both biochemical and molecular techniques revealed similar identifications at the genus level, although not surprisingly the clone library data identified potential organisms that were not cultivated. The bacteria identified in the SS wall-mounted dispensers were consistent with that observed for the other dispensers (Table 2). In total, the SS dispensers contained bacteria from five unique genera that included *Pseudomonas, Providencia, Serratia, Stenotrophomonas* and *Acinetobacter*. Interestingly, the molecular data did not reveal additional sequences that were not cultivated from the SS dispensers. In previous unpublished work, historical data indicated

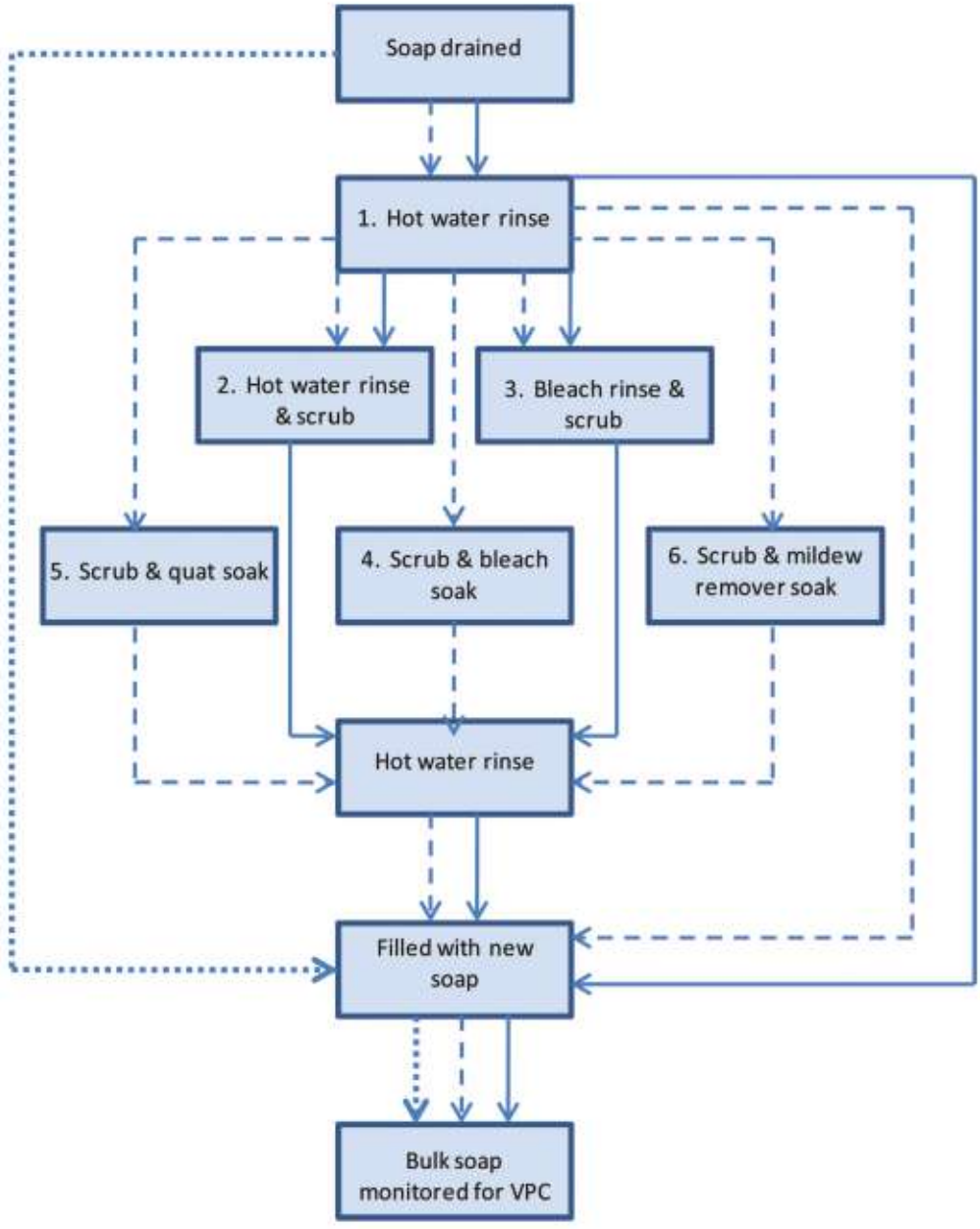

Figure 2. Schematic of the experimental design used to evaluate the effectiveness of dispenser remediation procedures. Procedures 1, 2, and 3 were followed for plastic wall-mounted dispensers (solid lines). Procedures 1–6 were tested for the SS dispensers (dashed lines). The dotted line denotes the control dispenser protocol.

that the dominant colony types in each dispenser were *Pseudomonas aeruginosa* and *Serratia liquefaciens*. This research confirmed that these genera were present in the respective dispensers but did not confirm that they were the dominant colony types. Bacterial isolates obtained from SS dispensers were also identified using both SSU rRNA gene sequencing biochemical profiling to compare the two techniques. The results from the comparison revealed equivalent identities at the genus level for all but one of 14 isolates.

Effectiveness of dispenser remediation techniques

The heterotrophic plate count results of the dispenser washing experiments are shown in Figures 5 and 6 for the plastic wall-mounted and SS wall-mounted dispensers, respectively. In Figure 5, the standard error of the mean (SEM) for the hot water rinse procedure was 0.10 and 0.47 on day 0 and day 4, as averaged over the three experiments. The SEM for the hot water rinse and scrub procedure on day 0 was 0.28 and ranged from 0.07 to 0.53 on days 0, 4, and 7 for the scrub and

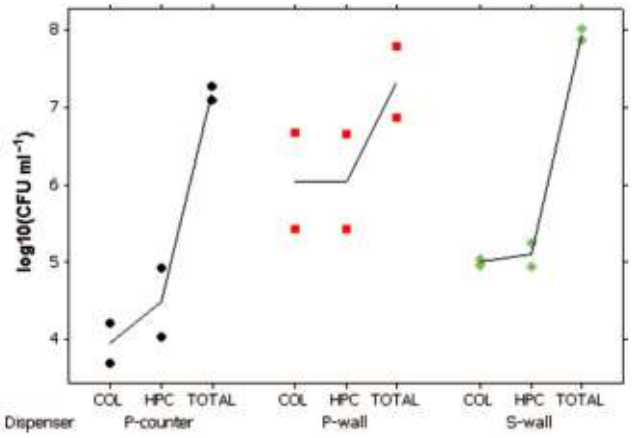

Figure 3. Coliform (COL), heterotrophic (HPC), and total cell count (TOTAL) results from the bulk soap for plastic counter-mount, plastic wall-mount, and SS wall-mount dispensers ($n = 2$ of each). The black solid line connects the mean $\log_{10}$(CFU ml^{-1}) of the data points.

sodium hypochlorite rinse washing procedure, over the three experiments. The triplicate experiments for these dispensers were not conducted consistently with respect to the frequency of plating. In experiment 1, the dispensers were only plated on day 0 and 14, whereas in experiment 2, they were plated on days 0, 2, 4, 7, and 10. The dispensers were plated on days 0, 1, 4, and 7 for experiment 3 and for all experiments, plating was discontinued once the bacterial counts returned to pre-test contamination levels. For these reasons, the SEM could not be calculated for all dispensers and all experiments for each day.

In Figure 6, the SEM for the hot water rinse procedure over the three experiments was 0.30, 0.14, and 0.20 for days 0, 2, and 4. The SEM could not be calculated for day 7 because some of the dispensers had reached their pre-test contamination levels and plating was discontinued. The SEM for the hot water rinse and scrub procedure was 0.27, 0.25, 0.15, and 0.15 for days 0, 2, 4, and 7 averaged over three experiment replicates. For the scrub and sodium hypochlorite rinse procedure, the SEM was 0.25, 0.52, 1.01, and 0.34 for days 0, 2, 4, and 7. The SEM could not be calculated on day 10 because some of the dispensers had already reached their pre-test contamination levels. For the 10 min sodium hypochlorite soak procedure and for the 10 min quat soak procedure, the SEM was 0.26, 0.31, 0.71, and 0.22, and 0.28, 0.15, 0.87, and 0.16 on days 0, 2, 4, and 7, respectively. For the 10 min mildew remover soak washing procedure, the SEM was 0.34, 0.63, 1.55, and 1.24 for days 0, 2, 4, and 7. The SEM could not be calculated for days 10 and 14 because some of the dispensers had already reached their pre-test contamination levels and plating was discontinued.

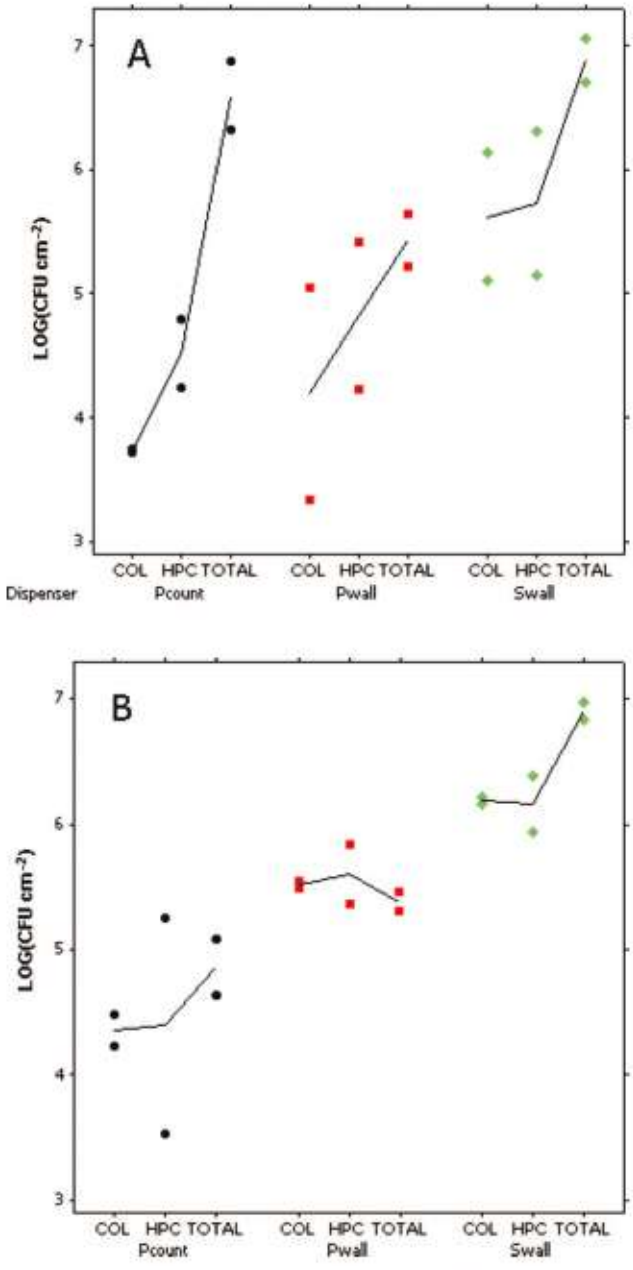

Figure 4. Coliform (COL), heterotrophic (HPC), and total cell count (TOTAL) results from the loosely-attached (Panel A) and strongly-adhered (Panel B) sampling steps for plastic counter-mounted, plastic wall-mounted, and SS wall-mounted dispensers ($n = 2$ of each). The black solid line connects the mean $\log_{10}$(CFU cm^{-2}) of the data points.

The dispensers initially contained 4.3 to 6.0 $\log_{10}$(CFU ml^{-1}) in the bulk soap dispensed after cleaning. Rinsing the dispenser with hot water, with or without scrubbing, did little to reduce the contamination levels in the soap. Based upon industry guidelines that suggest a microbial load limit of 1000 CFU ml^{-1}, these soaps would be considered contaminated within 1–2 days after performing the remediation procedures.

Table 1. Bacteria identified in wall-mounted plastic dispensers.

Organisms identified	Field identified	Lab identified	Clone library analysis
Providencia rettgeri	+	+	+
Pseudomonas sp.			
P. aeruginosa	+	+	+
P. fluorescens	+		
P. luteola	+		
P. stuzeri	+		
Citrobacter sp.			+
C. koseri	+		
C. freundii		+	
Serratia sp.			
S. oderifera	+		
S. liquefaciens		+	
S. rubidae	+		+
Stenotrophomonas sp.			+
S. maltophilia	+		
Klebsiella pneumoniae		+	
Aeromonas hydrophilia	+		
Burkholderia cepacia		+	
Enterobacter sp.			+
E. cloacae		+	
Achromobacter xylosoxidans			+
Alcaligenes xylosoxidans			+
Curvibacter sp.			+
Leptothrix sp.			+
Pelomonas sp.			+
Delftia acidovorans			+
Rubribacter xylanophilus			+

Table 2. Bacteria identified in SS wall-mounted dispensers.

Organisms identified	16S ID of isolates	Biochemical ID of isolates	Clone library analysis
Pseudomonas sp.			+
P. aeruginosa	+	+	
P. fluorescens/putida		+	
Providencia sp.	+		+
P. vericola	+		
P. rettgeri	+	+	
Serratia sp.	+		+
S. marcescens		+	
S. liquefaciens		+	
Stenotrophomonas sp.	+		+
S. maltophilia		+	
Acinetobacter lwoffii		+	
Alcaligenes/ Achromobacter sp.			+

The most effective remediation treatments were the sodium hypochlorite soak, sodium hypochlorite rinse and scrub, and the mildew remover soak, which were all able to reduce the bacterial contamination densities to below the 1000 CFU ml^{-1} threshold for $\sim$ 4 to 5 days after treatment. However, the levels in the soap continued to increase and returned to pre-remediation

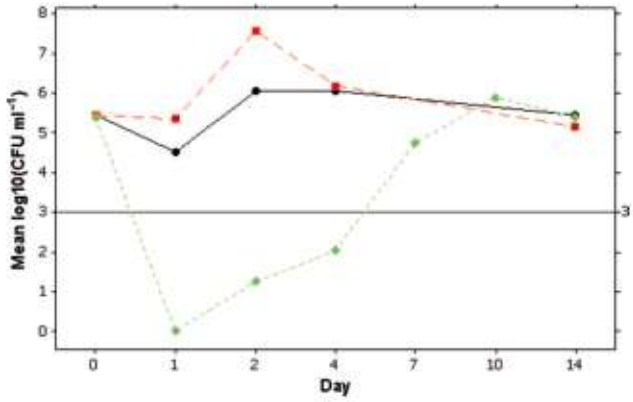

Figure 5. HPC results for plastic wall-mounted dispenser washing studies, averaged over three experiments. ● = hot water rinse procedure; ■ = hot water rinse and scrub procedure; ♦ = scrub and sodium hypochlorite rinse washing procedure. The solid horizontal line at 3 $\log_{10}$(CFU ml^{-1}) depicts the cosmetic industry guideline recommendation.

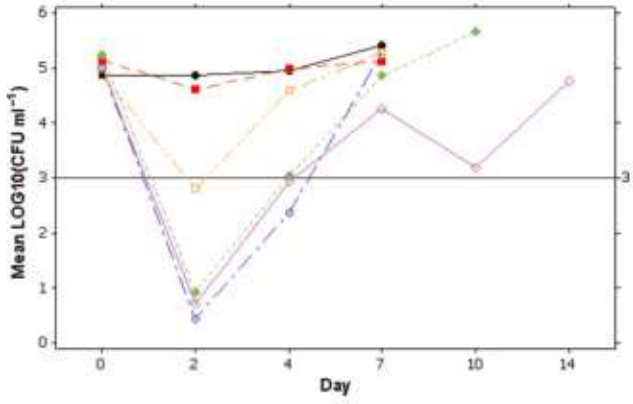

Figure 6. HPC results for SS wall-mounted dispenser washing studies, averaged over three experiments. ● = hot water rinse procedure; ■ = hot water rinse and scrub procedure; ♦ = scrub and sodium hypochlorite rinse washing procedure, ○ = 10 min sodium hypochlorite soak procedure; □ = 10 min quat soak procedure; ◇ = 10 min mildew remover soak washing procedure. The dispenser bulk soap was sampled until the populations reached pre-test contamination levels. The solid horizontal line at 3 $\log_{10}$(CFU ml^{-1}) depicts the cosmetic industry guideline recommendation.

levels after only 7 to 14 days post-remediation. The quat soak did little to decrease contamination levels, and on average, only decreased levels below the 3 $\log_{10}$(CFU ml^{-1}) microbial load limit for 2 days, post-treatment.

When considering the individual data points, the 10 min mildew remover soap procedure in experiment 3 took 10 days to recover beyond a 3 $\log_{10}$(CFU ml^{-1}) level. Interestingly, it had reached that level after 4 days in the first two experiments.

The effectiveness of the three remediation methods performed on both the plastic and SS dispensers (hot water rinse, hot water rinse and scrub, and sodium hypochlorite rinse and scrub) was not significantly different depending on dispenser type. Positive control dispensers, which were simply drained of soap and refilled with fresh soap, maintained their contamination levels at approximately 5 $\log_{10}$(CFU ml^{-1}), and no bacteria were detected from the negative control dispensers throughout the experiments (data not shown).

Discussion

The results of this study demonstrate that open, bulk-refillable soap dispensers found to contain contaminated soap also contained bacterial biofilms. Three samples were collected from each dispenser to assess the bacterial contamination, viz. bulk soap, loosely-attached cells, and biofilm. Analyzing the soap for bacteria in addition to the surface samples allowed for comparisons between historical findings, field data, and the present laboratory evaluation.

The density of surface-associated bacteria in SS wall-mounted dispensers was up to ten-fold greater than that seen for the other two dispenser types. This is interesting because the bacterial density in the soap was slightly greater than that recovered in the plastic counter-mounted dispensers and slightly less than the bacteria recovered from the soap in the plastic wall-mounted dispensers. This result suggests that there is no direct correlation between biofilm density in a dispenser and the level of contamination in the bulk soap.

Previous reports suggest that bulk liquid samples are not necessarily predictive of the microbial health of the system (Goeres 2010). In general, if the bulk soap is contaminated, then biofilm is also most likely present in the dispenser. Perhaps the most interesting case would be to determine whether dispensers containing no bulk soap contamination still contain biofilm. Additional factors that would be interesting to include in a correlation study are the type of soap, the location of dispenser, and the use pattern.

For this study, the type of dispenser (plastic wall-mounted, plastic counter-mounted and SS wall-mounted) did not appear to be a significant factor, although a slightly greater diversity of organisms was detected in the plastic dispensers. This is an interesting result given the design of the SS dispensers, which does not allow for the dispenser to ever completely empty.

Bacterial isolates from the soap were almost exclusively Gram-negative. While isolates were identified to at least the genus level, the identifications provided a qualitative description of organisms contaminating the dispensers but did not serve to quantify each species. In most cases, molecular typing of the isolates provided similar results to the biochemical typing. Identifications from both methods are limited to matching the biochemical profile or the sequence to an organism already in the database. Biochemical profiling of environmental isolates is particularly limited due to the extremely great diversity of organisms which have not yet been characterized as well as those multiple species which are similar, if not identical, in the limited size of the array used for profiling. While the bacterial diversity was relatively low compared to other environments, 16S rRNA gene sequencing demonstrated the presence of organisms not detected *via* cultivation-based techniques in plastic dispensers. The same was not true for the SS dispensers. Identified isolates are consistent with organisms previously reported to have been isolated from liquid soap (Chattman et al. 2011; Zapka et al. 2011). The molecular data can be used to further direct cultivation methods in order to isolate a broader diversity of the present microbiota, which could be useful information when crafting new formulations of soap. Intentional incubation of isolates already known to be well-suited for survival in soaps during the formulation phase would give insight into the ability of the new formulation to resist bacterial growth. Future work could include molecular techniques that differentiate bacterial populations in the bulk soap *vs* biofilm populations.

Inclusion of microscopy in these experiments proved to be useful for two reasons. First, the TCC demonstrated that only a fraction of the bacteria were recovered by the VPC. On average, the TCC were 1 to 2 $\log_{10}$(CFU ml^{-1}) higher than the VPC, indicating the presence of a population that was either non-viable or non-culturable by the plating techniques used in this study. Second, microscopy demonstrated whether or not the disaggregation method was adequate (Figure 7).

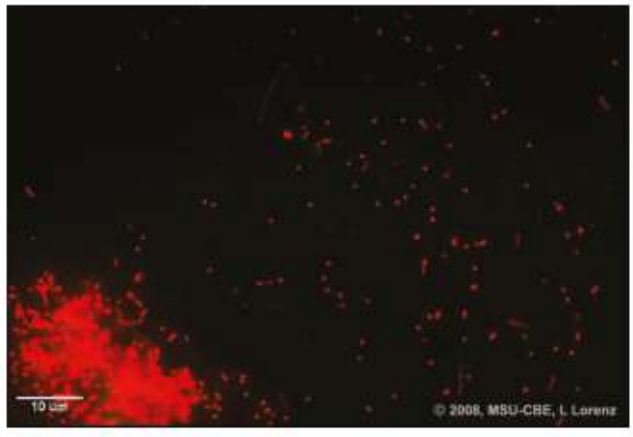

Figure 7. Total cell count image displaying biofilm clumping when disaggregation was inadequate. X100. Bar = 10 um.

The physical properties of soap makes it challenging to disaggregate cell clusters; it foams when homogenized and is difficult to vortex vigorously, so microscopy was an important means by which to assess the disaggregation method used. Improper disaggregation will result in an underestimate of the viable cells present in a sample (Hamilton et al. 2009). Previously published results obtained without using disaggregation techniques showed that contaminated bulk soap in public restrooms contains an average of 6 $\log_{10}$(CFU ml^{-1}) of heterotrophic bacteria, therefore, they may have underestimated the true levels of viable bacteria in the soaps (Chattman et al. 2011). Another interesting use of the imaging from the dispensers was to visually record that the dispensers often contained substances that presumably did not originate from the soap (Figure 8).

Once a biofilm has established on a surface, cleaning and eradicating the biofilm from that surface becomes a challenge, as the dispenser remediation experiments demonstrated. The ineffectiveness of washing soap bottles dates back to the 1960s, so these findings are not surprising (Burdon and Whitby 1967). The present study showed that even soaking the dispensers with sodium hypochlorite, a quat, or with a full strength mildew remover for 10 min before adding new soap, was ineffective at eradicating biofilm. Because the soap used to refill each dispenser contained no detectable bacteria, the results demonstrated that the recovery of bacterial populations in the bulk soap resulted from dispersal of bacteria from biofilms present inside the dispensers. The rate of recolonization was inconsistent between replicates and likely represents a host of different factors including density of the biofilm, age of the biofilm, species composition of the biofilm, and quality of disruption of the biofilm during disinfection. The slowest recovery took 14 days to reach pre-test contamination levels. This particular dispenser received the mildew remover treatment in experiment 3, where the recovery was 14 days, but this dispenser also received that treatment in experiment 1 and received the sodium hypochlorite rinse treatment in experiment 2. The mildew remover contains 24,000 mg l^{-1} sodium hypochlorite. It is conceivable that the two mildew sodium hypochlorite treatments, coupled with an approximate 5,000 mg l^{-1} sodium hypochlorite rinse treatment, all occurring within just under 2 months, were able to decrease the biofilm counts and delay regrowth and contamination, but still failed to completely eradicate the biofilm.

Figure 8. Stereoscope image of inner dispensing tube of a plastic counter-mounted dispenser coated with unknown brown substance. 7.5X.

The soap dispenser remediation procedures evaluated in this study were very time and labor intensive and would not realistically be utilized by a custodial staff, especially in a facility with multiple dispensers to maintain. Furthermore, the trials conducted in triplicate were completed in rather quick succession, sometimes with just a week between replicate experiments. A custodian would be very unlikely to add an every-other-week soap dispenser cleaning regimen to an already long list of cleaning duties. Finally, the design of the dispenser systems contributes to the challenges of keeping them clean. They are composed of intricate pieces that are difficult to reach with a scrubbing brush. For instance, some of the top openings are quite small, making it difficult to use a scrubbing brush or to get into them at all. Bulk soap dispensers are constructed of many materials including plastics, SS, and rubber (gaskets). SS and rubber are incompatible with high level concentrations of sodium hypochlorite, which makes continuous cleaning of these materials with such disinfectants impractical, as the dispenser components will begin to corrode or deteriorate.

It is possible that dispenser design guidelines could be written to facilitate easier cleaning and disinfecting protocols for bulk soap dispensers. The SS wall-mounted dispensers, for example, had an inefficient valve placement on the front of the dispenser, about 2.5 cm above the bottom, leaving a constant reservoir of soap. Valve systems that are both easily replaceable and not economically prohibitive would eliminate the need to clean intricate and delicate valve components. It is important to consider both the potential for contamination and the ease of cleaning a system as design parameters for a dispenser. As with any environment where microbial contamination could be a concern, including dispenser systems, these considerations must be evaluated in the engineering design.

Conclusions

Bulk soap dispensers were shown to be highly contaminated, both by bacteria in the soap, and also

by biofilm bacteria attached to the inner dispenser surfaces. The bacteria identified were consistent with those typically found in cosmetics/soap environments, as determined by both culture- and molecular-based identification analyses. The remediation effectiveness experiments demonstrated that, due to biofilm attached to the dispenser surfaces, even cleaning with highly concentrated disinfectants does not eliminate the bacterial populations that are adapted to live in the soap environment.

Acknowledgement

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Outbreak of *Serratia marcescens* in a neonatal intensive care unit: contaminated unmedicated liquid soap and risk factors

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KEYWORDS
Case–control study;
Neonate;
Serratia marcescens;
Soap

Summary This study describes an outbreak of *Serratia marcescens* and its investigation and control in a neonatal intensive care unit (NICU). During a three-month period, five infants were colonised or infected by a single strain of *S. marcescens*. A case–control study, culture surveys and pulse-field gel electrophoresis analysis implicated a bottle soap dispenser as a reservoir of *S. marcescens* ($P = 0.032$). Infants with *S. marcescens* colonisation or infection were also more likely to have been exposed to a central or percutaneous venous catheter ($P = 0.05$) and had had longer exposure to endotracheal intubation ($P = 0.05$). Soap dispensers are used in many hospitals and may be an unrecognised source of nosocomial infections. This potential source of infection could be reduced by using 'airless' dispensers which have no air intake for the distribution of soap. Prompt intervention and strict adherence to alcoholic hand disinfection were the key factors that led to the successful control of this outbreak.
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Introduction

Serratia marcescens is a nosocomial pathogen involved in many outbreaks and endemic nosocomial infections.[1] Outbreaks of *S. marcescens* have been traced to several sources, such as

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contaminated antiseptic solution or soap, tap water, hand soap, fluid tanks of nebulisers, breast pumps, milk bottles, laryngoscopes, bronchoscopes, heparin—saline solution, and recently, contaminated intravenous magnesium sulphate solution.[2–16] No source was identified in other studies.[17,18]

This study describes an outbreak of *S. marcescens* that occurred over a three-month period in a neonatal intensive care unit (NICU), in which a retrospective case—control study was performed to identify risk factors for infection or colonisation with *S. marcescens*.

Methods

Hospital

The study was carried out in an 1819-bed, tertiary care, university teaching hospital in Rennes, France. The neonatal intensive care unit (NICU) is a 12-bed unit with 10 rooms.

Epidemic investigation

Each week, all bacteriological positive results from the NICU are routinely discussed by a neonatologist and a bacteriologist. In early June 2006, four infants were identified with cultures of *S. marcescens*, and so all neonates on the unit were screened for respiratory and gastrointestinal carriage. This screening was repeated weekly and for each new admission. An audit of hygiene practices and infection control of the healthcare environment was carried out. Environmental samples were collected based on the results of the audit.

Culture surveys

Water samples (1000 mL) from each room were filtered, and the filters were cultured on blood agar. Samples of unmedicated soap (1 mL) were plated onto chocolate agar plates (bioMérieux, Marcy l'Etoile, France). All the plates were incubated for 48 h at 37 °C and for 72 h at 22 °C. Bacterial colonies were identified using a commercial identification strip (API 20E Systems, bioMérieux).

Antimicrobial susceptibility testing

S. marcescens isolates were tested for susceptibility to a panel of 23 antimicrobial agents: amoxicillin, amoxicillin/clavulanate, ticarcillin, ticarcillin/clavulanate, piperacillin/tazobactam, imipenem, aztreonam, cefalotin, cefoxitin, cefamandole, cefotaxime, ertapenem, ceftazidime, cefepime, amikacin, tobramycin, gentamicin, nalidixic acid, ciprofloxacin, norfloxacin, fosfomycin, colistin, co-trimoxazole.

Susceptibility testing was performed by using an agar diffusion method according to current recommendations of the French Society for Microbiology.

Pulsed-field gel electrophoresis (PFGE)

Chromosomal DNA was extracted from stored *S. marcescens* isolates (Cryobeds, AES Laboratoires, Bruz, France). DNA was digested with *Xba*I (Promega, Charbonnières, France) and PFGE was performed.[19] The pulse time was ramped from 10—90 s and gels were run for 24 h.

The gels were stained with ethidium bromide and photographed under ultraviolet light. Isolates were considered to be the same strain if all bands matched, to be subtypes of the same strain if one to three bands differed, and to be different strains if more than three bands differed.[20]

Case—control study

The infection control team reviewed the medical records to identify possible risk factors for colonisation or infection. Previously reported risk factors include: female gender, lower gestational age, birthweight, preterm birth, prolonged respiratory therapy, prolonged use of antibiotics, maternal antimicrobial therapy with β-lactams prior to delivery, and oral cleaning care.[7,21–25] Based on these studies, each case infant was matched to three randomly selected control infants by four criteria.

A case was defined as any patient who had the epidemic *S. marcescens* strain isolated from a clinical specimen. Controls were infants who: (a) were hospitalised in the NICU during the same period but whose clinical specimens did not yield the epidemic strain; (b) were hospitalised in the NICU for at least as long as the time from admission to infection for the matched case patient (i.e. exposure time); (c) had a primary diagnosis that was similar to that of the affected patient; and (d) were within two weeks of age of the case patient. If an exact match could not be identified, the selection criteria were prioritised in the order listed above.

Data on risk factors were taken from the patients' medical records and were analysed using Epi-Info, version 6.04 (CDC). Potential risk factors, represented by continuous variables, were assessed using Student's *t*-test or Wilcoxon test. Categorical variables were assessed using χ^2-test or

Fisher's exact test. $P \leq 0.05$ was considered to be statistically significant.

Results

Description of the epidemic

On 8 June 2006, the neonatologist and the bacteriologist in the NICU notified the infection control practitioner that two hospitalised infants were colonised (patients B, D; Figure 1) and two were infected (patients A, C; Figure 1) by *S. marcescens*. All the isolates were the same antibiotype (resistant to amoxicillin, amoxicillin/clavulanate, cefalotin, cefamandole and colistin; intermediate to cefoxitin; susceptible to ticarcillin, ticarcillin/clavulanate, piperacillin/tazobactam, imipenem, aztreonam, cefotaxime, ertapenem, ceftazidime, cefepime, amikacin, tobramycin, gentamicin, nalidixic acid, ciprofloxacin, norfloxacin, fosfomycin and cotrimoxazole). The infection control team implemented isolation precautions for the four infants. Screening for both respiratory and gastrointestinal carriage of all infants in the NICU was undertaken. Despite these precautions, a fifth patient (patient E; Figure 1) was identified as being infected with a strain of *S. marcescens* having a similar antibiotype. PFGE results indicated that all five patients were infected or colonised with the same strain of *S. marcescens*. The results of the infection control audit suggested that it was unlikely that devices, drugs or incubators were an environmental source. Devices used for multiple patients such as breast pumps, milk bottles, and bronchoscope were used with appropriate disinfection. Each bottle of antiseptic had been dated, and was discarded after each infant's discharge. The daily cleaning of incubators, and their periodic disinfection were observed to comply with infection control guidelines. Based on these observations, the investigation of the outbreak was extended, and tap water and liquid soap samples were analysed. However, the infection control audit also showed that alcohol-based hand rubbing and use of gloves between infants were not being performed adequately.

Environmental culture surveys

None of the water samples collected from the 10 patients' rooms was contaminated with *S. marcescens*. However, samples of the single soap dispenser collected from room no. 10 grew *S. marcescens*. This isolate had the same antibiotype and PFGE pattern as the epidemic strain of *S. marcescens*.

Intervention

Following the positive result from the soap sample, the unmedicated soap was removed from patient

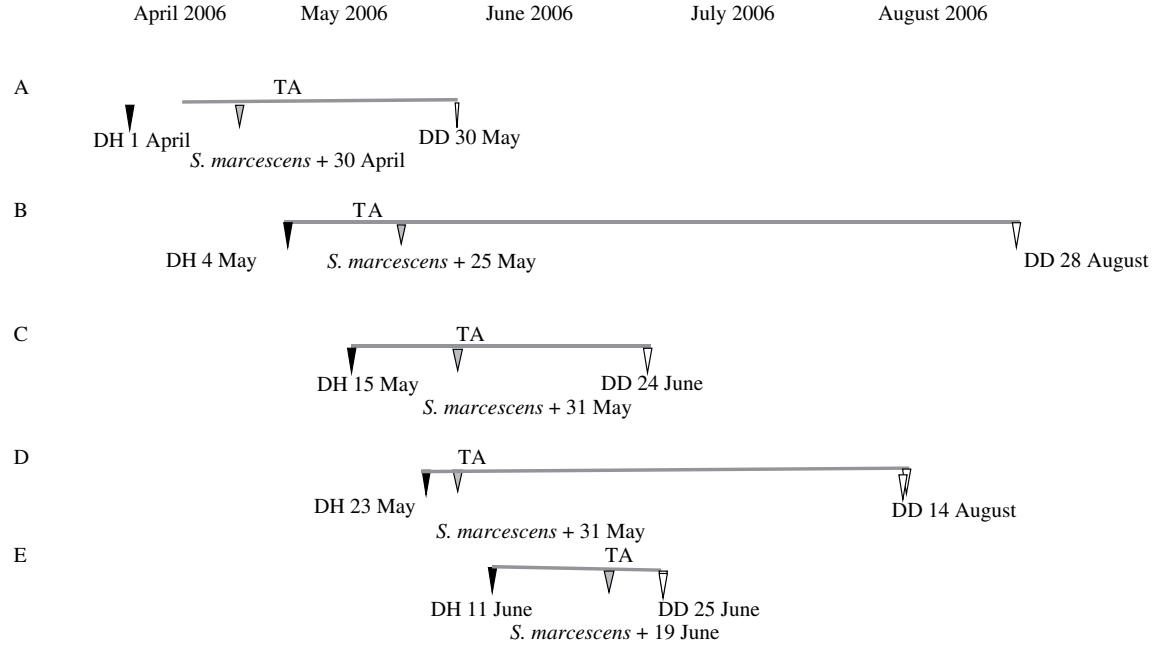

Figure 1 Graphic representation of *Serratia marcescens* outbreak. TA, transtracheal aspirate specimen positive for *S. marcescens*; DH, date of hospitalisation in the neonatal intensive care unit (NICU); DD, date of departure from the NICU.

rooms after each discharge. Before the outbreak, staff in the affected unit changed the soap only when the bottle soap dispenser was empty. The soap bottle dispensers were replaced with 'airless' dispensers in every room. These have a flexible bag as the reservoir and an internal pump, and were wall-mounted.

An education program was instituted to reinforce adherence to universal precautions, and the use of alcohol-based hand rub for all care. Despite these measures, a sixth case (patient F) was identified in November 2006. The infection control staff reinforced the use of alcohol-based hand rub for all care, and nearly one year later, no further epidemic cases have been identified.

Case–control study

All the case and control patients were matched for exposure time, primary diagnosis and age (Table I). As indicated in Table II, cases were more likely to be exposed to central or percutaneous venous catheters than controls ($P = 0.05$). However, the mean duration of exposure to central or percutaneous venous catheter was nine days for case patients and 12 days for control patients ($P = 0.46$) (Table II). Cases had longer exposure to endotracheal intubation (median of nine days), than controls (six days) ($P = 0.05$) (Table II). The case–control analysis confirmed that hospitalisation in the room contaminated by the unmedicated soap was a risk factor for infection or colonisation with *S. marcescens*. Three of the five cases were nursed in room no. 10 compared with one of 15 controls ($P = 0.032$) (Table II).

Table I Demographic and clinical characteristics of case and control patients

	Cases ($N = 5$)	Controls ($N = 15$)	*P* value
Male	4 (80)	8 (53)	0.6
Age of admission (days), median (range)	10 (1–23)	1 (1–30)	0.31
Birthweight (g), mean ± SD	924 ± 920	1689 ± 950	0.12
Weight on admission (g), median (range)	1892 (445–8160)	1225 (610–3280)	0.84
Reason for hospitalisation			
Prematurity	3 (60)	9 (60)	1
Congenital malformations	1 (20)	2 (13)	1
Respiratory distress syndrome	0 (0)	3 (20)	0.54
Operative procedures	0 (0)	1 (7)	1

ND, not done.
Data are no. (%) of patients, unless otherwise indicated.

Discussion

Serratia marcescens has been reported to cause 5% of nosocomial infections in pediatric intensive care and 15% in neonatal units.[26] Different contaminated

Table II Drugs and other treatments to which case and control patients were exposed

	Cases ($N = 5$)	Controls ($N = 15$)	*P* value
Antepartum corticosteroid therapy	3 (60)	9 (60)	1
β-Lactam	2 (40)	6 (40)	1
β-Lactam and aminoglycoside	1 (20)	3 (20)	1
β-Lactam and vancomycin	1 (20)	4 (27)	1
Bottlefeeding	1 (20)	1 (7)	0.45
Nasogastric feeding tube	5 (100)	15 (100)	ND
Median days (range)	14 (9–30)	6 (1–63)	0.15
Parenteral nutrition	4 (80)	13 (87)	1
Median days (range)	13 (3–29)	6 (2–43)	0.50
Arterial catheter	0 (0)	1 (7)	1
Central, percutaneous venous catheter	5 (100)	7 (47)	0.05
Median days (range)	9 (2–23)	12 (3–34)	0.46
Umbilical venous catheter	2 (40)	9 (60)	0.61
Median days (range)	5 (3–7)	4 (2–12)	0.81
Endotracheal intubation	5 (100)	10 (67)	0.13
Median days (range)	9 (8–11)	6 (1–39)	0.05
Continuous positive airway pressure	3 (60)	9 (60)	0.63
Median days (range)	7 (1–12)	6 (2–64)	0.64
Hospitalisation in room no. 10 (with contaminated unmedicated soap)	3 (60)	1 (7)	0.032

ND, not done.
Data are no. (%) of patients, unless otherwise indicated.

sources have been implicated in outbreaks with *S. marcescens*.[2–16] To our knowledge, this is the first reported outbreak in which a case–control study, culture surveys and PFGE implicated unmedicated soap from a dispenser as a reservoir.

We hypothesise that the soap dispenser acted as a continuous source of *S. marcescens*, facilitating handborne transmission of *S. marcescens* by healthcare workers (HCWs). Several facts support this proposed mechanism.

First, three of the five infants who became infected or colonised with the epidemic strain were nursed in the room with the contaminated soap dispenser (room no. 10). HCWs who were in charge of those three infants also looked after different infants in the neonatal unit.

Second, the infants who were infected or colonised with the epidemic strain were more likely to have been exposed to a central or percutaneous venous catheter ($P = 0.05$) and endotracheal intubation ($P = 0.05$). All cases had *S. marcescens* cultured from transtracheal aspirates. Oral cleaning care has been recognised as a risk factor.[7]

Third, it was unlikely that the outbreak strain was selected by antibiotic use. There was no significant difference between the five cases and 15 controls with regard to antimicrobial therapy with β-lactams, β-lactam and aminoglycoside combination or β-lactam and vancomycin combination (Table II).

We believe that the design of the soap dispenser was an important factor in the spread of the epidemic *S. marcescens* strain. Contamination of the soap was probably due to a retrograde contamination during hand washing. The 'airless' soap dispenser reduced this risk of soap contamination, and was probably an important part of controlling the outbreak.

Potential limitations of this study include the fact that the sixth *S. marcescens* epidemic strain was detected five months after replacement of the contaminated soap. This may be explained by prolonged carriage by HCWs. DeVries *et al.* sampled the hands of 100 HCWs and showed colonisation of a single HCW with the epidemic strain of *S. marcescens*.[27] Although this HCW went on leave, repeated culture surveys found prolonged carriage of the epidemic strain on the hands of the other HCWs for three months. This hypothesis cannot be proved in our study, as in France legal agreement is required for sampling HCWs' hands and this was not allowed in the unit. However, nearly one year later, no further cases with the epidemic strain of *S. marcescens* have been identified.

Our results suggest that the soap dispenser acted as the source of *S. marcescens* which facilitated handborne transmission of *S. marcescens* by HCWs.

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Guideline for Hand Hygiene in Health-Care Settings

Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force

INSIDE: Continuing Education Examination

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Guideline for Hand Hygiene in Health-Care Settings

Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force

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Summary

The Guideline for Hand Hygiene in Health-Care Settings provides health-care workers (HCWs) with a review of data regarding handwashing and hand antisepsis in health-care settings. In addition, it provides specific recommendations to promote improved hand-hygiene practices and reduce transmission of pathogenic microorganisms to patients and personnel in health-care settings. This report reviews studies published since the 1985 CDC guideline (Garner JS, Favero MS. CDC guideline for handwashing and hospital environmental control, 1985. Infect Control 1986;7:231–43) *and the 1995 APIC guideline* (Larson EL, APIC Guidelines Committee. APIC guideline for handwashing and hand antisepsis in health care settings. Am J Infect Control 1995;23:251–69) *were issued and provides an in-depth review of hand-hygiene practices of HCWs, levels of adherence of personnel to recommended handwashing practices, and factors adversely affecting adherence. New studies of the in vivo efficacy of alcohol-based hand rubs and the low incidence of dermatitis associated with their use are reviewed. Recent studies demonstrating the value of multidisciplinary hand-hygiene promotion programs and the potential role of alcohol-based hand rubs in improving hand-hygiene practices are summarized. Recommendations concerning related issues (e.g., the use of surgical hand antiseptics, hand lotions or creams, and wearing of artificial fingernails) are also included.*

Part I. Review of the Scientific Data Regarding Hand Hygiene

Historical Perspective

For generations, handwashing with soap and water has been considered a measure of personal hygiene (*1*). The concept of cleansing hands with an antiseptic agent probably emerged in the early 19th century. As early as 1822, a French pharmacist demonstrated that solutions containing chlorides of lime or soda could eradicate the foul odors associated with human corpses and that such solutions could be used as disinfectants and antiseptics (*2*). In a paper published in 1825, this pharmacist stated that physicians and other persons attending patients with contagious diseases would benefit from moistening their hands with a liquid chloride solution (*2*).

In 1846, Ignaz Semmelweis observed that women whose babies were delivered by students and physicians in the First Clinic at the General Hospital of Vienna consistently had a higher mortality rate than those whose babies were delivered by midwives in the Second Clinic (*3*). He noted that physicians who went directly from the autopsy suite to the obstetrics ward had a disagreeable odor on their hands despite washing their hands with soap and water upon entering the obstetrics clinic. He postulated that the puerperal fever that affected so many parturient women was caused by "cadaverous particles" transmitted from the autopsy suite to the obstetrics ward via the hands of students and physicians. Perhaps because of the known deodorizing effect of chlorine compounds, as of May 1847, he insisted that students and physicians clean their hands with a chlorine solution between each patient in the clinic. The maternal mortality rate in the First Clinic subsequently dropped dramatically and remained low for years. This intervention by Semmelweis represents the first evidence indicating that cleansing heavily contaminated hands with an antiseptic agent between patient contacts may reduce health-care–associated transmission of contagious diseases more effectively than handwashing with plain soap and water.

In 1843, Oliver Wendell Holmes concluded independently that puerperal fever was spread by the hands of health personnel (*1*). Although he described measures that could be taken to limit its spread, his recommendations had little impact on

The material in this report originated in the National Center for Infectious Diseases, James M. Hughes, M.D., Director; and the Division of Healthcare Quality Promotion, Steve Solomon, M.D., Acting Director.

obstetric practices at the time. However, as a result of the seminal studies by Semmelweis and Holmes, handwashing gradually became accepted as one of the most important measures for preventing transmission of pathogens in health-care facilities.

In 1961, the U. S. Public Health Service produced a training film that demonstrated handwashing techniques recommended for use by health-care workers (HCWs) (*4*). At the time, recommendations directed that personnel wash their hands with soap and water for 1–2 minutes before and after patient contact. Rinsing hands with an antiseptic agent was believed to be less effective than handwashing and was recommended only in emergencies or in areas where sinks were unavailable.

In 1975 and 1985, formal written guidelines on handwashing practices in hospitals were published by CDC (*5,6*). These guidelines recommended handwashing with nonantimicrobial soap between the majority of patient contacts and washing with antimicrobial soap before and after performing invasive procedures or caring for patients at high risk. Use of waterless antiseptic agents (e.g., alcohol-based solutions) was recommended only in situations where sinks were not available.

In 1988 and 1995, guidelines for handwashing and hand antisepsis were published by the Association for Professionals in Infection Control (APIC) (*7,8*). Recommended indications for handwashing were similar to those listed in the CDC guidelines. The 1995 APIC guideline included more detailed discussion of alcohol-based hand rubs and supported their use in more clinical settings than had been recommended in earlier guidelines. In 1995 and 1996, the Healthcare Infection Control Practices Advisory Committee (HICPAC) recommended that either antimicrobial soap or a waterless antiseptic agent be used for cleaning hands upon leaving the rooms of patients with multidrug-resistant pathogens (e.g., vancomycin-resistant enterococci [VRE] and methicillin-resistant *Staphylococcus aureus* [MRSA]) (*9,10*). These guidelines also provided recommendations for handwashing and hand antisepsis in other clinical settings, including routine patient care. Although the APIC and HICPAC guidelines have been adopted by the majority of hospitals, adherence of HCWs to recommended handwashing practices has remained low (*11,12*).

Recent developments in the field have stimulated a review of the scientific data regarding hand hygiene and the development of new guidelines designed to improve hand-hygiene practices in health-care facilities. This literature review and accompanying recommendations have been prepared by a Hand Hygiene Task Force, comprising representatives from HICPAC, the Society for Healthcare Epidemiology of America (SHEA), APIC, and the Infectious Diseases Society of America (IDSA).

Normal Bacterial Skin Flora

To understand the objectives of different approaches to hand cleansing, a knowledge of normal bacterial skin flora is essential. Normal human skin is colonized with bacteria; different areas of the body have varied total aerobic bacterial counts (e.g., 1×10^6 colony forming units (CFUs)/cm^2 on the scalp, 5×10^5 CFUs/cm^2 in the axilla, 4×10^4 CFUs/cm^2 on the abdomen, and 1×10^4 CFUs/cm^2 on the forearm) (*13*). Total bacterial counts on the hands of medical personnel have ranged from 3.9×10^4 to 4.6×10^6 (*14–17*). In 1938, bacteria recovered from the hands were divided into two categories: transient and resident (*14*). Transient flora, which colonize the superficial layers of the skin, are more amenable to removal by routine handwashing. They are often acquired by HCWs during direct contact with patients or contact with contaminated environmental surfaces within close proximity of the patient. Transient flora are the organisms most frequently associated with health-care–associated infections. Resident flora, which are attached to deeper layers of the skin, are more resistant to removal. In addition, resident flora (e.g., coagulase-negative staphylococci and diphtheroids) are less likely to be associated with such infections. The hands of HCWs may become persistently colonized with pathogenic flora (e.g., *S. aureus*), gram-negative bacilli, or yeast. Investigators have documented that, although the number of transient and resident flora varies considerably from person to person, it is often relatively constant for any specific person (*14,18*).

Physiology of Normal Skin

The primary function of the skin is to reduce water loss, provide protection against abrasive action and microorganisms, and act as a permeability barrier to the environment. The basic structure of skin includes, from outer- to innermost layer, the superficial region (i.e., the stratum corneum or horny layer, which is 10- to 20-µm thick), the viable epidermis (50- to 100-µm thick), the dermis (1- to 2-mm thick), and the hypodermis (1- to 2-mm thick). The barrier to percutaneous absorption lies within the stratum corneum, the thinnest and smallest compartment of the skin. The stratum corneum contains the corneocytes (or horny cells), which are flat, polyhedral-shaped nonnucleated cells, remnants of the terminally differentiated keratinocytes located in the viable epidermis. Corneocytes are composed primarily of insoluble bundled keratins surrounded by a cell envelope stabilized by cross-linked proteins and covalently bound lipid. Interconnecting the corneocytes of the stratum corneum are polar structures (e.g., corneodesmosomes), which contribute to stratum corneum cohesion.

The intercellular region of the stratum corneum is composed of lipid primarily generated from the exocytosis of lamellar bodies during the terminal differentiation of the keratinocytes. The intercellular lipid is required for a competent skin barrier and forms the only continuous domain. Directly under the stratum corneum is a stratified epidermis, which is composed primarily of 10–20 layers of keratinizing epithelial cells that are responsible for the synthesis of the stratum corneum. This layer also contains melanocytes involved in skin pigmentation; Langerhans cells, which are important for antigen presentation and immune responses; and Merkel cells, whose precise role in sensory reception has yet to be fully delineated. As keratinocytes undergo terminal differentiation, they begin to flatten out and assume the dimensions characteristic of the corneocytes (i.e., their diameter changes from 10–12 µm to 20–30 µm, and their volume increases by 10- to 20-fold). The viable epidermis does not contain a vascular network, and the keratinocytes obtain their nutrients from below by passive diffusion through the interstitial fluid.

The skin is a dynamic structure. Barrier function does not simply arise from the dying, degeneration, and compaction of the underlying epidermis. Rather, the processes of cornification and desquamation are intimately linked; synthesis of the stratum corneum occurs at the same rate as loss. Substantial evidence now confirms that the formation of the skin barrier is under homeostatic control, which is illustrated by the epidermal response to barrier perturbation by skin stripping or solvent extraction. Circumstantial evidence indicates that the rate of keratinocyte proliferation directly influences the integrity of the skin barrier. A general increase in the rate of proliferation results in a decrease in the time available for 1) uptake of nutrients (e.g., essential fatty acids), 2) protein and lipid synthesis, and 3) processing of the precursor molecules required for skin-barrier function. Whether chronic but quantitatively smaller increases in rate of epidermal proliferation also lead to changes in skin-barrier function remains unclear. Thus, the extent to which the decreased barrier function caused by irritants is caused by an increased epidermal proliferation also is unknown.

The current understanding of the formation of the stratum corneum has come from studies of the epidermal responses to perturbation of the skin barrier. Experimental manipulations that disrupt the skin barrier include 1) extraction of skin lipids with apolar solvents, 2) physical stripping of the stratum corneum using adhesive tape, and 3) chemically induced irritation. All of these experimental manipulations lead to a decreased skin barrier as determined by transepidermal water loss (TEWL). The most studied experimental system is the treatment of mouse skin with acetone. This experiment results in a marked and immediate increase in TEWL, and therefore a decrease in skin-barrier function. Acetone treatment selectively removes glycerolipids and sterols from the skin, which indicates that these lipids are necessary, though perhaps not sufficient in themselves, for barrier function. Detergents act like acetone on the intercellular lipid domain. The return to normal barrier function is biphasic: 50%–60% of barrier recovery typically occurs within 6 hours, but complete normalization of barrier function requires 5–6 days.

Definition of Terms

Alcohol-based hand rub. An alcohol-containing preparation designed for application to the hands for reducing the number of viable microorganisms on the hands. In the United States, such preparations usually contain 60%–95% ethanol or isopropanol.

Antimicrobial soap. Soap (i.e., detergent) containing an antiseptic agent.

Antiseptic agent. Antimicrobial substances that are applied to the skin to reduce the number of microbial flora. Examples include alcohols, chlorhexidine, chlorine, hexachlorophene, iodine, chloroxylenol (PCMX), quaternary ammonium compounds, and triclosan.

Antiseptic handwash. Washing hands with water and soap or other detergents containing an antiseptic agent.

Antiseptic hand rub. Applying an antiseptic hand-rub product to all surfaces of the hands to reduce the number of microorganisms present.

Cumulative effect. A progressive decrease in the numbers of microorganisms recovered after repeated applications of a test material.

Decontaminate hands. To Reduce bacterial counts on hands by performing antiseptic hand rub or antiseptic handwash.

Detergent. Detergents (i.e., surfactants) are compounds that possess a cleaning action. They are composed of both hydrophilic and lipophilic parts and can be divided into four groups: anionic, cationic, amphoteric, and nonionic detergents. Although products used for handwashing or antiseptic handwash in health-care settings represent various types of detergents, the term "soap" is used to refer to such detergents in this guideline.

Hand antisepsis. Refers to either antiseptic handwash or antiseptic hand rub.

Hand hygiene. A general term that applies to either handwashing, antiseptic handwash, antiseptic hand rub, or surgical hand antisepsis.

Handwashing. Washing hands with plain (i.e., non-antimicrobial) soap and water.

Persistent activity. Persistent activity is defined as the prolonged or extended antimicrobial activity that prevents or inhibits the proliferation or survival of microorganisms after application of the product. This activity may be demonstrated by sampling a site several minutes or hours after application and demonstrating bacterial antimicrobial effectiveness when compared with a baseline level. This property also has been referred to as "residual activity." Both substantive and nonsubstantive active ingredients can show a persistent effect if they substantially lower the number of bacteria during the wash period.

Plain soap. Plain soap refers to detergents that do not contain antimicrobial agents or contain low concentrations of antimicrobial agents that are effective solely as preservatives.

Substantivity. Substantivity is an attribute of certain active ingredients that adhere to the stratum corneum (i.e., remain on the skin after rinsing or drying) to provide an inhibitory effect on the growth of bacteria remaining on the skin.

Surgical hand antisepsis. Antiseptic handwash or antiseptic hand rub performed preoperatively by surgical personnel to eliminate transient and reduce resident hand flora. Antiseptic detergent preparations often have persistent antimicrobial activity.

Visibly soiled hands. Hands showing visible dirt or visibly contaminated with proteinaceous material, blood, or other body fluids (e.g., fecal material or urine).

Waterless antiseptic agent. An antiseptic agent that does not require use of exogenous water. After applying such an agent, the hands are rubbed together until the agent has dried.

Food and Drug Administration (FDA) product categories. The 1994 FDA Tentative Final Monograph for Health-Care Antiseptic Drug Products divided products into three categories and defined them as follows (*19*):

- *Patient preoperative skin preparation.* A fast-acting, broad-spectrum, and persistent antiseptic-containing preparation that substantially reduces the number of microorganisms on intact skin.
- *Antiseptic handwash or HCW handwash*. An antiseptic-containing preparation designed for frequent use; it reduces the number of microorganisms on intact skin to an initial baseline level after adequate washing, rinsing, and drying; it is broad-spectrum, fast-acting, and if possible, persistent.
- *Surgical hand scrub*. An antiseptic-containing preparation that substantially reduces the number of microorganisms on intact skin; it is broad-spectrum, fast-acting, and persistent.

Evidence of Transmission of Pathogens on Hands

Transmission of health-care–associated pathogens from one patient to another via the hands of HCWs requires the following sequence of events:

- Organisms present on the patient's skin, or that have been shed onto inanimate objects in close proximity to the patient, must be transferred to the hands of HCWs.
- These organisms must then be capable of surviving for at least several minutes on the hands of personnel.
- Next, handwashing or hand antisepsis by the worker must be inadequate or omitted entirely, or the agent used for hand hygiene must be inappropriate.
- Finally, the contaminated hands of the caregiver must come in direct contact with another patient, or with an inanimate object that will come into direct contact with the patient.

Health-care–associated pathogens can be recovered not only from infected or draining wounds, but also from frequently colonized areas of normal, intact patient skin (*20– 31*). The perineal or inguinal areas are usually most heavily colonized, but the axillae, trunk, and upper extremities (including the hands) also are frequently colonized (*23,25,26,28,30–32*). The number of organisms (e.g., *S. aureus*, *Proteus mirabilis*, *Klebsiella* spp., and *Acinetobacter* spp.) present on intact areas of the skin of certain patients can vary from 100 to $10^6/cm^2$ (*25,29,31,33*). Persons with diabetes, patients undergoing dialysis for chronic renal failure, and those with chronic dermatitis are likely to have areas of intact skin that are colonized with *S. aureus* (*34–41*). Because approximately 10^6 skin squames containing viable microorganisms are shed daily from normal skin (*42*), patient gowns, bed linen, bedside furniture, and other objects in the patient's immediate environment can easily become contaminated with patient flora (*30,43–46*). Such contamination is particularly likely to be caused by staphylococci or enterococci, which are resistant to dessication.

Data are limited regarding the types of patient-care activities that result in transmission of patient flora to the hands of personnel (*26,45–51*). In the past, attempts have been made to stratify patient-care activities into those most likely to cause hand contamination (*52*), but such stratification schemes were never validated by quantifying the level of bacterial contamination that occurred. Nurses can contaminate their hands with 100–1,000 CFUs of *Klebsiella* spp. during "clean" activities (e.g., lifting a patient; taking a patient's pulse, blood pressure, or oral temperature; or touching a patient's hand, shoulder, or groin) (*48*). Similarly, in another study, hands were cultured of nurses who touched the groins of patients heavily colonized with *P. mirabilis* (*25*); 10–600 CFUs/mL of this

organism were recovered from glove juice samples from the nurses' hands. Recently, other researchers studied contamination of HCWs' hands during activities that involved direct patient-contact wound care, intravascular catheter care, respiratory-tract care, and the handling of patient secretions (*51*). Agar fingertip impression plates were used to culture bacteria; the number of bacteria recovered from fingertips ranged from 0 to 300 CFUs. Data from this study indicated that direct patient contact and respiratory-tract care were most likely to contaminate the fingers of caregivers. Gram-negative bacilli accounted for 15% of isolates and *S. aureus* for 11%. Duration of patient-care activity was strongly associated with the intensity of bacterial contamination of HCWs' hands.

HCWs can contaminate their hands with gram-negative bacilli, *S. aureus*, enterococci, or *Clostridium difficile* by performing "clean procedures" or touching intact areas of the skin of hospitalized patients (*26,45,46,53*). Furthermore, personnel caring for infants with respiratory syncytial virus (RSV) infections have acquired RSV by performing certain activities (e.g., feeding infants, changing diapers, and playing with infants) (*49*). Personnel who had contact only with surfaces contaminated with the infants' secretions also acquired RSV by contaminating their hands with RSV and inoculating their oral or conjunctival mucosa. Other studies also have documented that HCWs may contaminate their hands (or gloves) merely by touching inanimate objects in patient rooms (*46,53–56*). None of the studies concerning hand contamination of hospital personnel were designed to determine if the contamination resulted in transmission of pathogens to susceptible patients.

Other studies have documented contamination of HCWs' hands with potential health-care–associated pathogens, but did not relate their findings to the specific type of preceding patient contact (*15,17,57–62*). For example, before glove use was common among HCWs, 15% of nurses working in an isolation unit carried a median of 1 x 10^4 CFUs of *S. aureus* on their hands (*61*). Of nurses working in a general hospital, 29% had *S. aureus* on their hands (median count: 3,800 CFUs), whereas 78% of those working in a hospital for dermatology patients had the organism on their hands (median count: 14.3 x 10^6 CFUs). Similarly, 17%–30% of nurses carried gram-negative bacilli on their hands (median counts: 3,400–38,000 CFUs). One study found that *S. aureus* could be recovered from the hands of 21% of intensive-care–unit personnel and that 21% of physician and 5% of nurse carriers had >1,000 CFUs of the organism on their hands (*59*). Another study found lower levels of colonization on the hands of personnel working in a neurosurgery unit, with an average of 3 CFUs of *S. aureus* and 11 CFUs of gram-negative bacilli (*16*). Serial cultures revealed that 100% of HCWs carried gram-negative bacilli at least once, and 64% carried *S. aureus* at least once.

Models of Hand Transmission

Several investigators have studied transmission of infectious agents by using different experimental models. In one study, nurses were asked to touch the groins of patients heavily colonized with gram-negative bacilli for 15 seconds — as though they were taking a femoral pulse (*25*). Nurses then cleaned their hands by washing with plain soap and water or by using an alcohol hand rinse. After cleaning their hands, they touched a piece of urinary catheter material with their fingers, and the catheter segment was cultured. The study revealed that touching intact areas of moist skin of the patient transferred enough organisms to the nurses' hands to result in subsequent transmission to catheter material, despite handwashing with plain soap and water.

The transmission of organisms from artificially contaminated "donor" fabrics to clean "recipient" fabrics via hand contact also has been studied. Results indicated that the number of organisms transmitted was greater if the donor fabric or the hands were wet upon contact (*63*). Overall, only 0.06% of the organisms obtained from the contaminated donor fabric were transferred to recipient fabric via hand contact. *Staphylococcus saprophyticus, Pseudomonas aeruginosa,* and *Serratia* spp. were also transferred in greater numbers than was *Escherichia coli* from contaminated fabric to clean fabric after hand contact (*64*). Organisms are transferred to various types of surfaces in much larger numbers (i.e., >10^4) from wet hands than from hands that are thoroughly dried (*65*).

Relation of Hand Hygiene and Acquisition of Health-Care–Associated Pathogens

Hand antisepsis reduces the incidence of health-care–associated infections (*66,67*). An intervention trial using historical controls demonstrated in 1847 that the mortality rate among mothers who delivered in the First Obstetrics Clinic at the General Hospital of Vienna was substantially lower when hospital staff cleaned their hands with an antiseptic agent than when they washed their hands with plain soap and water (*3*).

In the 1960s, a prospective, controlled trial sponsored by the National Institutes of Health and the Office of the Surgeon General demonstrated that infants cared for by nurses who did not wash their hands after handling an index infant colonized with *S. aureus* acquired the organism more often and more rapidly than did infants cared for by nurses who used hexachlorophene to clean their hands between infant

contacts *(68)*. This trial provided evidence that, when compared with no handwashing, washing hands with an antiseptic agent between patient contacts reduces transmission of health-care–associated pathogens.

Trials have studied the effects of handwashing with plain soap and water versus some form of hand antisepsis on health-care–associated infection rates (*69,70*). Health-care–associated infection rates were lower when antiseptic handwashing was performed by personnel (*69*). In another study, antiseptic handwashing was associated with lower health-care–associated infection rates in certain intensive-care units, but not in others (70).

Health-care–associated infection rates were lower after antiseptic handwashing using a chlorhexidine-containing detergent compared with handwashing with plain soap or use of an alcohol-based hand rinse (*71*). However, because only a minimal amount of the alcohol rinse was used during periods when the combination regimen also was in use and because adherence to policies was higher when chlorhexidine was available, determining which factor (i.e., the hand-hygiene regimen or differences in adherence) accounted for the lower infection rates was difficult. Investigators have determined also that health-care–associated acquisition of MRSA was reduced when the antimicrobial soap used for hygienic handwashing was changed (*72,73*).

Increased handwashing frequency among hospital staff has been associated with decreased transmission of *Klebsiella* spp. among patients (*48*); these studies, however, did not quantitate the level of handwashing among personnel. In a recent study, the acquisition of various health-care–associated pathogens was reduced when hand antisepsis was performed more frequently by hospital personnel (*74*); both this study and another (*75*) documented that the prevalence of health-care–associated infections decreased as adherence to recommended hand-hygiene measures improved.

Outbreak investigations have indicated an association between infections and understaffing or overcrowding; the association was consistently linked with poor adherence to hand hygiene. During an outbreak investigation of risk factors for central venous catheter-associated bloodstream infections (*76*), after adjustment for confounding factors, the patient-to-nurse ratio remained an independent risk factor for bloodstream infection, indicating that nursing staff reduction below a critical threshold may have contributed to this outbreak by jeopardizing adequate catheter care. The understaffing of nurses can facilitate the spread of MRSA in intensive-care settings (*77*) through relaxed attention to basic control measures (e.g., hand hygiene). In an outbreak of *Enterobacter cloacae* in a neonatal intensive-care unit (*78*), the daily number of hospitalized children was above the maximum capacity of the unit, resulting in an available space per child below current recommendations. In parallel, the number of staff members on duty was substantially less than the number necessitated by the workload, which also resulted in relaxed attention to basic infection-control measures. Adherence to hand-hygiene practices before device contact was only 25% during the workload peak, but increased to 70% after the end of the understaffing and overcrowding period. Surveillance documented that being hospitalized during this period was associated with a fourfold increased risk of acquiring a health-care–associated infection. This study not only demonstrates the association between workload and infections, but it also highlights the intermediate cause of antimicrobial spread: poor adherence to hand-hygiene policies.

Methods Used To Evaluate the Efficacy of Hand-Hygiene Products

Current Methods

Investigators use different methods to study the in vivo efficacy of handwashing, antiseptic handwash, and surgical hand antisepsis protocols. Differences among the various studies include 1) whether hands are purposely contaminated with bacteria before use of test agents, 2) the method used to contaminate fingers or hands, 3) the volume of hand-hygiene product applied to the hands, 4) the time the product is in contact with the skin, 5) the method used to recover bacteria from the skin after the test solution has been used, and 6) the method of expressing the efficacy of the product (i.e., either percent reduction in bacteria recovered from the skin or log reduction of bacteria released from the skin). Despite these differences, the majority of studies can be placed into one of two major categories: studies focusing on products to remove transient flora and studies involving products that are used to remove resident flora from the hands. The majority of studies of products for removing transient flora from the hands of HCWs involve artificial contamination of the volunteer's skin with a defined inoculum of a test organism before the volunteer uses a plain soap, an antimicrobial soap, or a waterless antiseptic agent. In contrast, products tested for the preoperative cleansing of surgeons' hands (which must comply with surgical hand-antisepsis protocols) are tested for their ability to remove resident flora from without artificially contaminating the volunteers' hands.

In the United States, antiseptic handwash products intended for use by HCWs are regulated by FDA's Division of Over-the-Counter Drug Products (OTC). Requirements for in vitro and in vivo testing of HCW handwash products and surgical

hand scrubs are outlined in the FDA Tentative Final Monograph for Healthcare Antiseptic Drug Products (TFM) (*19*). Products intended for use as HCW handwashes are evaluated by using a standardized method (*19*). Tests are performed in accordance with use directions for the test material. Before baseline bacterial sampling and before each wash with the test material, 5 mL of a standardized suspension of *Serratia marcescens* are applied to the hands and then rubbed over the surfaces of the hands. A specified volume of the test material is dispensed into the hands and is spread over the hands and lower one third of the forearms. A small amount of tap water is added to the hands, and hands are completely lathered for a specified time, covering all surfaces of the hands and the lower third of the forearms. Volunteers then rinse hands and forearms under 40°C tap water for 30 seconds. Ten washes with the test formulation are required. After the first, third, seventh, and tenth washes, rubber gloves or polyethylene bags used for sampling are placed on the right and left hands, and 75 mL of sampling solution is added to each glove; gloves are secured above the wrist. All surfaces of the hand are massaged for 1 minute, and samples are obtained aseptically for quantitative culture. No neutralizer of the antimicrobial is routinely added to the sampling solution, but if dilution of the antimicrobial in the sampling fluid does not result in demonstrable neutralization, a neutralizer specific for the test formulation is added to the sampling solution. For waterless formulations, a similar procedure is used. TFM criteria for efficacy are as follows: a 2-$\log_{10}$ reduction of the indicator organism on each hand within 5 minutes after the first use, and a 3-$\log_{10}$ reduction of the indicator organism on each hand within 5 minutes after the tenth use (*19*).

Products intended for use as surgical hand scrubs have been evaluated also by using a standardized method (*19*). Volunteers clean under fingernails with a nail stick and clip their fingernails. All jewelry is removed from hands and arms. Hands and two thirds of forearms are rinsed with tap water (38°C–42°C) for 30 seconds, and then they are washed with a nonantimicrobial soap for 30 seconds and are rinsed for 30 seconds under tap water. Baseline microbial hand counts can then be determined. Next, a surgical scrub is performed with the test formulation using directions provided by the manufacturer. If no instructions are provided with the formulation, two 5-minute scrubs of hands and forearms followed by rinsing are performed. Reduction from baseline microbial hand counts is determined in a series of 11 scrubs conducted during 5 days. Hands are sampled at 1 minute, 3 hours, and 6 hours after the first scrubs on day 1, day 2, and day 5. After washing, volunteers wear rubber gloves; 75 mL of sampling solution are then added to one glove, and all surfaces of the hands are massaged for 1 minute. Samples are then taken aseptically and cultured quantitatively. The other glove remains on the other hand for 6 hours and is sampled in the same manner. TFM requires that formulations reduce the number of bacteria 1 $\log_{10}$ on each hand within 1 minute of product application and that the bacterial cell count on each hand does not subsequently exceed baseline within 6 hours on day 1; the formulation must produce a 2-$\log_{10}$ reduction in microbial flora on each hand within 1 minute of product application by the end of the second day of enumeration and a 3-$\log_{10}$ reduction of microbial flora on each hand within 1 minute of product use by the end of the fifth day when compared with the established baseline (*19*).

The method most widely used in Europe to evaluate the efficacy of hand-hygiene agents is European Standard 1500–1997 (EN 1500—Chemical disinfectants and antiseptics. Hygienic hand-rub test method and requirements) (*79*). This method requires 12–15 test volunteers and an 18- to 24-hour growth of broth culture of *E. coli* K12. Hands are washed with a soft soap, dried, and then immersed halfway to the metacarpals in the broth culture for 5 seconds. Hands are removed from the broth culture, excess fluid is drained off, and hands are dried in the air for 3 minutes. Bacterial recovery for the initial value is obtained by kneading the fingertips of each hand separately for 60 seconds in 10 mL of tryptic soy broth (TSB) without neutralizers. The hands are removed from the broth and disinfected with 3 mL of the hand-rub agent for 30 seconds in a set design. The same operation is repeated with total disinfection time not exceeding 60 seconds. Both hands are rinsed in running water for 5 seconds and water is drained off. Fingertips of each hand are kneaded separately in 10 mL of TSB with added neutralizers. These broths are used to obtain the final value. Log_{10} dilutions of recovery medium are prepared and plated out. Within 3 hours, the same volunteers are tested with the reference disinfectant (60% 2-propanol [isopropanol]) and the test product. Colony counts are performed after 24 and 48 hours of incubation at 36°C. The average colony count of both left and right hand is used for evaluation. The log-reduction factor is calculated and compared with the initial and final values. The reduction factor of the test product should be superior or the same as the reference alcohol-based rub for acceptance. If a difference exists, then the results are analyzed statistically using the Wilcoxon test. Products that have log reductions substantially less than that observed with the reference alcohol-based hand rub (i.e., approximately 4 $\log_{10}$ reduction) are classified as not meeting the standard.

Because of different standards for efficacy, criteria cited in FDA TFM and the European EN 1500 document for establishing alcohol-based hand rubs vary (*1,19,79*). Alcohol-based

hand rubs that meet TFM criteria for efficacy may not necessarily meet the EN 1500 criteria for efficacy (*80*). In addition, scientific studies have not established the extent to which counts of bacteria or other microorganisms on the hands need to be reduced to minimize transmission of pathogens in health-care facilities (*1,8*); whether bacterial counts on the hands must be reduced by 1 $\log_{10}$ (90% reduction), 2 $\log_{10}$ (99%), 3 $\log_{10}$ (99.9%), or 4 $\log_{10}$ (99.99%) is unknown. Several other methods also have been used to measure the efficacy of antiseptic agents against various viral pathogens (*81–83*).

Shortcomings of Traditional Methodologies

Accepted methods of evaluating hand-hygiene products intended for use by HCWs require that test volunteers wash their hands with a plain or antimicrobial soap for 30 seconds or 1 minute, despite the observation in the majority of studies that the average duration of handwashing by hospital personnel is <15 seconds (*52,84–89*). A limited number of investigators have used 15-second handwashing or hygienic hand-wash protocols (*90–94*). Therefore, almost no data exist regarding the efficacy of plain or antimicrobial soaps under conditions in which they are actually used by HCWs. Similarly, certain accepted methods for evaluating waterless antiseptic agents for use as antiseptic hand rubs require that 3 mL of alcohol be rubbed into the hands for 30 seconds, followed by a repeat application for the same duration. This type of protocol also does not reflect actual usage patterns among HCWs. Furthermore, volunteers used in evaluations of products are usually surrogates for HCWs, and their hand flora may not reflect flora found on the hands of personnel working in health-care settings. Further studies should be conducted among practicing HCWs using standardized protocols to obtain more realistic views of microbial colonization and risk of bacterial transfer and cross-transmission (*51*).

Review of Preparations Used for Hand Hygiene

Plain (Non-Antimicrobial) Soap

Soaps are detergent-based products that contain esterified fatty acids and sodium or potassium hydroxide. They are available in various forms including bar soap, tissue, leaflet, and liquid preparations. Their cleaning activity can be attributed to their detergent properties, which result in removal of dirt, soil, and various organic substances from the hands. Plain soaps have minimal, if any, antimicrobial activity. However, handwashing with plain soap can remove loosely adherent transient flora. For example, handwashing with plain soap and water for 15 seconds reduces bacterial counts on the skin by 0.6–1.1 $\log_{10}$, whereas washing for 30 seconds reduces counts by 1.8–2.8 $\log_{10}$ (*1*). However, in several studies, handwashing with plain soap failed to remove pathogens from the hands of hospital personnel (*25,45*). Handwashing with plain soap can result in paradoxical increases in bacterial counts on the skin (*92,95–97*). Non-antimicrobial soaps may be associated with considerable skin irritation and dryness (*92,96,98*), although adding emollients to soap preparations may reduce their propensity to cause irritation. Occasionally, plain soaps have become contaminated, which may lead to colonization of hands of personnel with gram-negative bacilli (*99*).

Alcohols

The majority of alcohol-based hand antiseptics contain either isopropanol, ethanol, n-propanol, or a combination of two of these products. Although n-propanol has been used in alcohol-based hand rubs in parts of Europe for many years, it is not listed in TFM as an approved active agent for HCW handwashes or surgical hand-scrub preparations in the United States. The majority of studies of alcohols have evaluated individual alcohols in varying concentrations. Other studies have focused on combinations of two alcohols or alcohol solutions containing limited amounts of hexachlorophene, quaternary ammonium compounds, povidone-iodine, triclosan, or chlorhexidine gluconate (*61,93,100–119*).

The antimicrobial activity of alcohols can be attributed to their ability to denature proteins (*120*). Alcohol solutions containing 60%–95% alcohol are most effective, and higher concentrations are less potent (*120–122*) because proteins are not denatured easily in the absence of water (*120*). The alcohol content of solutions may be expressed as percent by weight (w/w), which is not affected by temperature or other variables, or as percent by volume (vol/vol), which can be affected by temperature, specific gravity, and reaction concentration (*123*). For example, 70% alcohol by weight is equivalent to 76.8% by volume if prepared at 15°C, or 80.5% if prepared at 25°C (*123*). Alcohol concentrations in antiseptic hand rubs are often expressed as percent by volume (*19*).

Alcohols have excellent in vitro germicidal activity against gram-positive and gram-negative vegetative bacteria, including multidrug-resistant pathogens (e.g., MRSA and VRE), *Mycobacterium tuberculosis*, and various fungi (*120–122,124–129*). Certain enveloped (lipophilic) viruses (e.g., herpes simplex virus, human immunodeficiency virus [HIV], influenza virus, respiratory syncytial virus, and vaccinia virus) are susceptible to alcohols when tested in vitro (*120,130,131*) (Table 1). Hepatitis B virus is an enveloped virus that is somewhat less susceptible but is killed by 60%–70% alcohol; hepatitis C virus also is likely killed by this percentage of alcohol (*132*). In a porcine tissue carrier model used to study antiseptic activity, 70% ethanol and 70% isopropanol were found to

TABLE 1. Virucidal activity of antiseptic agents against enveloped viruses

Ref. no.	Test method	Viruses	Agent	Results
(*379*)	Suspension	HIV	19% EA	LR = 2.0 in 5 minutes
(*380*)	Suspension	HIV	50% EA 35% IPA	LR > 3.5 LR > 3.7
(*381*)	Suspension	HIV	70% EA	LR = 7.0 in 1 minute
(*382*)	Suspension	HIV	70% EA	LR = 3.2B 5.5 in 30 seconds
(*383*)	Suspension	HIV	70% IPA/0.5% CHG 4% CHG	LR = 6.0 in 15 seconds LR = 6.0 in 15 seconds
(*384*)	Suspension	HIV	Chloroxylenol Benzalkonium chloride	Inactivated in 1 minute Inactivated in 1 minute
(*385*)	Suspension	HIV	Povidone-iodine Chlorhexidine	Inactivated Inactivated
(*386*)	Suspension	HIV	Detergent/0.5% PCMX	Inactivated in 30 seconds
(*387*)	Suspension/dried plasma chimpanzee challenge	HBV	70% IPA	LR = 6.0 in 10 minutes
(*388*)	Suspension/plasma chimpanzee challenge	HBV	80% EA	LR = 7.0 in 2 minutes
(*389*)	Suspension	HSV	95% EA 75% EA 95% IPA 70% EA + 0.5% CHG	LR > 5.0 in 1 minute LR > 5.0 LR > 5.0 LR > 5.0
(*130*)	Suspension	RSV	35% IPA 4% CHG	LR > 4.3 in 1 minute LR > 3.3
(*141*)	Suspension	Influenza Vaccinia	95% EA 95% EA	Undetectable in 30 seconds Undetectable in 30 seconds
(*141*)	Hand test	Influenza Vaccinia	95% EA 95% EA	LR > 2.5 LR > 2.5

Note: HIV = human immunodeficiency virus, EA = ethanol, LR = Log_{10} reduction, IPA = isopropanol, CHG = chlorhexidine gluconate, HBV = hepatitis B virus, RSV = respiratory syncitial virus, HSV = herpes simplex virus, HAV = hepatitis A virus, and PCMX = chloroxylenol.

reduce titers of an enveloped bacteriophage more effectively than an antimicrobial soap containing 4% chlorhexidine gluconate (*133*). Despite its effectiveness against these organisms, alcohols have very poor activity against bacterial spores, protozoan oocysts, and certain nonenveloped (nonlipophilic) viruses.

Numerous studies have documented the *in vivo* antimicrobial activity of alcohols. Alcohols effectively reduce bacterial counts on the hands (*14,121,125,134*). Typically, log reductions of the release of test bacteria from artificially contaminated hands average 3.5 log_{10} after a 30-second application and 4.0–5.0 log_{10} after a 1-minute application (*1*). In 1994, the FDA TFM classified ethanol 60%–95% as a Category I agent (i.e., generally safe and effective for use in antiseptic handwash or HCW hand-wash products) (*19*). Although TFM placed isopropanol 70%–91.3% in category IIIE (i.e., insufficient data to classify as effective), 60% isopropanol has subsequently been adopted in Europe as the reference standard against which alcohol-based hand-rub products are compared (*79*). Alcohols are rapidly germicidal when applied to the skin, but they have no appreciable persistent (i.e., residual) activity. However, regrowth of bacteria on the skin occurs slowly after use of alcohol-based hand antiseptics, presumably because of the sublethal effect alcohols have on some of the skin bacteria (*135,136*). Addition of chlorhexidine, quaternary ammonium compounds, octenidine, or triclosan to alcohol-based solutions can result in persistent activity (*1*).

Alcohols, when used in concentrations present in alcohol-based hand rubs, also have in vivo activity against several nonenveloped viruses (Table 2). For example, 70% isopropanol and 70% ethanol are more effective than medicated soap or nonmedicated soap in reducing rotavirus titers on fingerpads (*137,138*). A more recent study using the same test methods evaluated a commercially available product containing 60%

TABLE 2. Virucidal activity of antiseptic agents against nonenveloped viruses

Ref. no.	Test method	Viruses	Antiseptic	Result
(*390*)	Suspension	Rotavirus	4% CHG	LR < 3.0 in 1 minute
			10% Povidone-Iodine	LR > 3.0
			70% IPA/0.1% HCP	LR > 3.0
(*141*)	Hand test	Adenovirus	95% EA	LR > 1.4
		Poliovirus	95% EA	LR = 0.2–1.0
		Coxsackie	95% EA	LR = 1.1–1.3
	Finger test	Adenovirus	95% EA	LR > 2.3
		Poliovirus	95% EA	LR = 0.7–2.5
		Coxsackie	95% EA	LR = 2.9
(*389*)	Suspension	ECHO virus	95% EA	LR > 3.0 in 1 minute
			75% EA	LR $\leq$ 1.0
			95% IPA	LR = 0
			70% IPA + 0.5% CHG	LR = 0
(*140*)	Finger pad	HAV	70% EA	87.4% reduction
			62% EA foam	89.3% reduction
			plain soap	78.0% reduction
			4% CHG	89.6% reduction
			0.3% Triclosan	92.0% reduction
(*105*)	Finger tips	Bovine	n-propanol + IPA	LR = 3.8 in 30 seconds
		Rotavirus	70% IPA	LR = 3.1
			70% EA	LR = 2.9
			2% triclosan	LR = 2.1
			water (control)	LR = 1.3
			7.5% povidone-iodine	LR = 1.3
			plain soap	LR = 1.2
			4% CHG	LR = 0.5
(*137*)	Finger pad	Human	70% IPA	98.9% decrease in 10 seconds
		Rotavirus	plain soap	77.1%
(*138*)	Finger pad	Human	70% IPA	99.6% decrease in 10 seconds
		Rotavirus	2% CHG	80.3%
			plain soap	72.5%
(*81*)	Finger pad	Rotavirus	60% EA gel	LR > 3.0 in 10 seconds
		Rhinovirus	60% EA gel	LR > 3.0
		Adenovirus	60% EA gel	LR > 3.0
(*139*)	Finger pad	Poliovirus	70% EA	LR = 1.6 in 10 seconds
			70% IPA	LR = 0.8
(*200*)	Finger tips	Poliovirus	Plain soap	LR = 2.1
			80% EA	LR = 0.4

Note: HIV = human immunodeficiency virus, EA = ethanol, LR = Log_{10} reduction, IPA = isopropanol, CHG = chlorhexidine gluconate, HBV = hepatitis B virus, RSV = respiratory syncitial virus, HSV = herpes simplex virus, and HAV = hepatitis A virus.

ethanol and found that the product reduced the infectivity titers of three nonenveloped viruses (i.e., rotavirus, adenovirus, and rhinovirus) by >3 logs (*81*). Other nonenveloped viruses such as hepatitis A and enteroviruses (e.g., poliovirus) may require 70%–80% alcohol to be reliably inactivated (*82,139*). However, both 70% ethanol and a 62% ethanol foam product with emollients reduced hepatitis A virus titers on whole hands or fingertips more than nonmedicated soap; both were equally as effective as antimicrobial soap containing 4% chlorhexidine gluconate in reducing reduced viral counts on hands (*140*). In the same study, both 70% ethanol and the 62% ethanol foam product demonstrated greater virucidal activity against poliovirus than either non-antimicrobial soap or a 4% chlorhexidine gluconate-containing soap (*140*). However, depending on the alcohol concentration, the amount of time that hands are exposed to the alcohol, and viral variant, alcohol may not be effective against hepatitis A and other nonlipophilic viruses. The inactivation of nonenveloped viruses is influenced by temperature, disinfectant-virus volume ratio, and protein load (*141*). Ethanol has greater activity against viruses than isopropanol. Further in vitro and in vivo studies of both alcohol-based formulations and antimicrobial soaps are warranted to establish the minimal level of virucidal activity that is required to interrupt direct contact transmission of viruses in health-care settings.

Alcohols are not appropriate for use when hands are visibly dirty or contaminated with proteinaceous materials. However, when relatively small amounts of proteinaceous material (e.g., blood) are present, ethanol and isopropanol may reduce viable bacterial counts on hands more than plain soap or antimicrobial soap (*142*).

Alcohol can prevent the transfer of health-care–associated pathogens (*25,63,64*). In one study, gram-negative bacilli were transferred from a colonized patient's skin to a piece of catheter material via the hands of nurses in only 17% of experiments after antiseptic hand rub with an alcohol-based hand rinse (*25*). In contrast, transfer of the organisms occurred in 92% of experiments after handwashing with plain soap and water. This experimental model indicates that when the hands of HCWs are heavily contaminated, an antiseptic hand rub using an alcohol-based rinse can prevent pathogen transmission more effectively than can handwashing with plain soap and water.

Alcohol-based products are more effective for standard handwashing or hand antisepsis by HCWs than soap or antimicrobial soaps (Table 3) (*25,53,61,93,106–112,119,143–152*). In all but two of the trials that compared alcohol-based solutions with antimicrobial soaps or detergents, alcohol reduced bacterial counts on hands more than washing hands with soaps or detergents containing hexachlorophene, povidone-iodine, 4% chlorhexidine, or triclosan. In studies examining antimicrobial-resistant organisms, alcohol-based products reduced the number of multidrug-resistant pathogens recovered from the hands of HCWs more effectively than did handwashing with soap and water (*153–155*).

Alcohols are effective for preoperative cleaning of the hands of surgical personnel (*1,101,104,113–119,135,143,147,156–159*) (Tables 4 and 5). In multiple studies, bacterial counts on the hands were determined immediately after using the product and again 1–3 hours later; the delayed testing was performed to determine if regrowth of bacteria on the hands is inhibited during operative procedures. Alcohol-based solutions were more effective than washing hands with plain soap in all studies, and they reduced bacterial counts on the hands more than antimicrobial soaps or detergents in the majority of experiments (*101,104,113–119,135,143,147,157–159*). In addition, the majority of alcohol-based preparations were more effective than povidone-iodine or chlorhexidine.

The efficacy of alcohol-based hand-hygiene products is affected by several factors, including the type of alcohol used, concentration of alcohol, contact time, volume of alcohol used, and whether the hands are wet when the alcohol is applied. Applying small volumes (i.e., 0.2–0.5 mL) of alcohol to the hands is not more effective than washing hands with plain soap and water (*63,64*). One study documented that 1 mL of alcohol was substantially less effective than 3 mL (*91*). The ideal volume of product to apply to the hands is not known

TABLE 3. Studies comparing the relative efficacy (based on log_{10} reductions achieved) of plain soap or antimicrobial soaps versus alcohol-based antiseptics in reducing counts of viable bacteria on hands

Ref. no.	Year	Skin contamination	Assay method	Time (sec)	Relative efficacy
(*143*)	1965	Existing hand flora	Finger-tip agar culture	60	Plain soap < HCP < 50% EA foam
(*119*)	1975	Existing hand flora	Hand-rub broth culture	—	Plain soap < 95% EA
(*106*)	1978	Artificial contamination	Finger-tip broth culture	30	Plain soap < 4% CHG < P-I < 70% EA = alc. CHG
(*144*)	1978	Artificial contamination	Finger-tip broth culture	30	Plain soap < 4% CHG < 70% EA
(*107*)	1979	Existing hand flora	Hand-rub broth culture	120	Plain soap < 0.5% aq. CHG < 70% EA < 4% CHG < alc.CHG
(*145*)	1980	Artificial contamination	Finger-tip broth culture	60–120	4% CHG < P-I < 60% IPA
(*53*)	1980	Artificial contamination	Finger-tip broth culture	15	Plain soap < 3% HCP < P-I < 4% CHG < 70% EA
(*108*)	1982	Artificial contamination	Glove juice test	15	P-I < alc. CHG
(*109*)	1983	Artificial contamination	Finger-tip broth culture	120	0.3–2% triclosan = 60% IPA = alc. CHG < alc. triclosan
(*146*)	1984	Artificial contamination	Finger-tip agar culture	60	Phenolic < 4% CHG < P-I < EA < IPA < n-P
(*147*)	1985	Existing hand flora	Finger-tip agar culture	60	Plain soap < 70% EA < 95% EA
(*110*)	1986	Artificial contamination	Finger-tip broth culture	60	Phenolic = P-I < alc. CHG < n-P
(*93*)	1986	Existing hand flora	Sterile-broth bag technique	15	Plain soap < IPA < 4% CHG = IPA-E = alc. CHG
(*61*)	1988	Artificial contamination	Finger-tip broth culture	30	Plain soap < triclosan < P-I < IPA < alc. CHG < n-P
(*25*)	1991	Patient contact	Glove-juice test	15	Plain soap < IPA-E
(*148*)	1991	Existing hand flora	Agar-plate/image analysis	30	Plain soap < 1% triclosan < P-I < 4% CHG < IPA
(*111*)	1992	Artificial contamination	Finger-tip agar culture	60	Plain soap < IPA < EA < alc. CHG
(*149*)	1992	Artificial contamination	Finger-tip broth culture	60	Plain soap < 60% n-P
(*112*)	1994	Existing hand flora	Agar-plate/image analysis	30	Plain soap < alc. CHG
(*150*)	1999	Existing hand flora	Agar-plate culture	N.S.	Plain soap < commercial alcohol mixture
(*151*)	1999	Artificial contamination	Glove-juice test	20	Plain soap < 0.6% PCMX < 65% EA
(*152*)	1999	Artificial contamination	Finger-tip broth culture	30	4% CHG < plain soap < P-I < 70% EA

Note: Existing hand flora = without artificially contaminatiing hands with bacteria, alc. CHG = alcoholic chlorhexidine gluconate, aq. CHG = aqueous chlorhexidine gluconate, 4% CHG = chlorhexidine gluconate detergent, EA = ethanol, HCP = hexachlorophene soap/detergent, IPA = isopropanol, IPA-E = isopropanol + emollients, n-P = n-propanol, PCMX = chloroxylenol detergent, P-I = povidone-iodine detergent, and N.S. = not stated.

TABLE 4. Studies comparing the relative efficacy of plain soap or antimicrobial soap versus alcohol-containing products in reducing counts of bacteria recovered from hands immediately after use of products for pre-operative cleansing of hands

Ref. no.	Year	Assay method	Relative efficacy
(*143*)	1965	Finger-tip agar culture	HCP < 50% EA foam + QAC
(*157*)	1969	Finger-tip agar culture	HCP < P-I < 50% EA foam + QAC
(*101*)	1973	Finger-tip agar culture	HCP soap < EA foam + 0.23% HCP
(*135*)	1974	Broth culture	Plain soap < 0.5% CHG < 4% CHG < alc. CHG
(*119*)	1975	Hand-broth test	Plain soap < 0.5% CHG < 4% CHG < alc. CHG
(*118*)	1976	Glove-juice test	0.5% CHG < 4% CHG < alc. CHG
(*114*)	1977	Glove-juice test	P-I < CHG < alc. CHG
(*117*)	1978	Finger-tip agar culture	P-I = 46% EA + 0.23% HCP
(*113*)	1979	Broth culture of hands	Plain soap < P-I < alc. CHG < alc. P-I
(*116*)	1979	Glove-juice test	70% IPA = alc. CHG
(*147*)	1985	Finger-tip agar culture	Plain soap < 70% - 90% EA
(*115*)	1990	Glove-juice test, modified	Plain soap < triclosan < CHG < P-I < alc. CHG
(*104*)	1991	Glove-juice test	Plain soap < 2% triclosan < P-I < 70% IPA
(*158*)	1998	Finger-tip broth culture	70% IPA < 90% IPA = 60% n-P
(*159*)	1998	Glove-juice test	P-I < CHG < 70% EA

Note: QAC = quaternary ammonium compound, alc. CHG = alcoholic chlorhexidine gluconate, CHG = chlorhexidine gluconate detergent, EA = ethanol, HCP = hexachlorophene detergent, IPA = isopropanol, and P-I = povidone-iodine detergent.

TABLE 5. Efficacy of surgical hand-rub solutions in reducing the release of resident skin flora from clean hands

Study	Rub	Concentration* (%)	Time (min)	Mean log reduction	
				Immediate	Sustained (3 hr)
1	n-Propanol	60	5	2.9†	1.6†
2			5	2.7†	NA
3			5	2.5†	1.8†
4			5	2.3†	1.6†
5			3	2.9§	NA
4			3	2.0†	1.0†
4			1	1.1†	0.5†
6	Isopropanol	90	3	2.4§	1.4§
6		80	3	2.3§	1.2§
7		70	5	2.4†	2.1†
4			5	2.1†	1.0†
6			3	2.0§	0.7§
5			3	1.7c	NA
4			3	1.5†	0.8†
8			2	1.2	0.8
4			1	0.7†	0.2
9			1	0.8	NA
10		60	5	1.7	1.0
7	Isopropanol + chlorhexidine gluc. (w/v)	70 + 0.5	5	2.5†	2.7†
8			2	1.0	1.5
11	Ethanol	95	2	2.1	NA
5		85	3	2.4§	NA
12		80	2	1.5	NA
8		70	2	1.0	0.6
13	Ethanol + chlorhexidine gluc. (w/v)	95 + 0.5	2	1.7	NA
14		77 + 0.5	5	2.0	1.5¶
8		70 + 0.5	2	0.7	1.4
8	Chlorhexidine gluc. (aq. Sol., w/v)	0.5	2	0.4	1.2
15	Povidone-iodine (aq. Sol., w/v)	1.0	5	1.9†	0.8†
16	Peracetic acid (w/v)	0.5	5	1.9	NA

Note: NA = not available.

Source: Rotter M. Hand washing and hand disinfection [Chapter 87]. In: Mayhall CG, ed. Hospital epidemiology and infection control. 2nd ed. Philadelphia, PA: Lippincott Williams & Wilkins, 1999. Table 5 is copyrighted by Lippincott Williams & Wilkins; it is reprinted here with their permission and permission from Manfred Rotler, M.D., Professor of Hygiene and Microbiology, Klinisches Institute für Hygiene der Universitat Wien, Germany.

* Volume/volume unless otherwise stated.

† Tested according to Deutsche Gesellschaft fur Hygiene, and Mikrobiologic (DGHM)-German Society of Hygiene and Microbiology method.

§ Tested according to European Standard prEN.

¶ After 4 hours.

and may vary for different formulations. However, if hands feel dry after rubbing hands together for 10–15 seconds, an insufficient volume of product likely was applied. Because alcohol-impregnated towelettes contain a limited amount of alcohol, their effectiveness is comparable to that of soap and water (*63,160,161*).

Alcohol-based hand rubs intended for use in hospitals are available as low viscosity rinses, gels, and foams. Limited data are available regarding the relative efficacy of various formulations. One field trial demonstrated that an ethanol gel was slightly more effective than a comparable ethanol solution at reducing bacterial counts on the hands of HCWs (*162*). However, a more recent study indicated that rinses reduced bacterial counts on the hands more than the gels tested (*80*). Further studies are warranted to determine the relative efficacy of alcohol-based rinses and gels in reducing transmission of health-care–associated pathogens.

Frequent use of alcohol-based formulations for hand antisepsis can cause drying of the skin unless emollients, humectants, or other skin-conditioning agents are added to the formulations. The drying effect of alcohol can be reduced or eliminated by adding 1%–3% glycerol or other skin-conditioning agents (*90,93,100,101,106,135,143,163,164*). Moreover, in several recent prospective trials, alcohol-based rinses or gels containing emollients caused substantially less skin irritation and dryness than the soaps or antimicrobial detergents tested (*96,98,165,166*). These studies, which were conducted in clinical settings, used various subjective and objective methods for assessing skin irritation and dryness. Further studies are warranted to establish whether products with different formulations yield similar results.

Even well-tolerated alcohol hand rubs containing emollients may cause a transient stinging sensation at the site of any broken skin (e.g., cuts and abrasions). Alcohol-based hand-rub preparations with strong fragrances may be poorly tolerated by HCWs with respiratory allergies. Allergic contact dermatitis or contact urticaria syndrome caused by hypersensitivity to alcohol or to various additives present in certain alcohol hand rubs occurs only rarely (*167,168*).

Alcohols are flammable. Flash points of alcohol-based hand rubs range from 21°C to 24°C, depending on the type and concentration of alcohol present (*169*). As a result, alcohol-based hand rubs should be stored away from high temperatures or flames in accordance with National Fire Protection Agency recommendations. In Europe, where alcohol-based hand rubs have been used extensively for years, the incidence of fires associated with such products has been low (*169*). One recent U.S. report described a flash fire that occurred as a result of an unusual series of events, which included an HCW applying an alcohol gel to her hands, immediately removing a polyester isolation gown, and then touching a metal door before the alcohol had evaporated (*170*). Removing the polyester gown created a substantial amount of static electricity that generated an audible static spark when the HCW touched the metal door, igniting the unevaporated alcohol on her hands (*170*). This incident emphasizes the need to rub hands together after application of alcohol-based products until all the alcohol has evaporated.

Because alcohols are volatile, containers should be designed to minimize evaporation. Contamination of alcohol-based solutions has seldom been reported. One report documented a cluster of pseudoinfections caused by contamination of ethyl alcohol by *Bacillus cereus* spores (*171*).

Chlorhexidine

Chlorhexidine gluconate, a cationic bisbiguanide, was developed in England in the early 1950s and was introduced into the United States in the 1970s (*8,172*). Chlorhexidine base is only minimally soluble in water, but the digluconate form is water-soluble. The antimicrobial activity of chlorhexidine is likely attributable to attachment to, and subsequent disruption of, cytoplasmic membranes, resulting in precipitation of cellular contents (*1,8*). Chlorhexidine's immediate antimicrobial activity occurs more slowly than that of alcohols. Chlorhexidine has good activity against gram-positive bacteria, somewhat less activity against gram-negative bacteria and fungi, and only minimal activity against tubercle bacilli (*1,8,172*). Chlorhexidine is not sporicidal (*1,172*). It has in vitro activity against enveloped viruses (e.g., herpes simplex virus, HIV, cytomegalovirus, influenza, and RSV) but substantially less activity against nonenveloped viruses (e.g., rotavirus, adenovirus, and enteroviruses) (*130,131,173*). The antimicrobial activity of chlorhexidine is only minimally affected by the presence of organic material, including blood. Because chlorhexidine is a cationic molecule, its activity can be reduced by natural soaps, various inorganic anions, nonionic surfactants, and hand creams containing anionic emulsifying agents (*8,172,174*). Chlorhexidine gluconate has been incorporated into a number of hand-hygiene preparations. Aqueous or detergent formulations containing 0.5% or 0.75% chlorhexidine are more effective than plain soap, but they are less effective than antiseptic detergent preparations containing 4% chlorhexidine gluconate (*135,175*). Preparations with 2% chlorhexidine gluconate are slightly less effective than those containing 4% chlorhexidine (*176*).

Chlorhexidine has substantial residual activity (*106,114–116,118,135,146,175*). Addition of low concentrations (0.5%–1.0%) of chlorhexidine to alcohol-based preparations results in greater residual activity than alcohol alone (*116,135*). When used as recommended, chlorhexidine has a good safety

record (*172*). Minimal, if any, absorption of the compound occurs through the skin. Care must be taken to avoid contact with the eyes when using preparations with ≥1% chlorhexidine, because the agent can cause conjunctivitis and severe corneal damage. Ototoxicity precludes its use in surgery involving the inner or middle ear. Direct contact with brain tissue and the meninges should be avoided. The frequency of skin irritation is concentration-dependent, with products containing 4% most likely to cause dermatitis when used frequently for antiseptic handwashing (*177*); allergic reactions to chlorhexidine gluconate are uncommon (*118,172*). Occasional outbreaks of nosocomial infections have been traced to contaminated solutions of chlorhexidine (*178–181*).

Chloroxylenol

Chloroxylenol, also known as parachlorometaxylenol (PCMX), is a halogen-substituted phenolic compound that has been used as a preservative in cosmetics and other products and as an active agent in antimicrobial soaps. It was developed in Europe in the late 1920s and has been used in the United States since the 1950s (*182*).

The antimicrobial activity of PCMX likely is attributable to inactivation of bacterial enzymes and alteration of cell walls (*1*). It has good in vitro activity against gram-positive organisms and fair activity against gram-negative bacteria, mycobacteria, and certain viruses (*1,7,182*). PCMX is less active against *P. aeruginosa*, but addition of ethylenediaminetetraacetic acid (EDTA) increases its activity against *Pseudomonas* spp. and other pathogens.

A limited number of articles focusing on the efficacy of PCMX-containing preparations intended for use by HCWs have been published in the last 25 years, and the results of studies have sometimes been contradictory. For example, in studies in which antiseptics were applied to abdominal skin, PCMX had the weakest immediate and residual activity of any of the agents studied (*183*). However, when 30-second handwashes were performed using 0.6% PCMX, 2% chlorhexidine gluconate, or 0.3% triclosan, the immediate effect of PCMX was similar to that of the other agents. When used 18 times per day for 5 consecutive days, PCMX had less cumulative activity than did chlorhexidine gluconate (*184*). When PCMX was used as a surgical scrub, one report indicated that 3% PCMX had immediate and residual activity comparable to 4% chlorhexidine gluconate (*185*), whereas two other studies demonstrated that the immediate and residual activity of PCMX was inferior to both chlorhexidine gluconate and povidone-iodine (*176,186*). The disparity between published studies may be associated with the various concentrations of PCMX included in the preparations evaluated and with other aspects of the formulations tested, including the presence or absence of EDTA (*7,182*). PCMX is not as rapidly active as chlorhexidine gluconate or iodophors, and its residual activity is less pronounced than that observed with chlorhexidine gluconate (*7,182*). In 1994, FDA TFM tentatively classified PCMX as a Category IIISE active agent (i.e., insufficient data are available to classify this agent as safe and effective) (*19*). Further evaluation of this agent by the FDA is ongoing.

The antimicrobial activity of PCMX is minimally affected by the presence of organic matter, but it is neutralized by nonionic surfactants. PCMX, which is absorbed through the skin (*7,182*), is usually well-tolerated, and allergic reactions associated with its use are uncommon. PCMX is available in concentrations of 0.3%–3.75%. In-use contamination of a PCMX-containing preparation has been reported (*187*).

Hexachlorophene

Hexachlorophene is a bisphenol composed of two phenolic groups and three chlorine moieties. In the 1950s and early 1960s, emulsions containing 3% hexachlorophene were widely used for hygienic handwashing, as surgical scrubs, and for routine bathing of infants in hospital nurseries. The antimicrobial activity of hexachlorophene results from its ability to inactivate essential enzyme systems in microorganisms. Hexachlorophene is bacteriostatic, with good activity against *S. aureus* and relatively weak activity against gram-negative bacteria, fungi, and mycobacteria (*7*).

Studies of hexachlorophene as a hygienic handwash and surgical scrub demonstrated only modest efficacy after a single handwash (*53,143,188*). Hexachlorophene has residual activity for several hours after use and gradually reduces bacterial counts on hands after multiple uses (i.e., it has a cumulative effect) (*1,101,188,189*). With repeated use of 3% hexachlorophene preparations, the drug is absorbed through the skin. Infants bathed with hexachlorophene and personnel regularly using a 3% hexachlorophene preparation for handwashing have blood levels of 0.1–0.6 ppm hexachlorophene (*190*). In the early 1970s, certain infants bathed with hexachlorophene developed neurotoxicity (vacuolar degeneration) (*191*). As a result, in 1972, the FDA warned that hexachlorophene should no longer be used routinely for bathing infants. However, after routine use of hexachlorophene for bathing infants in nurseries was discontinued, investigators noted that the incidence of health-care–associated *S. aureus* infections in hospital nurseries increased substantially (*192,193*). In several instances, the frequency of infections decreased when hexachlorophene bathing of infants was reinstituted. However, current guidelines still recommend against the routine bathing of neonates with hexachlorophene because of its potential neurotoxic effects (*194*). The agent is classified by FDA TFM as not

generally recognized as safe and effective for use as an antiseptic handwash (*19*). Hexachlorophene should not be used to bathe patients with burns or extensive areas of susceptible, sensitive skin. Soaps containing 3% hexachlorophene are available by prescription only (*7*).

Iodine and Iodophors

Iodine has been recognized as an effective antiseptic since the 1800s. However, because iodine often causes irritation and discoloring of skin, iodophors have largely replaced iodine as the active ingredient in antiseptics.

Iodine molecules rapidly penetrate the cell wall of microorganisms and inactivate cells by forming complexes with amino acids and unsaturated fatty acids, resulting in impaired protein synthesis and alteration of cell membranes (*195*). Iodophors are composed of elemental iodine, iodide or triiodide, and a polymer carrier (i.e., the complexing agent) of high molecular weight. The amount of molecular iodine present (so-called "free" iodine) determines the level of antimicrobial activity of iodophors. "Available" iodine refers to the total amount of iodine that can be titrated with sodium thiosulfate (*196*). Typical 10% povidone-iodine formulations contain 1% available iodine and yield free iodine concentrations of 1 ppm (*196*). Combining iodine with various polymers increases the solubility of iodine, promotes sustained release of iodine, and reduces skin irritation. The most common polymers incorporated into iodophors are polyvinyl pyrrolidone (i.e., povidone) and ethoxylated nonionic detergents (i.e., poloxamers) (*195,196*). The antimicrobial activity of iodophors also can be affected by pH, temperature, exposure time, concentration of total available iodine, and the amount and type of organic and inorganic compounds present (e.g., alcohols and detergents).

Iodine and iodophors have bactericidal activity against gram-positive, gram-negative, and certain spore-forming bacteria (e.g., clostridia and *Bacillus* spp.) and are active against mycobacteria, viruses, and fungi (*8,195,197–200*). However, in concentrations used in antiseptics, iodophors are not usually sporicidal (*201*). In vivo studies have demonstrated that iodophors reduce the number of viable organisms that are recovered from the hands of personnel (*113,145,148,152,155*). Povidone-iodine 5%–10% has been tentatively classified by FDA TFM as a Category I agent (i.e., a safe and effective agent for use as an antiseptic handwash and an HCW handwash) (*19*). The extent to which iodophors exhibit persistent antimicrobial activity after they have been washed off the skin is unclear. In one study, persistent activity was noted for 6 hours (*176*); however, several other studies demonstrated persistent activity for only 30–60 minutes after washing hands with an iodophor (*61,117,202*). In studies in which bacterial counts were obtained after gloves were worn for 1–4 hours after washing, iodophors have demonstrated poor persistent activity (*1,104,115,189,203–208*). The in vivo antimicrobial activity of iodophors is substantially reduced in the presence of organic substances (e.g., blood or sputum) (*8*).

The majority of iodophor preparations used for hand hygiene contain 7.5%–10% povidone-iodine. Formulations with lower concentrations also have good antimicrobial activity because dilution can increase free iodine concentrations (*209*). However, as the amount of free iodine increases, the degree of skin irritation also may increase (*209*). Iodophors cause less skin irritation and fewer allergic reactions than iodine, but more irritant contact dermatitis than other antiseptics commonly used for hand hygiene (*92*). Occasionally, iodophor antiseptics have become contaminated with gram-negative bacilli as a result of poor manufacturing processes and have caused outbreaks or pseudo-outbreaks of infection (*196*).

Quaternary Ammonium Compounds

Quaternary ammonium compounds are composed of a nitrogen atom linked directly to four alkyl groups, which may vary in their structure and complexity (*210*). Of this large group of compounds, alkyl benzalkonium chlorides are the most widely used as antiseptics. Other compounds that have been used as antiseptics include benzethonium chloride, cetrimide, and cetylpyridium chloride (*1*). The antimicrobial activity of these compounds was first studied in the early 1900s, and a quaternary ammonium compound for preoperative cleaning of surgeons' hands was used as early as 1935 (*210*). The antimicrobial activity of this group of compounds likely is attributable to adsorption to the cytoplasmic membrane, with subsequent leakage of low molecular weight cytoplasmic constituents (*210*).

Quaternary ammonium compounds are primarily bacteriostatic and fungistatic, although they are microbicidal against certain organisms at high concentrations (*1*); they are more active against gram-positive bacteria than against gram-negative bacilli. Quaternary ammonium compounds have relatively weak activity against mycobacteria and fungi and have greater activity against lipophilic viruses. Their antimicrobial activity is adversely affected by the presence of organic material, and they are not compatible with anionic detergents (*1,210*). In 1994, FDA TFM tentatively classified benzalkonium chloride and benzethonium chloride as Category IIISE active agents (i.e., insufficient data exists to classify them as safe and effective for use as an antiseptic handwash) (*19*). Further evaluation of these agents by FDA is in progress.

Quaternary ammonium compounds are usually well tolerated. However, because of weak activity against

gram-negative bacteria, benzalkonium chloride is prone to contamination by these organisms. Several outbreaks of infection or pseudoinfection have been traced to quaternary ammonium compounds contaminated with gram-negative bacilli (*211–213*). For this reason, in the United States, these compounds have been seldom used for hand antisepsis during the last 15–20 years. However, newer handwashing products containing benzalkonium chloride or benzethonium chloride have recently been introduced for use by HCWs. A recent study of surgical intensive-care unit personnel found that cleaning hands with antimicrobial wipes containing a quaternary ammonium compound was about as effective as using plain soap and water for handwashing; both were less effective than decontaminating hands with an alcohol-based hand rub (*214*). One laboratory-based study reported that an alcohol-free hand-rub product containing a quaternary ammonium compound was efficacious in reducing microbial counts on the hands of volunteers (*215*). Further studies of such products are needed to determine if newer formulations are effective in health-care settings.

Triclosan

Triclosan (chemical name: 2,4,4' –trichloro-2'-hydroxydiphenyl ether) is a nonionic, colorless substance that was developed in the 1960s. It has been incorporated into soaps for use by HCWs and the public and into other consumer products. Concentrations of 0.2%–2% have antimicrobial activity. Triclosan enters bacterial cells and affects the cytoplasmic membrane and synthesis of RNA, fatty acids, and proteins (*216*). Recent studies indicate this agent's antibacterial activity is attributable to binding to the active site of enoyl-acyl carrier protein reductase (*217,218*).

Triclosan has a broad range of antimicrobial activity, but it is often bacteriostatic (*1*). Minimum inhibitory concentrations (MICs) range from 0.1 to 10 ug/mL, whereas minimum bactericidal concentrations are 25–500 ug/mL. Triclosan's activity against gram-positive organisms (including MRSA) is greater than against gram-negative bacilli, particularly *P. aeruginosa* (*1,216*). The agent possesses reasonable activity against mycobacterial and *Candida* spp., but it has limited activity against filamentous fungi. Triclosan (0.1%) reduces bacterial counts on hands by 2.8 $\log_{10}$ after a 1-minute hygienic handwash (*1*). In several studies, log reductions have been lower after triclosan is used than when chlorhexidine, iodophors, or alcohol-based products are applied (*1,61,149,184,219*). In 1994, FDA TFM tentatively classified triclosan ≤1.0% as a Category IIISE active agent (i.e., insufficient data exist to classify this agent as safe and effective for use as an antiseptic handwash) (*19*). Further evaluation of this agent by the FDA is underway. Like chlorhexidine, triclosan has persistent activity on the skin. Its activity in hand-care products is affected by pH, the presence of surfactants, emollients, or humectants and by the ionic nature of the particular formulation (*1,216*). Triclosan's activity is not substantially affected by organic matter, but it can be inhibited by sequestration of the agent in micelle structures formed by surfactants present in certain formulations. The majority of formulations containing <2% triclosan are well-tolerated and seldom cause allergic reactions. Certain reports indicate that providing hospital personnel with a triclosan-containing preparation for hand antisepsis has led to decreased MRSA infections (*72,73*). Triclosan's lack of potent activity against gram-negative bacilli has resulted in occasional reports of contamination (*220*).

Other Agents

Approximately 150 years after puerperal-fever–related maternal mortality rates were demonstrated by Semmelweis to be reduced by use of a hypochlorite hand rinse, the efficacy of rubbing hands for 30 seconds with an aqueous hypochlorite solution was studied once again (*221*). The solution was demonstrated to be no more effective than distilled water. The regimen used by Semmelweis, which called for rubbing hands with a 4% [w/w] hypochlorite solution until the hands were slippery (approximately 5 minutes), has been revisited by other researchers (*222*). This more current study indicated that the regimen was 30 times more effective than a 1-minute rub using 60% isopropanol. However, because hypochlorite solutions are often irritating to the skin when used repeatedly and have a strong odor, they are seldom used for hand hygiene.

Certain other agents are being evaluated by FDA for use in health-care-related antiseptics (*19*). However, the efficacy of these agents has not been evaluated adequately for use in handwashing preparations intended for use by HCWs. Further evaluation of these agents is warranted. Products that use different concentrations of traditional antiseptics (e.g., low concentrations of iodophor) or contain novel compounds with antiseptic properties are likely to be introduced for use by HCWs. For example, preliminary studies have demonstrated that adding silver-containing polymers to an ethanol carrier (i.e., Surfacine®) results in a preparation that has persistent antimicrobial activity on animal and human skin (*223*). New compounds with good in vitro activity must be tested in vivo to determine their abilities to reduce transient and resident skin flora on the hands of HCWs.

Activity of Antiseptic Agents Against Spore-Forming Bacteria

The widespread prevalence of health-care–associated diarrhea caused by *Clostridium difficile* and the recent occurrence

in the United States of human *Bacillus anthracis* infections associated with contaminated items sent through the postal system has raised concern regarding the activity of antiseptic agents against spore-forming bacteria. None of the agents (including alcohols, chlorhexidine, hexachlorophene, iodophors, PCMX, and triclosan) used in antiseptic handwash or antiseptic hand-rub preparations are reliably sporicidal against *Clostridium* spp. or *Bacillus* spp. (*120,172,224,225*). Washing hands with non-antimicrobial or antimicrobial soap and water may help to physically remove spores from the surface of contaminated hands. HCWs should be encouraged to wear gloves when caring for patients with *C. difficile*-associated diarrhea (*226*). After gloves are removed, hands should be washed with a non-antimicrobial or an antimicrobial soap and water or disinfected with an alcohol-based hand rub. During outbreaks of *C. difficile*-related infections, washing hands with a non-antimicrobial or antimicrobial soap and water after removing gloves is prudent. HCWs with suspected or documented exposure to *B. anthracis*-contaminated items also should be encouraged to wash their hands with a non-antimicrobial or antimicrobial soap and water.

Reduced Susceptibility of Bacteria to Antiseptics

Reduced susceptibility of bacteria to antiseptic agents can either be an intrinsic characteristic of a species or can be an acquired trait (*227*). Several reports have described strains of bacteria that appear to have acquired reduced susceptibility (when defined by MICs established in vitro) to certain antiseptics (e.g., chlorhexidine, quaternary ammonium compounds, and triclosan) (*227–230*). However, because the antiseptic concentrations that are actually used by HCWs are often substantially higher than the MICs of strains with reduced antiseptic susceptibility, the clinical relevance of the in vitro findings is questionable. For example, certain strains of MRSA have chlorhexidine and quaternary ammonium compound MICs that are several-fold higher than methicillin-susceptible strains, and certain strains of *S. aureus* have elevated MICs to triclosan (*227,228*). However, such strains were readily inhibited by the concentrations of these antiseptics that are actually used by practicing HCWs (*227,228*). The description of a triclosan-resistant bacterial enzyme has raised the question of whether resistance to this agent may develop more readily than to other antiseptic agents (*218*). In addition, exposing *Pseudomonas* strains containing the MexAB-OprM efflux system to triclosan may select for mutants that are resistant to multiple antibiotics, including fluoroquinolones (*230*). Further studies are needed to determine whether reduced susceptibility to antiseptic agents is of epidemiologic significance and whether resistance to antiseptics has any influence on the prevalence of antibiotic-resistant strains (*227*).

Surgical Hand Antisepsis

Since the late 1800s, when Lister promoted the application of carbolic acid to the hands of surgeons before procedures, preoperative cleansing of hands and forearms with an antiseptic agent has been an accepted practice (*231*). Although no randomized, controlled trials have been conducted to indicate that surgical-site infection rates are substantially lower when preoperative scrubbing is performed with an antiseptic agent rather than a non-antimicrobial soap, certain other factors provide a strong rationale for this practice. Bacteria on the hands of surgeons can cause wound infections if introduced into the operative field during surgery (*232*); rapid multiplication of bacteria occurs under surgical gloves if hands are washed with a non-antimicrobial soap. However, bacterial growth is slowed after preoperative scrubbing with an antiseptic agent (*14,233*). Reducing resident skin flora on the hands of the surgical team for the duration of a procedure reduces the risk of bacteria being released into the surgical field if gloves become punctured or torn during surgery (*1,156,169*). Finally, at least one outbreak of surgical-site infections occurred when surgeons who normally used an antiseptic surgical scrub preparation began using a non-antimicrobial product (*234*).

Antiseptic preparations intended for use as surgical hand scrubs are evaluated for their ability to reduce the number of bacteria released from hands at different times, including 1) immediately after scrubbing, 2) after wearing surgical gloves for 6 hours (i.e., persistent activity), and 3) after multiple applications over 5 days (i.e., cumulative activity). Immediate and persistent activity are considered the most important in determining the efficacy of the product. U.S. guidelines recommend that agents used for surgical hand scrubs should substantially reduce microorganisms on intact skin, contain a nonirritating antimicrobial preparation, have broad-spectrum activity, and be fast-acting and persistent (*19,235*).

Studies have demonstrated that formulations containing 60%–95% alcohol alone or 50%–95% when combined with limited amounts of a quaternary ammonium compound, hexachlorophene, or chlorhexidine gluconate, lower bacterial counts on the skin immediately postscrub more effectively than do other agents (Table 4). The next most active agents (in order of decreasing activity) are chlorhexidine gluconate, iodophors, triclosan, and plain soap (*104,119,186,188, 203,204,206,208,236*). Because studies of PCMX as a surgical scrub have yielded contradictory results, further studies are needed to establish how the efficacy of this compound compares with the other agents (*176,185,186*).

Although alcohols are not considered to have persistent antimicrobial activity, bacteria appear to reproduce slowly on the hands after a surgical scrub with alcohol, and bacterial counts on hands after wearing gloves for 1–3 hours seldom exceed baseline (i.e., prescrub) values (*1*). However, a recent study demonstrated that a formulation containing 61% ethanol alone did not achieve adequate persistent activity at 6 hours postscrub (*237*). Alcohol-based preparations containing 0.5% or 1% chlorhexidine gluconate have persistent activity that, in certain studies, has equaled or exceeded that of chlorhexidine gluconate-containing detergents (*1,118,135,237*).*

Persistent antimicrobial activity of detergent-based surgical scrub formulations is greatest for those containing 2% or 4% chlorhexidine gluconate, followed by hexachlorophene, triclosan, and iodophors (*1,102,113–115,159,189,203, 204,206–208,236*). Because hexachlorophene is absorbed into the blood after repeated use, it is seldom used as a surgical scrub.

Surgical staff have been traditionally required to scrub their hands for 10 minutes preoperatively, which frequently leads to skin damage. Several studies have demonstrated that scrubbing for 5 minutes reduces bacterial counts as effectively as a 10-minute scrub (*117,238,239*). In other studies, scrubbing for 2 or 3 minutes reduced bacterial counts to acceptable levels (*156,205,207,240,241*).

Studies have indicated that a two-stage surgical scrub using an antiseptic detergent, followed by application of an alcohol-containing preparation, is effective. For example, an initial 1- or 2-minute scrub with 4% chlorhexidine gluconate or povidone-iodine followed by application of an alcohol-based product has been as effective as a 5-minute scrub with an antiseptic detergent (*114,242*).

Surgical hand-antisepsis protocols have required personnel to scrub with a brush. But this practice can damage the skin of personnel and result in increased shedding of bacteria from the hands (*95,243*). Scrubbing with a disposable sponge or combination sponge-brush has reduced bacterial counts on the hands as effectively as scrubbing with a brush (*244–246*). However, several studies indicate that neither a brush nor a sponge is necessary to reduce bacterial counts on the hands of surgical personnel to acceptable levels, especially when alcohol-based products are used (*102,117,159,165,233,237, 247,248*). Several of these studies performed cultures immediately or at 45–60 minutes postscrub (*102,117, 233,247,248*), whereas in other studies, cultures were obtained 3 and 6 hours postscrub (*159,237*). For example, a recent laboratory-based study using volunteers demonstrated that brushless application of a preparation containing 1% chlorhexidine gluconate plus 61% ethanol yielded lower bacterial counts on the hands of participants than using a sponge/brush to apply a 4% chlorhexidine-containing detergent preparation (*237*).

Relative Efficacy of Plain Soap, Antiseptic Soap/Detergent, and Alcohols

Comparing studies related to the in vivo efficacy of plain soap, antimicrobial soaps, and alcohol-based hand rubs is problematic, because certain studies express efficacy as the percentage reduction in bacterial counts achieved, whereas others give $\log_{10}$ reductions in counts achieved. However, summarizing the relative efficacy of agents tested in each study can provide an overview of the in vivo activity of various formulations intended for handwashing, hygienic handwash, antiseptic hand rub, or surgical hand antisepsis (Tables 2–4).

Irritant Contact Dermatitis Resulting from Hand-Hygiene Measures

Frequency and Pathophysiology of Irritant Contact Dermatitis

In certain surveys, approximately 25% of nurses report symptoms or signs of dermatitis involving their hands, and as many as 85% give a history of having skin problems (*249*). Frequent and repeated use of hand-hygiene products, particularly soaps and other detergents, is a primary cause of chronic irritant contact dermatitis among HCWs (*250*). The potential of detergents to cause skin irritation can vary considerably and can be ameliorated by the addition of emollients and humectants. Irritation associated with antimicrobial soaps may be caused by the antimicrobial agent or by other ingredients of the formulation. Affected persons often complain of a feeling of dryness or burning; skin that feels "rough;" and erythema, scaling, or fissures. Detergents damage the skin by causing denaturation of stratum corneum proteins, changes in intercellular lipids (either depletion or reorganization of lipid moieties), decreased corneocyte cohesion, and decreased stratum corneum water-binding capacity (*250,251*). Damage

* In a recent randomized clinical trial, surgical site infection rates were monitored among patients who were operated on by surgical personnel who cleaned their hands preoperatively either by performing a traditional 5-minute surgical hand scrub using 4% povidone-iodine or 4% antisepsis antimicrobial soap, or by washing their hands for 1 minute with a non-antimicrobial soap followed by a 5-minute hand-rubbing technique using an alcohol-based hand rinse containing 0.2% mecetronium etilsulfate. The incidence of surgical site infections was virtually identical in the two groups of patients. (**Source:** Parienti JJ, Thibon P, Heller R, et al. for Members of the Antisepsie Chirurgicale des Mains Study Group. Hand-rubbing with an aqueous alcoholic solution vs traditional surgical hand-scrubbing and 30-day surgical site infection rates: a randomized equivalence study. JAMA 2002;288:722–7).

to the skin also changes skin flora, resulting in more frequent colonization by staphylococci and gram-negative bacilli (*17,90*). Although alcohols are among the safest antiseptics available, they can cause dryness and irritation of the skin (*1,252*). Ethanol is usually less irritating than n-propanol or isopropanol (*252*).

Irritant contact dermatitis is more commonly reported with iodophors (*92*). Other antiseptic agents that can cause irritant contact dermatitis (in order of decreasing frequency) include chlorhexidine, PCMX, triclosan, and alcohol-based products. Skin that is damaged by repeated exposure to detergents may be more susceptible to irritation by alcohol-based preparations (*253*). The irritancy potential of commercially prepared hand-hygiene products, which is often determined by measuring transepidermal water loss, may be available from the manufacturer. Other factors that can contribute to dermatitis associated with frequent handwashing include using hot water for handwashing, low relative humidity (most common in winter months), failure to use supplementary hand lotion or cream, and the quality of paper towels (*254,255*). Shear forces associated with wearing or removing gloves and allergy to latex proteins may also contribute to dermatitis of the hands of HCWs.

Allergic Contact Dermatitis Associated with Hand-Hygiene Products

Allergic reactions to products applied to the skin (i.e., contact allergies) may present as delayed type reactions (i.e., allergic contact dermatitis) or less commonly as immediate reactions (i.e., contact urticaria). The most common causes of contact allergies are fragrances and preservatives; emulsifiers are less common causes (*256–259*). Liquid soaps, hand lotions or creams, and "udder ointments" may contain ingredients that cause contact allergies among HCWs (*257,258*).

Allergic reactions to antiseptic agents, including quaternary ammonium compounds, iodine or iodophors, chlorhexidine, triclosan, PCMX, and alcohols have been reported (*118,167,172,256,260–265*). Allergic contact dermatitis associated with alcohol-based hand rubs is uncommon. Surveillance at a large hospital in Switzerland, where a commercial alcohol hand rub has been used for >10 years, failed to identify a single case of documented allergy to the product (*169*). In late 2001, a Freedom of Information Request for data in the FDA's Adverse Event Reporting System regarding adverse reactions to popular alcohol hand rubs in the United States yielded only one reported case of an erythematous rash reaction attributed to such a product (John M. Boyce, M.D., Hospital of St. Raphael, New Haven, Connecticut, personal communication, 2001). However, with increasing use of such products by HCWs, true allergic reactions to such products likely will be encountered.

Allergic reactions to alcohol-based products may represent true allergy to alcohol, allergy to an impurity or aldehyde metabolite, or allergy to another constituent of the product (*167*). Allergic contact dermatitis or immediate contact urticarial reactions may be caused by ethanol or isopropanol (*167*). Allergic reactions can be caused by compounds that may be present as inactive ingredients in alcohol-based hand rubs, including fragrances, benzyl alcohol, stearyl or isostearyl alcohol, phenoxyethanol, myristyl alcohol, propylene glycol, parabens, and benzalkonium chloride (*167,256,266–270*).

Proposed Methods for Reducing Adverse Effects of Agents

Potential strategies for minimizing hand-hygiene–related irritant contact dermatitis among HCWs include reducing the frequency of exposure to irritating agents (particularly anionic detergents), replacing products with high irritation potential with preparations that cause less damage to the skin, educating personnel regarding the risks of irritant contact dermatitis, and providing caregivers with moisturizing skin-care products or barrier creams (*96,98,251,271–273*). Reducing the frequency of exposure of HCWs to hand-hygiene products would prove difficult and is not desirable because of the low levels of adherence to hand-hygiene policies in the majority of institutions. Although hospitals have provided personnel with non-antimicrobial soaps in hopes of minimizing dermatitis, frequent use of such products may cause greater skin damage, dryness, and irritation than antiseptic preparations (*92,96,98*). One strategy for reducing the exposure of personnel to irritating soaps and detergents is to promote the use of alcohol-based hand rubs containing various emollients. Several recent prospective, randomized trials have demonstrated that alcohol-based hand rubs containing emollients were better tolerated by HCWs than washing hands with non-antimicrobial soaps or antimicrobial soaps (*96,98,166*). Routinely washing hands with soap and water immediately after using an alcohol hand rub may lead to dermatitis. Therefore, personnel should be reminded that it is neither necessary nor recommended to routinely wash hands after each application of an alcohol hand rub.

Hand lotions and creams often contain humectants and various fats and oils that can increase skin hydration and replace altered or depleted skin lipids that contribute to the barrier function of normal skin (*251,271*). Several controlled trials have demonstrated that regular use (e.g., twice a day) of such products can help prevent and treat irritant contact dermatitis caused by hand-hygiene products (*272,273*). In one study, frequent and scheduled use of an oil-containing lotion improved skin condition, and thus led to a 50% increase in

handwashing frequency among HCWs (273). Reports from these studies emphasize the need to educate personnel regarding the value of regular, frequent use of hand-care products.

Recently, barrier creams have been marketed for the prevention of hand-hygiene–related irritant contact dermatitis. Such products are absorbed to the superficial layers of the epidermis and are designed to form a protective layer that is not removed by standard handwashing. Two recent randomized, controlled trials that evaluated the skin condition of caregivers demonstrated that barrier creams did not yield better results than did the control lotion or vehicle used (*272,273*). As a result, whether barrier creams are effective in preventing irritant contact dermatitis among HCWs remains unknown.

In addition to evaluating the efficacy and acceptability of hand-care products, product-selection committees should inquire about the potential deleterious effects that oil-containing products may have on the integrity of rubber gloves and on the efficacy of antiseptic agents used in the facility (*8,236*).

Factors To Consider When Selecting Hand-Hygiene Products

When evaluating hand-hygiene products for potential use in health-care facilities, administrators or product-selection committees must consider factors that can affect the overall efficacy of such products, including the relative efficacy of antiseptic agents against various pathogens (Appendix) and acceptance of hand-hygiene products by personnel (*274,275*). Soap products that are not well-accepted by HCWs can be a deterrent to frequent handwashing (*276*). Characteristics of a product (either soap or alcohol-based hand rub) that can affect acceptance by personnel include its smell, consistency (i.e., "feel"), and color (*92,277,278*). For soaps, ease of lathering also may affect user preference.

Because HCWs may wash their hands from a limited number of times per shift to as many as 30 times per shift, the tendency of products to cause skin irritation and dryness is a substantial factor that influences acceptance, and ultimate usage (*61,98,274,275,277,279*). For example, concern regarding the drying effects of alcohol was a primary cause of poor acceptance of alcohol-based hand-hygiene products in hospitals in the United States (*5,143*). However, several studies have demonstrated that alcohol-based hand rubs containing emollients are acceptable to HCWs (*90,93,98,100,101,106, 143,163,164,166*). With alcohol-based products, the time required for drying may also affect user acceptance.

Studies indicate that the frequency of handwashing or antiseptic handwashing by personnel is affected by the accessibility of hand-hygiene facilities (*280–283*). In certain health-care facilities, only one sink is available in rooms housing several patients, or sinks are located far away from the door of the room, which may discourage handwashing by personnel leaving the room. In intensive-care units, access to sinks may be blocked by bedside equipment (e.g., ventilators or intravenous infusion pumps). In contrast to sinks used for handwashing or antiseptic handwash, dispensers for alcohol-based hand rubs do not require plumbing and can be made available adjacent to each patient's bed and at many other locations in patient-care areas. Pocket carriage of alcohol-based hand-rub solutions, combined with availability of bedside dispensers, has been associated with substantial improvement in adherence to hand-hygiene protocols (*74,284*). To avoid any confusion between soap and alcohol hand rubs, alcohol hand-rub dispensers should not be placed adjacent to sinks. HCWs should be informed that washing hands with soap and water after each use of an alcohol hand rub is not necessary and is not recommended, because it may lead to dermatitis. However, because personnel feel a "build-up" of emollients on their hands after repeated use of alcohol hand gels, washing hands with soap and water after 5–10 applications of a gel has been recommended by certain manufacturers.

Automated handwashing machines have not been demonstrated to improve the quality or frequency of handwashing (*88,285*). Although technologically advanced automated handwashing devices and monitoring systems have been developed recently, only a minimal number of studies have been published that demonstrate that use of such devices results in enduring improvements in hand-hygiene adherence among HCWs. Further evaluation of automated handwashing facilities and monitoring systems is warranted.

Dispenser systems provided by manufacturers or vendors also must be considered when evaluating hand-hygiene products. Dispensers may discourage use by HCWs when they 1) become blocked or partially blocked and do not deliver the product when accessed by personnel, and 2) do not deliver the product appropriately onto the hands. In one hospital where a viscous alcohol-based hand rinse was available, only 65% of functioning dispensers delivered product onto the caregivers' hands with one press of the dispenser lever, and 9% of dispensers were totally occluded (*286*). In addition, the volume delivered was often suboptimal, and the product was sometimes squirted onto the wall instead of the caregiver's hand.

Only limited information is available regarding the cost of hand-hygiene products used in health-care facilities (*165,287*). These costs were evaluated in patient-care areas at a 450-bed community teaching hospital (*287*); the hospital spent $22,000 ($0.72 per patient-day) on 2% chlorhexidine-containing preparations, plain soap, and an alcohol hand rinse. *(287)* When

hand-hygiene supplies for clinics and nonpatient care areas were included, the total annual budget for soaps and hand antiseptic agents was $30,000 (approximately $1 per patient-day). Annual hand-hygiene product budgets at other institutions vary considerably because of differences in usage patterns and varying product prices. One researcher (*287*) determined that if non-antimicrobial liquid soap were assigned an arbitrary relative cost of 1.0, the cost per liter would be 1.7 times as much for 2% chlorhexidine gluconate detergent, 1.6–2.0 times higher for alcohol-based hand-rub products, and 4.5 times higher for an alcohol-based foam product. A recent cost comparison of surgical scrubbing with an antimicrobial soap versus brushless scrubbing with an alcohol-based hand rub revealed that costs and time required for preoperative scrubbing were less with the alcohol-based product (*165*). In a trial conducted in two critical-care units, the cost of using an alcohol hand rub was half as much as using an antimicrobial soap for handwashing ($0.025 versus $0.05 per application, respectively) (*166*).

To put expenditures for hand-hygiene products into perspective, health-care facilities should consider comparing their budget for hand-hygiene products to estimated excess hospital costs resulting from health-care–associated infections. The excess hospital costs associated with only four or five health-care–associated infections of average severity may equal the entire annual budget for hand-hygiene products used in inpatient-care areas. Just one severe surgical site infection, lower respiratory tract infection, or bloodstream infection may cost the hospital more than the entire annual budget for antiseptic agents used for hand hygiene (*287*). Two studies provided certain quantitative estimates of the benefit of hand-hygiene–promotion programs (*72,74*). One study demonstrated a cost saving of approximately $17,000 resulting from reduced use of vancomycin after the observed decrease in MRSA incidence in a 7-month period (*72*). In another study that examined both direct costs associated with the hand-hygiene promotion program (increased use of hand-rub solution and poster production) and indirect costs associated with health-care–personnel time (*74*), costs of the program were an estimated $57,000 or less per year (an average of $1.42 per patient admitted). Supplementary costs associated with the increased use of alcohol-based hand-rub solution averaged $6.07 per 100 patient-days. Based on conservative estimates of $2,100 saved per infection averted and on the assumption that only 25% of the observed reduction in the infection rate was associated with improved hand-hygiene practice, the program was substantially cost-effective. Thus, hospital administrators must consider that by purchasing more effective or more acceptable hand-hygiene products to improve hand-hygiene practices, they will avoid the occurrence of nosocomial infections; preventing only a limited number of additional health-care–associated infections per year will lead to savings that will exceed any incremental costs of improved hand-hygiene products.

Hand-Hygiene Practices Among HCWs

In observational studies conducted in hospitals, HCWs washed their hands an average of five times per shift to as many as 30 times per shift (Table 6) (*17,61,90,98,274,288*); certain nurses washed their hands ≤100 times per shift (*90*). Hospitalwide surveillance of hand hygiene reveals that the average number of handwashing opportunities varies markedly between hospital wards. For example, nurses in pediatric wards had an average of eight opportunities for hand hygiene per hour of patient care compared with an average of 20 for nurses in intensive-care units (*11*). The duration of handwashing or hygienic handwash episodes by HCWs has averaged 6.6–24.0 seconds in observational studies (Table 7) (*17,52,59,84–87,89,249,279*). In addition to washing their

TABLE 6. Handwashing frequency among health-care workers

Ref. no.	Year	Avg. no./ time period	Range	Avg. no./hr
(*61*)	1988	5/8 hour	N.S.	
(*89*)	1984	5–10/shift	N.S.	
(*96*)	2000	10/shift	N.S.	
(*273*)	2000	12–18/day	2–60	
(*98*)	2000	13–15/8 hours	5–27	1.6–1.8/hr
(*90*)	1977	20–42/8 hours	10–100	
(*391*)	2000	21/12 hours	N.S.	
(*272*)	2000	22/day	0–70	
(*88*)	1991			1.7–2.1/hr
(*17*)	1998			2.1/hr
(*279*)	1978			3/hr
(*303*)	1994			3.3/hr

Note: N.S. = Not Stated.

TABLE 7. Average duration of handwashing by health-care workers

Ref. no.	Year	Mean/median time
(*392*)	1997	4.7–5.3 seconds
(*303*)	1994	6.6 seconds
(*52*)	1974	8–9.3 seconds
(*85*)	1984	8.6 seconds
(*86*)	1994	<9 seconds
(*87*)	1994	9.5 seconds
(*88*)	1991	<10 seconds
(*294*)	1990	10 seconds
(*89*)	1984	11.6 seconds
(*300*)	1992	12.5 seconds
(*59*)	1988	15.6–24.4 seconds
(*17*)	1998	20.6 seconds
(*279*)	1978	21 seconds
(*293*)	1989	24 seconds

hands for limited time periods, personnel often fail to cover all surfaces of their hands and fingers (*288*).

Adherence of HCWs to Recommended Hand-Hygiene Practices

Observational Studies of Hand-Hygiene Adherence. Adherence of HCWs to recommended hand-hygiene procedures has been poor, with mean baseline rates of 5%–81% (overall average: 40%) (Table 8) (*71,74,86,87,276,280,281,283,285, 289–313*). The methods used for defining adherence (or nonadherence) and those used for conducting observations vary considerably among studies, and reports do not provide detailed information concerning the methods and criteria used. The majority of studies were conducted with hand-hygiene adherence as the major outcome measure, whereas a limited number measured adherence as part of a broader investigation. Several investigators reported improved adherence after implementing various interventions, but the majority of studies had short follow-up periods and did not confirm whether behavioral improvements were long-lasting. Other studies established that sustained improvements in handwashing behavior occurred during a long-term program to improve adherence to hand-hygiene policies (*74,75*).

TABLE 8. Hand-hygiene adherence by health-care workers (1981–2000)

Ref. no.	Year	Setting	Before/ after	Adherence baseline	Adherence after intervention	Invervention
(*280*)	1981	ICU	A	16%	30%	More convenient sink locations
(*289*)	1981	ICU	A	41%	—	
		ICU	A	28%	—	
(*290*)	1983	All wards	A	45%	—	
(*281*)	1986	SICU	A	51%	—	
		MICU	A	76%	—	
(*276*)	1986	ICU	A	63%	92%	Performance feedback
(*291*)	1987	PICU	A	31%	30%	Wearing overgown
(*292*)	1989	MICU	B/A	14%/28%*	73%/81%	Feedback, policy reviews, memo, and posters
		MICU	B/A	26%/23%	38%/60%	
(*293*)	1989	NICU	A/B	75%/50%	—	
(*294*)	1990	ICU	A	32%	45%	Alcohol rub introduced
(*295*)	1990	ICU	A	81%	92%	Inservices first, then group feedback
(*296*)	1990	ICU	B/A	22%	30%	
(*297*)	1991	SICU	A	51%	—	
(*298*)	1991	Pedi OPDs	B	49%	49%	Signs, feedback, and verbal reminders to physicians
(*299*)	1991	Nursery and NICU	B/A†	28%	63%	Feedback, dissemination of literature, and results of environmental cultures
(*300*)	1992	NICU/others	A	29%	—	
(*71*)	1992	ICU	N.S.	40%	—	
(*301*)	1993	ICUs	A	40%	—	
(*87*)	1994	Emergency Room	A	32%	—	
(*86*)	1994	All wards	A	32%	—	
(*285*)	1994	SICU	A	22%	38%	Automated handwashing machines available
(*302*)	1994	NICU	A	62%	60%	No gowning required
(*303*)	1994	ICU Wards	AA	30%29%	—	
(*304*)	1995	ICU Oncol Ward	A	56%	—	
(*305*)	1995	ICU	N.S.	5%	63%	Lectures, feedback, and demonstrations
(*306*)	1996	PICU	B/A	12%/11%	68%/65%	Overt observation, followed by feedback
(*307*)	1996	MICU	A	41%	58%	Routine wearing of gowns and gloves
(*308*)	1996	Emergency Dept	A	54%	64%	Signs/distributed review paper
(*309*)	1998	All wards	A	30%	—	
(*310*)	1998	Pediatric wards	B/A	52%/49%	74%/69%	Feedback, movies, posters, and brochures
(*311*)	1999	MICU	B/A	12%/55%	—	
(*74*)	2000	All wards	B/A	48%	67%	Posters, feedback, administrative support, and alcohol rub
(*312*)	2000	MICU	A	42%	61%	Alcohol hand rub made available
(*283*)	2000	MICU	B/A	10%/22%	23%/48%	Education, feedback, and alcohol gel made available
		CTICU	B/A	4%/13%	7%/14%	
(*313*)	2000	Medical wards	A	60%	52%	Education, reminders, and alcohol gel made available

Note: ICU = intensive care unit, SICU = surgical ICU, MICU = medical ICU, PICU = pediatric ICU, NICU = neonatal ICU, Emerg = emergency, Oncol = oncology, CTICU = cardiothoracic ICU, and N.S. = not stated.

* Percentage compliance before/after patient contact.

† After contact with inanimate objects.

Factors Affecting Adherence. Factors that may influence hand hygiene include those identified in epidemiologic studies and factors reported by HCWs as being reasons for lack of adherence to hand-hygiene recommendations. Risk factors for poor adherence to hand hygiene have been determined objectively in several observational studies or interventions to improve adherence (*11,12,274,292,295,314–317*). Among these, being a physician or a nursing assistant, rather than a nurse, was consistently associated with reduced adherence (Box 1).

In the largest hospitalwide survey of hand-hygiene practices among HCWs *(11),* predictors of poor adherence to recommended hand-hygiene measures were identified. Predictor variables included professional category, hospital ward, time of day/week, and type and intensity of patient care, defined as the number of opportunities for hand hygiene per hour of patient care. In 2,834 observed opportunities for hand hygiene, average adherence was 48%. In multivariate analysis, nonadherence was lowest among nurses and during weekends

BOX 1. Factors influencing adherence to hand-hygiene practices*

Observed risk factors for poor adherence to recommended hand-hygiene practices

- Physician status (rather than a nurse)
- Nursing assistant status (rather than a nurse)
- Male sex
- Working in an intensive-care unit
- Working during the week (versus the weekend)
- Wearing gowns/gloves
- Automated sink
- Activities with high risk of cross-transmission
- High number of opportunities for hand hygiene per hour of patient care

Self-reported factors for poor adherence with hand hygiene

- Handwashing agents cause irritation and dryness
- Sinks are inconveniently located/shortage of sinks
- Lack of soap and paper towels
- Often too busy/insufficient time
- Understaffing/overcrowding
- Patient needs take priority
- Hand hygiene interferes with health-care worker relationships with patients
- Low risk of acquiring infection from patients
- Wearing of gloves/beliefs that glove use obviates the need for hand hygiene
- Lack of knowledge of guidelines/protocols
- Not thinking about it/forgetfulness
- No role model from colleagues or superiors
- Skepticism regarding the value of hand hygiene
- Disagreement with the recommendations
- Lack of scientific information of definitive impact of improved hand hygiene on health-care–associated infection rates

Additional perceived barriers to appropriate hand hygiene

- Lack of active participation in hand-hygiene promotion at individual or institutional level
- Lack of role model for hand hygiene
- Lack of institutional priority for hand hygiene
- Lack of administrative sanction of noncompliers/rewarding compliers
- Lack of institutional safety climate

* **Source:** Adapted from Pittet D. Improving compliance with hand hygiene in hospitals. Infect Control Hosp Epidemiol 2000;21:381–6.

(Odds Ratio [OR]: 0.6; 95% confidence interval [CI] = 0.4–0.8). Nonadherence was higher in intensive-care units compared with internal medicine wards (OR: 2.0; 95% CI = 1.3–3.1), during procedures that carried a high risk of bacterial contamination (OR: 1.8; 95% CI = 1.4–2.4), and when intensity of patient care was high (21–40 handwashing opportunities — OR: 1.3; 95% CI = 1.0-1.7; 41–60 opportunities — OR: 2.1; 95% CI = 1.5-2.9; >60 opportunities — OR: 2.1; 95% CI = 1.3–3.5). The higher the demand for hand hygiene, the lower the adherence; on average, adherence decreased by 5% (± 2%) for each increase of 10 opportunities per hour when the intensity of patient care exceeded 10 opportunities per hour. Similarly, the lowest adherence rate (36%) was found in intensive-care units, where indications for hand hygiene were typically more frequent (on average, 20 opportunities per patient-hour). The highest adherence rate (59%) was observed in pediatrics wards, where the average intensity of patient care was lower than in other hospital areas (an average of eight opportunities per patient-hour). The results of this study indicate that full adherence to previous guidelines may be unrealistic, and that facilitated access to hand hygiene could help improve adherence (*11,12,318*).

Perceived barriers to adherence with hand-hygiene practice recommendations include skin irritation caused by hand-hygiene agents, inaccessible hand-hygiene supplies, interference with HCW-patient relationships, priority of care (i.e., the patients' needs are given priority over hand hygiene), wearing of gloves, forgetfulness, lack of knowledge of the guidelines, insufficient time for hand hygiene, high workload and understaffing, and the lack of scientific information indicating a definitive impact of improved hand hygiene on health-care–associated infection rates (*11,274,292,295,315–317*). Certain perceived barriers to adherence with hand-hygiene guidelines have been assessed or quantified in observational studies (*12,274,292,295,314–317*) (Box 1).

Skin irritation by hand-hygiene agents constitutes a substantial barrier to appropriate adherence (*319*). Because soaps and detergents can damage skin when applied on a regular basis, HCWs must be better informed regarding the possible adverse effects associated with hand-hygiene agents. Lack of knowledge and education regarding this subject is a barrier to motivation. In several studies, alcohol-based hand rubs containing emollients (either isopropanol, ethanol, or n-propanol in 60%–90% vol/vol) were less irritating to the skin than the soaps or detergents tested. In addition, the alcohol-based products containing emollients that were tested were at least as tolerable and efficacious as the detergents tested. Also, studies demonstrate that several hand lotions have reduced skin scaling and cracking, which may reduce microbial shedding from the hands (*67,272,273*).

Easy access to hand-hygiene supplies, whether sink, soap, medicated detergent, or alcohol-based hand-rub solution, is essential for optimal adherence to hand-hygiene recommendations. The time required for nurses to leave a patient's bedside, go to a sink, and wash and dry their hands before attending the next patient is a deterrent to frequent handwashing or hand antisepsis (*11,318*). Engineering controls could facilitate adherence, but careful monitoring of hand-hygiene behavior should be conducted to exclude the possible negative effect of newly introduced handwashing devices (*88*).

The impact of wearing gloves on adherence to hand-hygiene policies has not been definitively established, because published studies have yielded contradictory results (*87,290,301,320*). Hand hygiene is required regardless of whether gloves are used or changed. Failure to remove gloves after patient contact or between "dirty" and "clean" body-site care on the same patient must be regarded as nonadherence to hand-hygiene recommendations (*11*). In a study in which experimental conditions approximated those occurring in clinical practice (*321*), washing and reusing gloves between patient contacts resulted in observed bacterial counts of 0–4.7 log on the hands after glove removal. Therefore, this practice should be discouraged; handwashing or disinfection should be performed after glove removal.

Lack of 1) knowledge of guidelines for hand hygiene, 2) recognition of hand-hygiene opportunities during patient care, and 3) awareness of the risk of cross-transmission of pathogens are barriers to good hand-hygiene practices. Furthermore, certain HCWs believe they have washed their hands when necessary, even when observations indicate they have not (*89,92,295,296,322*).

Perceived barriers to hand-hygiene behavior are linked not only to the institution, but also to HCWs' colleagues. Therefore, both institutional and small-group dynamics need to be considered when implementing a system change to secure an improvement in HCWs' hand-hygiene practice.

Possible Targets for Hand-Hygiene Promotion

Targets for the promotion of hand hygiene are derived from studies assessing risk factors for nonadherence, reported reasons for the lack of adherence to recommendations, and additional factors perceived as being important to facilitate appropriate HCW behavior. Although certain factors cannot be modified (Box 1), others can be changed.

One factor that must be addressed is the time required for HCWs to clean their hands. The time required for traditional handwashing may render full adherence to previous guidelines unrealistic (*11,12,318*) and more rapid access to hand-hygiene materials could help improve adherence. One study conducted in an intensive-care unit demonstrated that it took

nurses an average of 62 seconds to leave a patient's bedside, walk to a sink, wash their hands, and return to patient care (*318*). In contrast, an estimated one fourth as much time is required when using alcohol-based hand rub placed at each patient's bedside. Providing easy access to hand-hygiene materials is mandatory for appropriate hand-hygiene behavior and is achievable in the majority of health-care facilities (*323*). In particular, in high-demand situations (e.g., the majority of critical-care units), under hectic working conditions, and at times of overcrowding or understaffing, HCWs may be more likely to use an alcohol-based hand rub than to wash their hands (*323*). Further, using alcohol-based hand rubs may be a better option than traditional handwashing with plain soap and water or antiseptic handwash, because they not only require less time (*166,318*) but act faster (*1*) and irritate hands less often (*1,67,96,98,166*). They also were used in the only program that reported a sustained improvement in hand-hygiene adherence associated with decreased infection rates (*74*). However, making an alcohol-based hand rub available to personnel without providing ongoing educational and motivational activities may not result in long-lasting improvement in hand-hygiene practices (*313*). Because increased use of hand-hygiene agents might be associated with skin dryness, the availability of free skin-care lotion is recommended.

Education is a cornerstone for improvement with hand-hygiene practices. Topics that must be addressed by educational programs include the lack of 1) scientific information for the definitive impact of improved hand hygiene on health-care–associated infection and resistant organism transmission rates; 2) awareness of guidelines for hand hygiene and insufficient knowledge concerning indications for hand hygiene during daily patient care; 3) knowledge concerning the low average adherence rate to hand hygiene by the majority of HCWs; and 4) knowledge concerning the appropriateness, efficacy, and understanding of the use of hand-hygiene and skin-care–protection agents.

HCWs necessarily evolve within a group that functions within an institution. Possible targets for improvement in hand-hygiene behavior not only include factors linked to individual HCWs, but also those related to the group(s) and the institution as a whole (*317,323*). Examples of possible targets for hand-hygiene promotion at the group level include education and performance feedback on hand-hygiene adherence; efforts to prevent high workload, downsizing, and understaffing; and encouragement and provision of role models from key members in the work unit. At the institutional level, targets for improvement include 1) written guidelines, hand-hygiene agents, skin-care promotions and agents, or hand-hygiene facilities; 2) culture or tradition of adherence; and 3) administrative leadership, sanction, support, and rewards. Several studies, conducted in various types of institutions, reported modest and even low levels of adherence to recommended hand-hygiene practices, indicating that such adherence varied by hospital ward and by type of HCW. These results indicate educational sessions may need to be designed specifically for certain types of personnel (*11,289,290,294,317,323)*.

Lessons Learned from Behavioral Theories

In 1998, the prevailing behavioral theories and their applications with regard to the health professions were reviewed by researchers in an attempt to better understand how to target more successful interventions (*317*). The researchers proposed a hypothetical framework to enhance hand-hygiene practices and stressed the importance of considering the complexity of individual and institutional factors when designing behavioral interventions.

Although behavioral theories and secondary interventions have primarily targeted individual workers, this practice might be insufficient to produce sustained change (*317,324,325*). Interventions aimed at improving hand-hygiene practices must account for different levels of behavior interaction (*12,317,326*). Thus, the interdependence of individual factors, environmental constraints, and the institutional climate must be taken into account in the strategic planning and development of hand-hygiene campaigns. Interventions to promote hand hygiene in hospitals should consider variables at all these levels. Various factors involved in hand-hygiene behavior include intention, attitude towards the behavior, perceived social norm, perceived behavioral control, perceived risk for infection, hand-hygiene practices, perceived role model, perceived knowledge, and motivation (*317*). The factors necessary for change include 1) dissatisfaction with the current situation, 2) perception of alternatives, and 3) recognition, both at the individual and institutional level, of the ability and potential to change. Although the latter implies education and motivation, the former two necessitate a system change.

Among the reported reasons for poor adherence with hand-hygiene recommendations (Box 1), certain ones are clearly associated with the institution or system (e.g., lack of institutional priority for hand hygiene, administrative sanctions, and a safety climate). Although all of these reasons would require a system change in the majority of institutions, the third requires management commitment, visible safety programs, an acceptable level of work stress, a tolerant and supportive attitude toward reported problems, and belief in the efficacy

of preventive strategies (*12,317,325,327*). Most importantly, an improvement in infection-control practices requires 1) questioning basic beliefs, 2) continuous assessment of the group (or individual) stage of behavioral change, 3) intervention(s) with an appropriate process of change, and 4) supporting individual and group creativity (*317*). Because of the complexity of the process of change, single interventions often fail. Thus, a multimodal, multidisciplinary strategy is likely necessary (*74,75,317,323,326*).

Methods Used To Promote Improved Hand Hygiene

Hand-hygiene promotion has been challenging for >150 years. In-service education, information leaflets, workshops and lectures, automated dispensers, and performance feedback on hand-hygiene adherence rates have been associated with transient improvement (*291,294–296,306,314*).

Several strategies for promotion of hand hygiene in hospitals have been published (Table 9). These strategies require education, motivation, or system change. Certain strategies are based on epidemiologic evidence, others on the authors' and other investigators' experience and review of current knowledge. Some strategies may be unnecessary in certain circumstances, but may be helpful in others. In particular, changing the hand-hygiene agent could be beneficial in institutions or hospital wards with a high workload and a high demand for hand hygiene when alcohol-based hand rubs are not available (*11,73,78,328*). However, a change in the recommended hand-hygiene agent could be deleterious if introduced during winter, at a time of higher hand-skin irritability, and if not accompanied by the provision of skin-care products (e.g., protective creams and lotions). Additional specific elements should be considered for inclusion in educational and motivational programs (Box 2).

Several strategies that could potentially be associated with successful promotion of hand hygiene require a system change (Box 1). Hand-hygiene adherence and promotion involve factors at both the individual and system level. Enhancing individual and institutional attitudes regarding the feasibility of making changes (self-efficacy), obtaining active participation of personnel at both levels, and promoting an institutional safety climate represent challenges that exceed the current perception of the role of infection-control professionals.

Whether increased education, individual reinforcement technique, appropriate rewarding, administrative sanction, enhanced self-participation, active involvement of a larger number of organizational leaders, enhanced perception of health threat, self-efficacy, and perceived social pressure (*12,317,329,330*), or combinations of these factors can improve HCWs' adherence with hand hygiene needs further investigation. Ultimately, adherence to recommended hand-hygiene practices should become part of a culture of patient safety where a set of interdependent quality elements interact to achieve a shared objective (*331*).

On the basis of both these hypothetical considerations and successful, actual experiences in certain institutions, strategies to improve adherence to hand-hygiene practices should be both multimodal and multidisciplinary. However, strategies must be further researched before they are implemented.

TABLE 9. Stategies for successful promotion of hand hygiene in hospitals

Strategy	Tool for change*	Selected references†
Education	E (M, S)	(*74,295,306,326,393*)
Routine observation and feedback	S (E, M)	(*74,294,306,326,393*)
Engineering control		
Make hand hygiene possible, easy, and convenient	S	(*74,281,326,393*)
Make alcohol-based hand rub available	S	(*74*)
(at least in high-demand situations)	S	(*74,283,312*)
Patient education	S (M)	(*283,394*)
Reminders in the workplace	S	(*74,395*)
Administrative sanction/rewarding	S	(*12,317*)
Change in hand-hygiene agent	S (E)	(*11,67,71,283,312*)
Promote/facilitate skin care for health-care–workers' hands	S (E)	(*67,74,274,275*)
Obtain active participation at individual and institutional level	E, M, S	(*74,75,317*)
Improve institutional safety climate	S (M)	(*74,75,317*)
Enhance individual and institutitional self-efficacy	S (E, M)	(*74,75,317*)
Avoid overcrowding, understaffing, and excessive workload	S	(*11,74,78,297,396*)
Combine several of above strategies	E, M, S	(*74,75,295,306,317,326*)

* The dynamic of behavioral change is complex and involves a combination of education (E), motivation (M), and system change (S).
† Only selected references have been listed; readers should refer to more extensive reviews for exhaustive reference lists (*1,8,317,323,397*).

BOX 2. Elements of health-care worker educational and motivational programs

Rationale for hand hygiene
- Potential risks of transmission of microorganisms to patients
- Potential risks of health-care worker colonization or infection caused by organisms acquired from the patient
- Morbidity, mortality, and costs associated with health-care–associated infections

Indications for hand hygiene
- Contact with a patient's intact skin (e.g., taking a pulse or blood pressure, performing physical examinations, lifting the patient in bed) (*25,26,45,48,51,53*)
- Contact with environmental surfaces in the immediate vicinity of patients (*46,51,53,54*)
- After glove removal (*50,58,71*)

Techniques for hand hygiene
- Amount of hand-hygiene solution
- Duration of hand-hygiene procedure
- Selection of hand-hygiene agents
  - — Alcohol-based hand rubs are the most efficacious agents for reducing the number of bacteria on the hands of personnel. Antiseptic soaps and detergents are the next most effective, and non-antimicrobial soaps are the least effective (*1,398*).
  - — Soap and water are recommended for visibly soil hands.
  - — Alcohol-based hand rubs are recommended for routine decontamination of hands for all clinical indications (except when hands are visibly soiled) and as one of the options for surgical hand hygiene.

Methods to maintain hand skin health
- Lotions and creams can prevent or minimize skin dryness and irritation caused by irritant contact dermatitis
- Acceptable lotions or creams to use
- Recommended schedule for applying lotions or creams

Expectations of patient care managers/administrators
- Written statements regarding the value of, and support for, adherence to recommended hand-hygiene practices
- Role models demonstrating adherence to recommended hand hygiene practices (*399*)

Indications for, and limitations of, glove use
- Hand contamination may occur as a result of small, undetected holes in examination gloves (*321,361*)
- Contamination may occur during glove removal (50)
- Wearing gloves does not replace the need for hand hygiene (58)
- Failure to remove gloves after caring for a patient may lead to transmission of microorganizations from one patient to another *(373).*

Efficacy of Promotion and Impact of Improved Hand Hygiene

The lack of scientific information of the definitive impact of improved hand hygiene on health-care–associated infection rates is a possible barrier to appropriate adherence with hand-hygiene recommendations (Box 1). However, evidence supports the belief that improved hand hygiene can reduce health-care–associated infection rates. Failure to perform appropriate hand hygiene is considered the leading cause of health-care–associated infections and spread of multiresistant organisms and has been recognized as a substantial contributor to outbreaks.

Of nine hospital-based studies of the impact of hand hygiene on the risk of health-care–associated infections (Table 10) (*48,69–75,296*), the majority demonstrated a temporal relationship between improved hand-hygiene practices and reduced infection rates.

In one of these studies, endemic MRSA in a neonatal intensive-care unit was eliminated 7 months after introduction of a new

TABLE 10. Association between improved adherence with hand-hygiene practice and health-care–associated infection rates

Year	Ref. no.	Hospital setting	Results	Duration of follow-up
1977	(*48*)	Adult ICU	Reduction in health-care–associated infections caused by endemic *Klebsiella* spp.	2 years
1982	(*69*)	Adult ICU	Reduction in health-care-associated infection rates	N.S.
1984	(*70*)	Adult ICU	Reduction in health-care–associated infection rates	N.S.
1990	(*296*)	Adult ICU	No effect (average hand hygiene adherence improvement did not reach statistical significance)	11 months
1992	(*71*)	Adult ICU	Substantial difference between rates of health-care–associated infection between two different hand-hygiene agents	8 months
1994	(*72*)	NICU	Elimination of MRSA, when combined with multiple other infection-control measures. Reduction of vancomycin use	9 months
1995	(*73*)	Newborn nursery	Elimination of MRSA, when combined with multiple other infection-control measures	3.5 years
2000	(*75*)	MICU/NICU	85% relative reduction of VRE rate in the intervention hospital; 44% relative reduction in control hospital; no change in MRSA	8 months
2000	(*74*)	Hospitalwide	Substantial reduction in the annual overall prevalence of health-care–associated infections and MRSA cross-transmission rates. Active surveillance cultures and contact precautions were implemented during same period	5 years

Note: ICU = intensive care unit, NICU = neonatal ICU, MRSA = methicillin-resistant *Staphylococcus aureus*, MICU = medical ICU, and N.S. = not stated.

hand antiseptic (1% triclosan); all other infection-control measures remained in place, including the practice of conducting weekly active surveillance by obtaining cultures (*72*). Another study reported an MRSA outbreak involving 22 infants in a neonatal unit (*73*). Despite intensive efforts, the outbreak could not be controlled until a new antiseptic was added (i.e., 0.3% triclosan); all previously used control measures remained in place, including gloves and gowns, cohorting, and obtaining cultures for active surveillance.

The effectiveness of a longstanding, hospitalwide program to promote hand hygiene at the University of Geneva hospitals was recently reported (*74*). Overall adherence to hand-hygiene guidelines during routine patient care was monitored during hospitalwide observational surveys. These surveys were conducted biannually during December 1994–December 1997, before and during implementation of a hand-hygiene campaign that specifically emphasized the practice of bedside, alcohol-based hand disinfection. Individual-sized bottles of hand-rub solution were distributed to all wards, and custom-made holders were mounted on all beds to facilitate access to hand disinfection. HCWs were also encouraged to carry bottles in their pockets, and in 1996, a newly designed flat (instead of round) bottle was made available to further facilitate pocket carriage. The promotional strategy was multimodal and involved a multidisciplinary team of HCWs, the use of wall posters, the promotion of antiseptic hand rubs located at bedsides throughout the institution, and regular performance feedback to all HCWs (see http://www.hopisafe.ch for further details on methodology). Health-care–associated infection rates, attack rates of MRSA cross-transmission, and consumption of hand-rub disinfectant were measured. Adherence to recommended hand-hygiene practices improved progressively from 48% in 1994 to 66% in 1997 ($p < 0.001$). Whereas recourse to handwashing with soap and water remained stable, frequency of hand disinfection markedly increased during the study period ($p < 0.001$), and the consumption of alcohol-based hand-rub solution increased from 3.5 to 15.4 liters per 1,000 patient-days during 1993–1998 ($p < 0.001$). The increased frequency of hand disinfection was unchanged after adjustment for known risk factors of poor adherence. During the same period, both overall health-care–associated infection and MRSA transmission rates decreased (both $p < 0.05$). The observed reduction in MRSA transmission may have been affected by both improved hand-hygiene adherence and the simultaneous implementation of active surveillance cultures for detecting and isolating patients colonized with MRSA (*332*). The experience from the University of Geneva hospitals constitutes the first report of a hand-hygiene campaign with a sustained improvement over several years. An additional multimodal program also yielded sustained improvements in hand-hygiene practices over an extended period (*75*); the majority of studies have been limited to a 6- to 9-month observation period.

Although these studies were not designed to assess the independent contribution of hand hygiene on the prevention of health-care–associated infections, the results indicate that

improved hand-hygiene practices reduce the risk of transmission of pathogenic microorganisms. The beneficial effects of hand-hygiene promotion on the risk of cross-transmission also have been reported in surveys conducted in schools and day care centers (*333–338*), as well as in a community setting (*339–341*).

Other Policies Related to Hand Hygiene

Fingernails and Artificial Nails

Studies have documented that subungual areas of the hand harbor high concentrations of bacteria, most frequently coagulase-negative staphylococci, gram-negative rods (including *Pseudomonas* spp.), Corynebacteria, and yeasts (*14,342,343*). Freshly applied nail polish does not increase the number of bacteria recovered from periungual skin, but chipped nail polish may support the growth of larger numbers of organisms on fingernails (*344,345*). Even after careful handwashing or the use of surgical scrubs, personnel often harbor substantial numbers of potential pathogens in the subungual spaces (*346–348*).

Whether artificial nails contribute to transmission of health-care–associated infections is unknown. However, HCWs who wear artificial nails are more likely to harbor gram-negative pathogens on their fingertips than are those who have natural nails, both before and after handwashing (*347–349*). Whether the length of natural or artificial nails is a substantial risk factor is unknown, because the majority of bacterial growth occurs along the proximal 1 mm of the nail adjacent to subungual skin (*345,347,348*). Recently, an outbreak of *P. aeruginosa* in a neonatal intensive care unit was attributed to two nurses (one with long natural nails and one with long artificial nails) who carried the implicated strains of *Pseudomonas* spp. on their hands (*350*). Patients were substantially more likely than controls to have been cared for by the two nurses during the exposure period, indicating that colonization of long or artificial nails with *Pseudomonas* spp. may have contributed to causing the outbreak. Personnel wearing artificial nails also have been epidemiologically implicated in several other outbreaks of infection caused by gram-negative bacilli and yeast (*351–353*). Although these studies provide evidence that wearing artificial nails poses an infection hazard, additional studies are warranted.

Gloving Policies

CDC has recommended that HCWs wear gloves to 1) reduce the risk of personnel acquiring infections from patients, 2) prevent health-care worker flora from being transmitted to patients, and 3) reduce transient contamination of the hands of personnel by flora that can be transmitted from one patient to another (*354*). Before the emergence of the acquired immunodeficiency syndrome (AIDS) epidemic, gloves were worn primarily by personnel caring for patients colonized or infected with certain pathogens or by personnel exposed to patients with a high risk of hepatitis B. Since 1987, a dramatic increase in glove use has occurred in an effort to prevent transmission of HIV and other bloodborne pathogens from patients to HCWs (*355*). The Occupational Safety and Health Administration (OSHA) mandates that gloves be worn during all patient-care activities that may involve exposure to blood or body fluids that may be contaminated with blood (*356*).

The effectiveness of gloves in preventing contamination of HCWs' hands has been confirmed in several clinical studies (*45,51,58*). One study found that HCWs who wore gloves during patient contact contaminated their hands with an average of only 3 CFUs per minute of patient care, compared with 16 CFUs per minute for those not wearing gloves (*51*). Two other studies, involving personnel caring for patients with *C. difficile* or VRE, revealed that wearing gloves prevented hand contamination among the majority of personnel having direct contact with patients (*45,58*). Wearing gloves also prevented personnel from acquiring VRE on their hands when touching contaminated environmental surfaces (*58*). Preventing heavy contamination of the hands is considered important, because handwashing or hand antisepsis may not remove all potential pathogens when hands are heavily contaminated (*25,111*).

Several studies provide evidence that wearing gloves can help reduce transmission of pathogens in health-care settings. In a prospective controlled trial that required personnel to routinely wear vinyl gloves when handling any body substances, the incidence of *C. difficile* diarrhea among patients decreased from 7.7 cases/1,000 patient discharges before the intervention to 1.5 cases/1,000 discharges during the intervention (*226*). The prevalence of asymptomatic *C. difficile* carriage also decreased substantially on "glove" wards, but not on control wards. In intensive-care units where VRE or MRSA have been epidemic, requiring all HCWs to wear gloves to care for all patients in the unit (i.e., universal glove use) likely has helped control outbreaks (*357,358*).

The influence of glove use on the hand-hygiene habits of personnel is not clear. Several studies found that personnel who wore gloves were less likely to wash their hands upon leaving a patient's room (*290,320*). In contrast, two other studies found that personnel who wore gloves were substantially more likely to wash their hands after patient care (*87,301*).

The following caveats regarding use of gloves by HCWs must be considered. Personnel should be informed that gloves

do not provide complete protection against hand contamination. Bacterial flora colonizing patients may be recovered from the hands of ≤30% of HCWs who wear gloves during patient contact (*50,58*). Further, wearing gloves does not provide complete protection against acquisition of infections caused by hepatitis B virus and herpes simplex virus (*359,360*). In such instances, pathogens presumably gain access to the caregiver's hands via small defects in gloves or by contamination of the hands during glove removal (*50,321,359,361*).

Gloves used by HCWs are usually made of natural rubber latex and synthetic nonlatex materials (e.g., vinyl, nitrile, and neoprene [polymers and copolymers of chloroprene]). Because of the increasing prevalence of latex sensitivity among HCWs and patients, FDA has approved several powdered and powder-free latex gloves with reduced protein contents, as well as synthetic gloves that can be made available by health-care institutions for use by latex-sensitive employees. In published studies, the barrier integrity of gloves varies on the basis of type and quality of glove material, intensity of use, length of time used, manufacturer, whether gloves were tested before or after use, and method used to detect glove leaks (*359,361–366*). In published studies, vinyl gloves have had defects more frequently than latex gloves, the difference in defect frequency being greatest after use (*359,361,364,367*). However, intact vinyl gloves provide protection comparable to that of latex gloves (*359*). Limited studies indicate that nitrile gloves have leakage rates that approximate those of latex gloves (*368–371*). Having more than one type of glove available is desirable, because it allows personnel to select the type that best suits their patient-care activities. Although recent studies indicate that improvements have been made in the quality of gloves (*366*), hands should be decontaminated or washed after removing gloves (*8,50,58,321,361*). Gloves should not be washed or reused (*321,361*). Use of petroleum-based hand lotions or creams may adversely affect the integrity of latex gloves (*372*). After use of powdered gloves, certain alcohol hand rubs may interact with residual powder on the hands of personnel, resulting in a gritty feeling on the hands. In facilities where powdered gloves are commonly used, various alcohol-based hand rubs should be tested after removal of powdered gloves to avoid selecting a product that causes this undesirable reaction. Personnel should be reminded that failure to remove gloves between patients may contribute to transmission of organisms (*358,373*).

Jewelry

Several studies have demonstrated that skin underneath rings is more heavily colonized than comparable areas of skin on fingers without rings (*374–376*). One study found that 40% of nurses harbored gram-negative bacilli (e.g., *E. cloacae*, *Klebsiella*, and *Acinetobacter*) on skin under rings and that certain nurses carried the same organism under their rings for several months (*375*). In a more recent study involving >60 intensive care unit nurses, multivariable analysis revealed that rings were the only substantial risk factor for carriage of gram-negative bacilli and *S. aureus* and that the concentration of organisms recovered correlated with the number of rings worn (*377*). Whether the wearing of rings results in greater transmission of pathogens is unknown. Two studies determined that mean bacterial colony counts on hands after handwashing were similar among persons wearing rings and those not wearing rings (*376,378*). Further studies are needed to establish if wearing rings results in greater transmission of pathogens in health-care settings.

Hand-Hygiene Research Agenda

Although the number of published studies concerning hand hygiene has increased considerably in recent years, many questions regarding hand-hygiene products and strategies for improving adherence of personnel to recommended policies remain unanswered. Several concerns must still be addressed by researchers in industry and by clinical investigators (Box 3).

Web-Based Hand-Hygiene Resources

Additional information regarding improving hand hygiene is available at http://www.hopisafe.ch
University of Geneva Hospitals, Geneva, Switzerland
http://www.cdc.gov/ncidod/hip
CDC, Atlanta, Georgia
http://www.jr2.ox.ac.uk/bandolier/band88/b88-8.html
Bandolier journal, United Kingdom
http://www.med.upenn.edu
University of Pennsylvania, Philadelphia, Pennsylvania

BOX 3. Hand-hygiene research agenda

Education and promotion

- Provide health-care workers (HCWs) with better education regarding the types of patient care activities that can result in hand contamination and cross-transmission of microorganisms.
- Develop and implement promotion hand-hygiene programs in pregraduate courses.
- Study the impact of population-based education on hand-hygiene behavior.
- Design and conduct studies to determine if frequent glove use should be encouraged or discouraged.
- Determine evidence-based indications for hand cleansing (considering that it might be unrealistic to expect HCWs to clean their hands after every contact with the patient).
- Assess the key determinants of hand-hygiene behavior and promotion among the different populations of HCWs.
- Develop methods to obtain management support.
- Implement and evaluate the impact of the different components of multimodal programs to promote hand hygiene.

Hand-hygiene agents and hand care

- Determine the most suitable formulations for hand-hygiene products.
- Determine if preparations with persistent antimicrobial activity reduce infection rates more effectively than do preparations whose activity is limited to an immediate effect.
- Study the systematic replacement of conventional handwashing by the use of hand disinfection.
- Develop devices to facilitate the use and optimal application of hand-hygiene agents.
- Develop hand-hygiene agents with low irritancy potential.
- Study the possible advantages and eventual interaction of hand-care lotions, creams, and other barriers to help minimize the potential irritation associated with hand-hygiene agents.

Laboratory-based and epidemiologic research and development

- Develop experimental models for the study of cross-contamination from patient to patient and from environment to patient.
- Develop new protocols for evaluating the in vivo efficacy of agents, considering in particular short application times and volumes that reflect actual use in health-care facilities.
- Monitor hand-hygiene adherence by using new devices or adequate surrogate markers, allowing frequent individual feedback on performance.
- Determine the percentage increase in hand-hygiene adherence required to achieve a predictable risk reduction in infection rates.
- Generate more definitive evidence for the impact on infection rates of improved adherence to recommended hand-hygiene practices.
- Provide cost-effectiveness evaluation of successful and unsuccessful promotion campaigns.

Part II. Recommendations

Categories

These recommendations are designed to improve hand-hygiene practices of HCWs and to reduce transmission of pathogenic microorganisms to patients and personnel in health-care settings. This guideline and its recommendations are not intended for use in food processing or food-service establishments, and are not meant to replace guidance provided by FDA's Model Food Code.

As in previous CDC/HICPAC guidelines, each recommendation is categorized on the basis of existing scientific data, theoretical rationale, applicability, and economic impact. The CDC/HICPAC system for categorizing recommendations is as follows:

Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.

Category IB. Strongly recommended for implementation and supported by certain experimental, clinical, or epidemiologic studies and a strong theoretical rationale.

Category IC. Required for implementation, as mandated by federal or state regulation or standard.

Category II. Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale.

No recommendation. Unresolved issue. Practices for which insufficient evidence or no consensus regarding efficacy exist.

Recommendations

1. Indications for handwashing and hand antisepsis
   - A. When hands are visibly dirty or contaminated with proteinaceous material or are visibly soiled with blood or other body fluids, wash hands with either a non-antimicrobial soap and water or an antimicrobial soap and water (IA) (*66*).
   - B. If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands in all other clinical situations described in items 1C–J (IA) (*74,93,166,169,283,294,312,398*). Alternatively, wash hands with an antimicrobial soap and water in all clinical situations described in items 1C–J (IB) (*69-71,74*).
   - C. Decontaminate hands before having direct contact with patients (IB) (*68,400*).
   - D. Decontaminate hands before donning sterile gloves when inserting a central intravascular catheter (IB) (*401,402*).
   - E. Decontaminate hands before inserting indwelling urinary catheters, peripheral vascular catheters, or other invasive devices that do not require a surgical procedure (IB) (*25,403*).
   - F. Decontaminate hands after contact with a patient's intact skin (e.g., when taking a pulse or blood pressure, and lifting a patient) (IB) (*25,45,48,68*).
   - G. Decontaminate hands after contact with body fluids or excretions, mucous membranes, nonintact skin, and wound dressings if hands are not visibly soiled (IA) (*400*).
   - H. Decontaminate hands if moving from a contaminated-body site to a clean-body site during patient care (II) (*25,53*).
   - I. Decontaminate hands after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient (II) (*46,53,54*).
   - J. Decontaminate hands after removing gloves (IB) (*50,58,321*).
   - K. Before eating and after using a restroom, wash hands with a non-antimicrobial soap and water or with an antimicrobial soap and water (IB) (*404-409*).
   - L. Antimicrobial-impregnated wipes (i.e., towelettes) may be considered as an alternative to washing hands with non-antimicrobial soap and water. Because they are not as effective as alcohol-based hand rubs or washing hands with an antimicrobial soap and water for reducing bacterial counts on the hands of HCWs, they are not a substitute for using an alcohol-based hand rub or antimicrobial soap (IB) (*160,161*).
   - M. Wash hands with non-antimicrobial soap and water or with antimicrobial soap and water if exposure to *Bacillus anthracis* is suspected or proven. The physical action of washing and rinsing hands under such circumstances is recommended because alcohols, chlorhexidine, iodophors, and other antiseptic agents have poor activity against spores (II) (*120,172, 224,225*).
   - N. No recommendation can be made regarding the routine use of nonalcohol-based hand rubs for hand hygiene in health-care settings. Unresolved issue.
2. Hand-hygiene technique
   - A. When decontaminating hands with an alcohol-based hand rub, apply product to palm of one hand and rub hands together, covering all surfaces of hands and fingers, until hands are dry (IB) (*288,410*). Follow the manufacturer's recommendations regarding the volume of product to use.
   - B. When washing hands with soap and water, wet hands first with water, apply an amount of product recommended by the manufacturer to hands, and rub hands together vigorously for at least 15 seconds, covering all surfaces of the hands and fingers. Rinse hands with water and dry thoroughly with a disposable towel. Use towel to turn off the faucet (IB) (*90-92,94,411*). Avoid using hot water, because repeated exposure to hot water may increase the risk of dermatitis (IB) (*254,255*).
   - C. Liquid, bar, leaflet or powdered forms of plain soap are acceptable when washing hands with a non-antimicrobial soap and water. When bar soap is used, soap racks that facilitate drainage and small bars of soap should be used (II) (*412-415*).
   - D. Multiple-use cloth towels of the hanging or roll type are not recommended for use in health-care settings (II) (*137,300*).
3. Surgical hand antisepsis
   - A. Remove rings, watches, and bracelets before beginning the surgical hand scrub (II) (*375,378,416*).
   - B. Remove debris from underneath fingernails using a nail cleaner under running water (II) (*14,417*).

C. Surgical hand antisepsis using either an antimicrobial soap or an alcohol-based hand rub with persistent activity is recommended before donning sterile gloves when performing surgical procedures (IB) (*115,159,232,234,237,418*).

D. When performing surgical hand antisepsis using an antimicrobial soap, scrub hands and forearms for the length of time recommended by the manufacturer, usually 2–6 minutes. Long scrub times (e.g., 10 minutes) are not necessary (IB) (*117,156,205, 207,238-241*).

E. When using an alcohol-based surgical hand-scrub product with persistent activity, follow the manufacturer's instructions. Before applying the alcohol solution, prewash hands and forearms with a non-antimicrobial soap and dry hands and forearms completely. After application of the alcohol-based product as recommended, allow hands and forearms to dry thoroughly before donning sterile gloves (IB) (*159,237*).

4. Selection of hand-hygiene agents

A. Provide personnel with efficacious hand-hygiene products that have low irritancy potential, particularly when these products are used multiple times per shift (IB) (*90,92,98,166,249*). This recommendation applies to products used for hand antisepsis before and after patient care in clinical areas and to products used for surgical hand antisepsis by surgical personnel.

B. To maximize acceptance of hand-hygiene products by HCWs, solicit input from these employees regarding the feel, fragrance, and skin tolerance of any products under consideration. The cost of hand-hygiene products should not be the primary factor influencing product selection (IB) (*92,93,166, 274,276-278*).

C. When selecting non-antimicrobial soaps, antimicrobial soaps, or alcohol-based hand rubs, solicit information from manufacturers regarding any known interactions between products used to clean hands, skin care products, and the types of gloves used in the institution (II) (*174,372*).

D. Before making purchasing decisions, evaluate the dispenser systems of various product manufacturers or distributors to ensure that dispensers function adequately and deliver an appropriate volume of product (II) (*286*).

E. Do not add soap to a partially empty soap dispenser. This practice of "topping off" dispensers can lead to bacterial contamination of soap (IA) (*187,419*).

5. Skin care

A. Provide HCWs with hand lotions or creams to minimize the occurrence of irritant contact dermatitis associated with hand antisepsis or handwashing (IA) (*272,273*).

B. Solicit information from manufacturers regarding any effects that hand lotions, creams, or alcohol-based hand antiseptics may have on the persistent effects of antimicrobial soaps being used in the institution (IB) (*174,420,421*).

6. Other Aspects of Hand Hygiene

A. Do not wear artificial fingernails or extenders when having direct contact with patients at high risk (e.g., those in intensive-care units or operating rooms) (IA) (*350–353*).

B. Keep natural nails tips less than 1/4-inch long (II) (*350*).

C. Wear gloves when contact with blood or other potentially infectious materials, mucous membranes, and nonintact skin could occur (IC) (*356*).

D. Remove gloves after caring for a patient. Do not wear the same pair of gloves for the care of more than one patient, and do not wash gloves between uses with different patients (IB) (*50,58,321,373*).

E. Change gloves during patient care if moving from a contaminated body site to a clean body site (II) (*50,51,58*).

F. No recommendation can be made regarding wearing rings in health-care settings. Unresolved issue.

7. Health-care worker educational and motivational programs

A. As part of an overall program to improve hand-hygiene practices of HCWs, educate personnel regarding the types of patient-care activities that can result in hand contamination and the advantages and disadvantages of various methods used to clean their hands (II) (*74,292,295,299*).

B. Monitor HCWs' adherence with recommended hand-hygiene practices and provide personnel with information regarding their performance (IA) (*74,276,292,295,299,306,310*).

C. Encourage patients and their families to remind HCWs to decontaminate their hands (II) (*394,422*).

8. Administrative measures

A. Make improved hand-hygiene adherence an institutional priority and provide appropriate

administrative support and financial resources (IB) (*74,75*).

B. Implement a multidisciplinary program designed to improve adherence of health personnel to recommended hand-hygiene practices (IB) (*74,75*).

C. As part of a multidisciplinary program to improve hand-hygiene adherence, provide HCWs with a readily accessible alcohol-based hand-rub product (IA) (*74,166,283,294,312*).

D. To improve hand-hygiene adherence among personnel who work in areas in which high workloads and high intensity of patient care are anticipated, make an alcohol-based hand rub available at the entrance to the patient's room or at the bedside, in other convenient locations, and in individual pocket-sized containers to be carried by HCWs (IA) (*11,74,166,283,284,312,318,423*).

E. Store supplies of alcohol-based hand rubs in cabinets or areas approved for flammable materials (IC).

Part III. Performance Indicators

1. The following performance indicators are recommended for measuring improvements in HCWs' hand-hygiene adherence:

   A. Periodically monitor and record adherence as the number of hand-hygiene episodes performed by personnel/number of hand-hygiene opportunities, by ward or by service. Provide feedback to personnel regarding their performance.

   B. Monitor the volume of alcohol-based hand rub (or detergent used for handwashing or hand antisepsis) used per 1,000 patient-days.

   C. Monitor adherence to policies dealing with wearing of artificial nails.

   D. When outbreaks of infection occur, assess the adequacy of health-care worker hand hygiene.

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Appendix

Antimicrobial Spectrum and Characteristics of Hand-Hygiene Antiseptic Agents*

Group	Gram-positive bacteria	Gram-negative bacteria	Mycobacteria	Fungi	Viruses	Speed of action	Comments
Alcohols	+++	+++	+++	+++	+++	Fast	Optimum concentration 60%–95%; no persistent activity
Chlorhexidine (2% and 4% aqueous)	+++	++	+	+	+++	Intermediate	Persistent activity; rare allergic reactions
Iodine compounds	+++	+++	+++	++	+++	Intermediate	Causes skin burns; usually too irritating for hand hygiene
Iodophors	+++	+++	+	++	++	Intermediate	Less irritating than iodine; acceptance varies
Phenol derivatives	+++	+	+	+	+	Intermediate	Activity neutralized by nonionic surfactants
Tricolsan	+++	++	+	—	+++	Intermediate	Acceptability on hands varies
Quaternary ammonium compounds	+	++	—	—	+	Slow	Used only in combination with alcohols; ecologic concerns

Note: +++ = excellent; ++ = good, but does not include the entire bacterial spectrum; + = fair; — = no activity or not sufficient.
* Hexachlorophene is not included because it is no longer an accepted ingredient of hand disinfectants.

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Continuing Education Activity Sponsored by CDC
Guideline for Hand Hygiene in Health-Care Settings

Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force

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Goal and Objectives

This *MMWR* provides evidence-based recommendations for hand hygiene in health-care settings. These recommendations were developed by the Healthcare Infection Control Practices Advisory Committee (HICPAC), the Society for Healthcare Epidemiology of America, the Association for Professionals in Infection Control and Epidemiology, and the Infectious Diseases Society of America Hand Hygiene Task Force. The goal of this report is to provide guidance for clinicians and other health-care practitioners regarding strategies to improve hand-hygiene practices and reduce transmission of microorganisms in health-care settings. Upon completion of this educational activity, the reader should be able to 1) describe the indications for hand hygiene in health-care settings; 2) list the advantages of alcohol-based hand rubs; and 3) describe the barriers to hand hygiene in health-care settings.

To receive continuing education credit, please answer all of the following questions.

1. Hand hygiene refers to . . .
- A. handwashing using plain soap and water.
- B. using an antiseptic hand rub (e.g alcohol, chlorhexidine, iodine).
- C. handwashing using antimicrobial soap and water.
- D. all of the above.

2. Hand hygiene adherence in health-care facilities might be improved by . . .
- A. providing personnel with individual containers of alcohol-based hand rubs.
- B. providing personnel with hand lotions or creams.
- C. providing personnel with feedback regarding hand-hygiene adherence/performance.
- D. all of the above.

3. Alcohol-based hand rubs have good or excellent antimicrobial activity against all of the following except . . .
- A. viruses.
- B. fungi.
- C. mycobacteria.
- D. bacterial spores.
- E. gram-positive and gram-negative bacteria.

4. Alcohol-based hand rubs are indicated for all of the following clinical situations except . . .
- A. when the hands are visibly soiled.
- B. preoperative cleaning of hands by surgical personnel.
- C. before inserting urinary catheters, intravascular catheters, or other invasive devices.
- D. after removing gloves.

5. Each of the following statements regarding alcohol-based hand rubs is true except . . .
- A. alcohol-based hand rubs reduce bacterial counts on the hands of health-care personnel more effectively than plain soaps.
- B. alcohol-based hand rubs can be made more accessible than sinks or other handwashing facilities.
- C. alcohol-based hand rubs require less time to use than traditional handwashing.
- D. alcohol-based hand rubs have been demonstrated to cause less skin irritation and dryness than handwashing using soap and water.
- E. alcohol-based hand rubs are only effective if they are applied for ≥60 seconds.

6. Which of the following statements regarding preoperative surgical hand antisepsis is true?
- A. Antimicrobial counts on hands are reduced as effectively with a 5-minute scrub as with a 10-minute scrub.
- B. A brush or sponge must be used when applying the antiseptic agent to adequately reduce bacterial counts on hands.
- C. Alcohol-based hand rubs for preoperative surgical scrub have been associated with increased surgical site infection rates.
- D. A and B are true.
- E. A and C are true.

7. Antimicrobial-impregnated wipes (i.e., towelettes) . . .
- A. might be considered as an alternative to handwashing with plain soap and water.
- B. are as effective as alcohol-based hands rubs.
- C. are as effective as washing hands with antimicrobial soap and water.
- D. A and C.

8. The following statements regarding hand hygiene in health-care settings are true except . . .
- A. Overall adherence among health-care personnel is approximately 40%.
- B. Poor adherence to hand-hygiene practice is a primary contributor to health-care–associated infection and transmission of antimicrobial-resistant pathogens.
- C. Personnel wearing artificial nails or extenders have been linked to nosocomial outbreaks.
- D. Hand hygiene is not necessary if gloves are worn.

9. Indicate your work setting.
- A. State/local health department.
- B. Other public health setting.
- C. Hospital clinic/private practice.
- D. Managed care organization.
- E. Academic institution.
- F. Other.

10. Which best describes your professional activities?
- A. Patient care — emergency/urgent care department.
- B. Patient care — inpatient.
- C. Patient care — primary-care clinic or office.
- D. Laboratory/pharmacy.
- E. Public health.
- F. Other.

11. I plan to use these recommendations as the basis for . . . (*Indicate all that apply.*)
- A. health education materials.
- B. insurance reimbursement policies.
- C. local practice guidelines.
- D. public policy.
- E. other.

12. Each month, approximately how many patients do you examine?
- A. None.
- B. 1–5.
- C. 6–20.
- D. 21–50.
- E. 51–100.
- F. >100.

13. How much time did you spend reading this report and completing the exam?
- A. 1–1.5 hours.
- B. More than 1.5 hours but fewer than 2 hours.
- C. 2–2.5 hours.
- D. More than 2.5 hours.

14. After reading this report, I am confident I can describe the guidance for clinicians and other health-care practitioners regarding strategies to improve hand-hygiene practices and reduce transmission of microorganisms in health-care settings.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

15. After reading this report, I am confident I can describe the indications for hand hygiene in health-care settings.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

16. After reading this report, I am confident I can list the advantages of alcohol-based hand rubs.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

17. After reading this report, I am confident I can describe the barriers to hand hygiene in health-care settings.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

18. The objectives are relevant to the goal of this report.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

19. The tables and text boxes are useful.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

20. Overall, the presentation of the report enhanced my ability to understand the material.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

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Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force

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4. [ ] A [ ] B [ ] C [ ] D	17. [ ] A [ ] B [ ] C [ ] D [ ] E	
5. [ ] A [ ] B [ ] C [ ] D [ ] E	18. [ ] A [ ] B [ ] C [ ] D [ ] E	
6. [ ] A [ ] B [ ] C [ ] D [ ] E	19. [ ] A [ ] B [ ] C [ ] D [ ] E	
7. [ ] A [ ] B [ ] C [ ] D	20. [ ] A [ ] B [ ] C [ ] D [ ] E	
8. [ ] A [ ] B [ ] C [ ] D	21. [ ] A [ ] B [ ] C [ ] D [ ] E	
9. [ ] A [ ] B [ ] C [ ] D [ ] E [ ] F	22. [ ] A [ ] B [ ] C [ ] D [ ] E	
10. [ ] A [ ] B [ ] C [ ] D [ ] E [ ] F	23. [ ] A [ ] B [ ] C [ ] D [ ] E [ ] F	
11. [ ] A [ ] B [ ] C [ ] D [ ] E		
12. [ ] A [ ] B [ ] C [ ] D [ ] E [ ] F		
13. [ ] A [ ] B [ ] C [ ] D		

Signature ***Date I Completed Exam***

21. These recommendations will affect my practice.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

22. The availability of continuing education credit influenced my decision to read this report.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

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Correct answers for questions 1–8

1. D; 2. D; 3. D; 4. A; 5. E; 6. A; 7. A; 8. D.

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Ozone Data for CFP 2023 (2012)

This document includes excerpts from “Ozone in Food Processing, First Edition” book written by P. J. Cullen and Rip Rice, published in 2012. In addition, there is a list of references used in developing this book, published efficacy lab testing and other relevant information summarized for the council to support the submitted issue.

Ozone in Food Processing, First Edition. Edited by Colm O’Donnell, B.K. Tiwari, P.J. Cullen, and Rip G. Rice.
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15.3.3 Safety history of ozone in commercial/industrial applications

Ozone has been in commercial use for the treatment of drinking water since 1906, when the city of Nice, France installed ozone to disinfect mountain spring water. This Mediterranean resort town has now used ozone continually for the treatment of its drinking water for over 100 years without incident, and today thousands of potable water plants throughout the world

are also using this technology. Many of the most recent new-construction industrial plants, and even many older upgraded plants, use high-purity oxygen to generate ozone, without experiencing hazards, either from the ozone or from the high-purity oxygen. In these many drinking water plants, ozone is generated routinely in quantities ranging from grams per hour (small plants) up to tons per day (large municipal plants). Many other commercial/industrial applications for ozone also exist throughout the world, including pulp bleaching, kaolin bleaching, wastewater treatment and reuse, bottled water treatment, swimming pools, cooling towers, synthesis of nylon intermediates, air treatment, marine aquaria, aquaculture, food storage and processing plants, wineries and so on.

In the century that has passed since ozone was first installed in Nice, there has never been a reported death due to ozone exposure. Why? Because engineers were quick to recognize the potential danger to humans of ozone exposure. Consequently, processes involving ozone are routinely designed with appropriate precautions to avoid exposure of workers to ozone.

The situation is analogous to that of chlorine, also a very strong disinfectant and oxidizing agent, and a chlorinating agent as well. This chemical was used as a poison gas during World War I, and many troops were killed on both sides of the trenches when exposed to it. But today, chlorine is an essential industrial chemical used safely in tons/day quantities for a variety of commercial/industrial processes, all as a result of attention to the safety of humans handling this strong disinfecting, oxidizing and chlorinating material.

Ozone Data for CFP 2023 (2012)

15.2 Points of application of ozone during food processing

Specific health and safety aspects of ozone in food processing are direct functions of the presence of ozone at specific points in the processing plant. Because of ozone's great versatility as an oxidant/disinfectant, there are a great number of places within any food processing plant where it can be and is being utilized. These applications can be considered in the two primary categories of aqueous ozone and gaseous ozone phases. Wherever ozone is applied in a food processing plant there is a resultant safety responsibility.

15.2.1 Aqueous phase ozone applications

Ozone in aqueous solution can be used to process plant influent water and product water (such as juice products), to provide ozone-containing water for spray washing of incoming food products prior to processing, for treatment of process water (sometimes for reuse, sometimes prior to discharge), for spray washing food products, for sanitizing plant equipment (clean-in-place, CIP) and for spray sanitation of floors and drains, as well as of food contact and non-food contact surfaces (surface sanitation). Food transportation trucks can also benefit from spray washing of empty food containers and the truck interiors, not only to reduce levels of microorganisms present, but also to destroy odors, colors and flavors and prevent odor transfers between foods during shipments. Ozone-containing water can be fed to an ice-making machine, where the small amount of ozone that off-gasses then gathers at the bottom of the ice storage chamber (the density of ozone gas is slightly higher than that of air) and its presence maintains the ice and chamber slime-free. When ozone is applied to treat a food processing plant's influent or effluent waters or to treat food processing waters for reuse, the water/ wastewater equipment is usually designed and operated as a mini-water/ wastewater treatment plant. Such subunits normally will be an adjunct to, but not an integral part of, the food storage and food processing lines. Consequently, system equipment will be designed with all of the necessary controls to ensure that no ozone will escape to come in contact with humans in those subunit areas.

Surface Sanitation. Another common application of ozone is for food contact surface sanitation. The inclusion of ozone-containing water within clean-in-place (CIP) cycles offers opportunities to food processors to treat manufacturing plant surfaces more efficiently and with greater efficacy. Aqueous ozone can also be used as a sanitizing rinse for food contact surfaces, such as cutting tables, as well as for nonfood contact surfaces, such as floors. Ozone can also be used to treat aseptic food packaging materials for surface disinfection.

Ozone Data for CFP 2023 (2012)

Opportunities for the Future

Interest in ozone is expected to continue to rise in response to consumer demands for environmentally friendly food processing technologies. A recent publication mapped trends in implementation or potential for implementation of ozone in the food industry. It found that ozone scored very high in terms of potential applications for fresh produce, seafood, and beverages. Another potential future application for ozone is its use to degrade pesticide residues, including organophosphates and organochlorinated compounds. As with many process technologies, ozone also has good potential for use as a hurdle technology to be combined with other sanitation and disinfection technologies to improve the safety of foods and beverages while extending their shelf life.

15.4.4 Third-party evaluation of aqueous ozone spray wash equipment

In 2002, the Toxicology Group, a wholly owned company of NSF International (Ann Arbor MI), conducted detailed third-party efficacy and hazard assessments and analyses for DEL Agricultural (a subsidiary of DEL Ozone, San Luis Obispo, CA) and Air Liquide America. Two devices (DEL AGW-0500 Mobile Ozone Surface Sanitation System, AL SSS 0500 Mobile Ozone Surface Sanitation System, and the DEL AGW-1500G Mobile Recirculating Ozone Sanitation System, AL SSS 1500 Mobile Recirculating Ozone Sanitation System) are manufactured by DEL Ozone and marketed by these two firms for spray washing applications in food processing plants. Both models are mobile. One provides a 10 gal/min water spray with a 3.0–3.5 ppm applied ozone dose, and is designed to sanitise equipment, walls, floors, drains, tables, conveyors, containers, tanks and barrels. The other, designed for CIP and COP (clean-out-of-place) processes, recirculates ozone-containing water at 35 gal/min with a 3.0 ppm applied ozone dose through tanks ranging in size from 50 to 2500 gallons. In any of these systems, the residual ozone dose that is applied as a spray is in the range of 1.5–2.0 ppm; and in the case of the recirculation system, the residual ozone dose is monitored and controlled at 2.0–2.5 ppm.

Third-party efficacy testing:

The methods used for the efficacy tests were AOAC Official Methods 960.09, Germicidal and Detergent Sanitizing Action of Disinfectants, and 961.02, Germicidal Spray Products as Disinfectants (Boisrobert 2002). Ozone spray washing was conducted on samples of individual microorganisms listed in Table 15.3, which also shows the number of log reductions obtained for each microorganism tested. Each microorganism received an ozone dosage of 1.85–2.25 ppm from the spray nozzle, except for *Escherichia coli*, which received an ozone dosage of 2.1 ppm.

Table 15.3 Efficacy testing of mobile ozone surface washing system (Boisrobert 2002; cited in Pascual et al. 2007).:

Microorganism	Log reduction
Trichophyton mentagrophytes (ATCC 9533)	6
Salmonella choleraesuis (ATCC 9533)	6
Staphylococcus aureus (ATCC 6358)	6
Pseudomonas aeruginosa (ATCC 15442)	6
Campylobacter jejuni (ATCC 33250)	4
Listeria monocytogenes (ATCC 7644)	4
Aspergillus flavus (ATCC 9296)	4
Brettanomyces bruxellensis (ATCC 10560)	4
Escherichia coli (ATCC 11229)	5

The results obtained (log reductions of 4–6 for the nine microorganisms tested) substantiate the efficacy of these two systems in sanitising previously cleaned nonporous surfaces, including processing equipment, which has come into contact with food (Pascual et al. 2007).

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Efficacy of Ozonated Water against Various Food-Related Microorganisms

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The antimicrobial effects of ozonated water in a recirculating concurrent reactor were evaluated against four gram-positive and four gram-negative bacteria, two yeasts, and spores of *Aspergillus niger*. More than 5 log units each of *Salmonella typhimurium* and *Escherichia coli* cells were killed instantaneously in ozonated water with or without addition of 20 ppm of soluble starch (SS). In ozonated water, death rates among the gram-negative bacteria—*S. typhimurium*, *E. coli*, *Pseudomonas aeruginosa*, and *Yersinia enterocolitica*—were not significantly different ($P > 0.05$). Among gram-positive bacteria, *Listeria monocytogenes* was significantly ($P < 0.05$) more sensitive than either *Staphylococcus aureus* or *Enterococcus faecalis*. In the presence of organic material, death rates of *S. aureus* compared with *L. monocytogenes* and *E. coli* compared with *S. typhimurium* in ozonated water were not significantly ($P > 0.05$) affected by SS addition but were significantly reduced ($P < 0.05$) by addition of 20 ppm of bovine serum albumin (BSA). More than 4.5 log units each of *Candida albicans* and *Zygosaccharomyces bailii* cells were killed instantaneously in ozonated water, whereas less than 1 log unit of *Aspergillus niger* spores was killed after a 5-min exposure. The average ozone output levels in the deionized water (0.188 mg/ml) or water with SS (0.198 mg/ml) did not differ significantly ($P < 0.05$) but were significantly lower in water containing BSA (0.149 mg/ml).

"The treatment of domestic water to provide a microbiologically safe, aesthetic, potable end product has been normal practice since before the turn of the twentieth century" (5). Chlorine at low concentrations has been the usual agent of choice in drinking-water purification. At the low concentrations of chlorine used, however, its limitations as a bactericide (3, 4) as well as limitations in its effectiveness against certain eukaryotic pathogens and viruses (18, 20, 21, 25, 27) have been recognized. Furthermore, chlorine at low concentrations may alter certain organic compounds in water producing off tastes and odors as well as forming chloro-organic compounds with carcinogenic potential (22).

As an alternative to chlorination in drinking-water disinfection, ozonation of water supplies, which was done first a century ago (29), has become an established means of disinfection and has been reviewed by Rice et al. (25). Bacteria, including *Escherichia coli*, *Staphylococcus aureus*, *Bacillus cereus*, *Bacillus megaterium*, *Salmonella typhimurium*, *Shigella flexneri*, and *Vibrio cholerae* are sensitive to ozonated water under various conditions (5, 6, 13, 17). Limited information on ozone's effectiveness against bacterial endospores (5, 17) and viruses (6, 20) as well as against eukaryotic pathogens including *Cryptosporidium parvum* (11, 21, 24) and *Giardia lamblia* and *Giardia muris* (12, 31, 32) also exists.

The use of ozone in the food industry has been investigated for food preservation, shelf life extension, equipment sterilization, and improvement of food plant effluents (9, 14, 19, 28).

The purpose of this investigation was to determine the antimicrobial efficacy of ozonated deionized water (with and without added organic material) generated by a recirculating ozone reactor (Lifex EV 2000R) against various heterotrophic bacteria and fungi important in the food industry as pathogens, spoilage organisms, and indicators of fecal contamination.

Pseudomonas aeruginosa ATCC 15442, *E. coli* ATCC 25922, *S. typhimurium* ATCC 6994, *S. aureus* ATCC 6538, *B. cereus* (food isolate), *Listeria monocytogenes* 4b (courtesy of Silliker Laboratories, Chicago Heights, Ill.), *Enterococcus faecalis* (food isolate), *Yersinia enterocolitica* ATCC 27729, *Candida albicans* ATCC 22572, *Zygosaccharomyces bailii* (purchased from Silliker Laboratories; isolated from mayonnaise), and *Aspergillus niger* (courtesy of James Grosklags, Northern Illinois University, DeKalb) were used in this investigation. The bacterial cultures were maintained on Difco (Detroit, Mich.) brain heart infusion agar slants except for *E. faecalis*, which was stored on Difco APT agar slants. All the bacterial cultures were stored at 4 to 6°C and transferred every 4 weeks. The two yeast cultures and *A. niger* were maintained on Difco potato dextrose agar slants, stored at 4 to 6°C, and transferred every 12 weeks. Loopfuls of cells from each of the bacterial strains except *E. faecalis* were aseptically transferred into 40 ml of brain heart infusion broth in 250-ml Erlenmeyer flasks and incubated at 35°C for 24 h, whereas *B. cereus* cells were incubated at 30°C for 24 h. *E. faecalis* cells were transferred to 40 ml of Difco APT broth in 250-ml Erlenmeyer flasks and incubated at 30°C for 24 h. For *C. albicans* and *Z. bailii*, loopfuls of cells were transferred to 40 ml of Difco potato dextrose broth in 250-ml Erlenmeyer flasks, placed in a gyratory water bath shaker model G76 (New Brunswick Scientific, Edison, N.J.) (100 to 125 rpm), and incubated at room temperature (18 to 22°C) for 48 h. After incubation, 30-ml volumes of each culture were centrifuged at 1,450 × *g* for 25 min at room temperature. The pellets were resuspended in 20 ml of sterile saline and centrifuged again at 1,450 × *g* for 25 min. After the second centrifugation, the pellets were resuspended in 10 ml of sterile saline. For the tests with soluble starch (SS; Fischer Chemical, Fairlawn, N.J.) and bovine serum albumin (BSA; Fraction V 96 to 99% albumin; Sigma, St. Louis, Mo.), the pellets were

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resuspended in 10 ml of sterile saline containing 20 ppm (20 mg/liter) of the corresponding organic material.

For *A. niger*, the spores from the stock culture were aseptically transferred to two potato dextrose agar slants and incubated at room temperature (18 to 22°C) for 8 days. After incubation, 15 ml of sterile 0.05% Triton X-100 (Sigma) was added to each tube and the spores were resuspended by using a vortex mixer (Baxter, McGaw Park, Ill.). The spore suspensions were centrifuged as described above, and the final pellet was resuspended in 15 ml of sterile saline. All washed cells and spores were chilled before use.

Ozone levels (in milligrams per liter) were measured by the indigo colorimetric method (1). Ozonated water was generated by a Lifex ozone apparatus (model EV 2000 R; Life Ozone Corp., Southfield, Mich.) using a 115 to 120 variable alternating current power source.

Duplicate ozone determinations of uninoculated solutions were performed directly at the generator outlet faucet and in the reservoir near the inlet tube before each organism was passed through the ozone apparatus. A concurrent system in which the ozone gas and water flowed in the same direction was used in this investigation. According to Lev and Regli (23), ozone concentrations (in milligrams per liter) can be conservatively measured in a "cocurrent" (sic) system in two ways: (i) outlet faucet concentration (C_{out}) and (ii) average concentration (C_{avg}), calculated as (C_{out} + inlet C_0)/2, where C_0 is the concentration near the inlet. Since C_0 was substantially lower in our system, C_{out} was a better measure for determining overall ozone concentration versus antimicrobial efficacy (23).

The antimicrobial effects of ozone were determined in deionized water with or without added organic material in the form of 20 ppm of SS or BSA, which may simulate organic levels in treated wastewater (30). BSA was dissolved directly in the deionized water, whereas SS was first dissolved by boiling a concentrated solution in deionized water before diluting. All solutions were ozonated at room temperature (19 to 21°C). The pH levels of nonozonated deionized water and ozonated deionized water were 5.7 and 6.1, respectively, whereas before and after ozonation in the presence of SS the pH remained at 6.0. In the presence of BSA, the pH was reduced from 6.4 to 6.0 after ozonation.

To a previously sanitized (70% ethanol followed by air drying) polyethylene container (capacity, 3.785 liters), 1.5 liters of deionized water with or without 20 ppm of SS or BSA was added. Four milliliters of washed cells or spores was pipetted into the polyethylene container, and the contents were stirred, yielding approximately 10^6 cells or spores per ml. Triplicate samples were extracted from the container to determine the initial cell or spore concentrations before ozonation. The ozone apparatus was equipped with a peristaltic pump producing a constant flow rate of 660 ml/30.0 s and an outlet faucet with an on-and-off lever. The hoses attached to and contained inside the ozone apparatus had a total volume of 150 ml. The hose attached to the peristaltic pump was primed and placed in uninoculated water while the faucet in the open position was placed over an empty container. The ozone apparatus was turned on, and the uninoculated water was pumped through the machine for 15 s, allowing approximately 330 ml to flush through the system. While still on, the inlet hose was momentarily blocked aseptically, removed from the uninoculated deionized water, and immediately immersed into the inoculated menstruum. After the uninoculated deionized water was allowed to purge the system for 25 s, a minimum of 400 ml of the inoculated suspension was flushed through the system and a sample designated "time zero" was taken. Immediately after the time zero sample, the faucet was placed in the inoculated container just over the water level, forming a recirculation loop. During inoculum recirculation, samples were taken after 1, 2, and 5 min. Final volumes in the container and ozone apparatus ranged from 1.0 to 1.1 liter with a recirculation rate of 47 s. A minimum of two separate evaluations were made for each organism.

After each run, the inlet hose was immersed in 1.0 liter of deionized water and the ozone apparatus was completely cleansed and rinsed. The apparatus was disassembled, and all hoses, the polyethylene container, beakers, and screens were sanitized with 70% ethanol and air dried. The apparatus was reassembled, and 1 liter of uninoculated deionized water was pumped through the system. Samples taken to check for residual contamination showed <10 cells or spores per ml.

Samples were collected from the ozone faucet into sterile test tubes (16 by 125 mm) and 1.1 ml was immediately pipetted into 10 ml of Difco D/E neutralizing broth and subjected to vortex mixing. Sterile deionized water was used for all subsequent dilutions. The pour plate technique was used to enumerate the surviving cells and spores. All platings were performed in duplicate. For all bacterial strains, except *E. faecalis*, Difco tryptic soy agar was used, whereas Difco APT agar was used to enumerate *E. faecalis*. All tryptic soy agar plates were incubated at 35°C for 48 h except for *B. cereus* plates, which were incubated at 30°C for 48 h. Potato dextrose agar plates incubated at room temperature (18 to 22°C) for 4 to 7 days were used to enumerate surviving yeast and mold spores.

Data were converted to $\log_{10}$ values, and the geometric means of duplicate plates per organism from at least two separate experiments were calculated. The log number of cells or spores killed per milliliter equaled the geometric mean before exposure to ozone minus the corresponding geometric mean after treatment for the various time periods. By using general linear-model procedures, the means and ranges for the C_{out} and C_{avg} ozone levels in the deionized water with 20 ppm of SS or BSA and deionized water without SS or BSA were calculated.

Statistical analysis programs PROC GLM (26) were used to test the significance of the data. Repeated-measures analysis of variance (univariate tests of the hypotheses) was used to compare survivorship of *E. coli*, *S. typhimurium*, *S. aureus*, and *L. monocytogenes* cells in ozonated deionized water containing SS or BSA with survivorship in ozonated deionized water without SS or BSA. The survival comparisons for each cell wall type were made in ozonated deionized water without SS and BSA. The conservative Greenhouse-Geisser adjustments were used to modify the F values. Bonferroni adjustments were used for multiple pairwise contrasts (0.017). Tukey's studentized range test (95% confidence level) was used to test the ozone concentrations for all possible comparisons of deionized water with and without added 20 ppm of SS or BSA. Ozone levels in deionized water, deionized water plus SS, and deionized water plus BSA were compared by a one-way analysis of variance.

The antimicrobial effects of ozone against two gram-positive bacteria, *S. aureus* and *L. monocytogenes*, are shown in Fig. 1. Statistical analyses of the curves indicated that neither organism showed a significant difference ($P > 0.05$) in a paired death rate comparison between the antimicrobial effect of ozonated deionized water with SS and the effect of that without SS or in the comparison between ozonated deionized water containing SS and that containing BSA. When the death rates in ozonated deionized water and ozonated water containing BSA were compared, however, the antimicrobial effects with no added organic material were significantly ($P < 0.05$) greater than in the presence of BSA. Overall, more than 4 log units of *L. monocytogenes* cells per ml was killed at time zero (instanta-

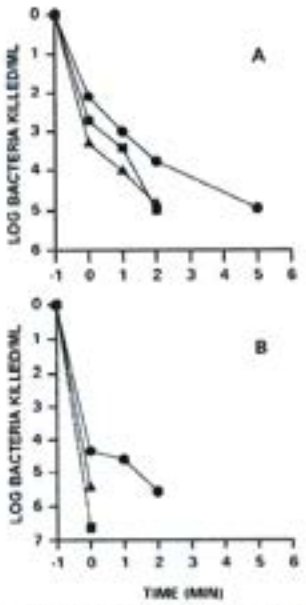

FIG. 1. Killing of viable cells of *S. aureus* (A) and *L. monocytogenes* (B) by ozone in deionized water containing no added organic material (▲) or 20 ppm of SS (■) or BSA (●). The data are means for at least two replicate experiments.

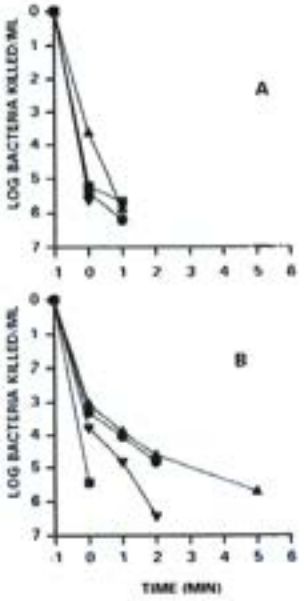

FIG. 3. Antimicrobial efficacy of ozone in deionized water against gram-negative bacteria *E. coli* (●), *S. typhimurium* (■), *P. aeruginosa* (▲), and *Y. enterocolitica* (▼) (A) and gram-positive bacteria *S. aureus* (●), *L. monocytogenes* (■), *B. cereus* (▲), and *E. faecalis* (▼) (B). The data are means for at least two replicate experiments.

neously) in the absence or presence of added organic material (Fig. 1A).

The death rate curves of ozonated deionized water with and without added organic material for *S. typhimurium* and *E. coli* are shown in Fig. 2. No significant difference ($P > 0.05$) between ozonated deionized water with SS and that without SS in the death rates or in the patterns of the curves for these two gram-negative bacteria was observed. For each bacterium, however, the death rates as well as the overall pattern of death

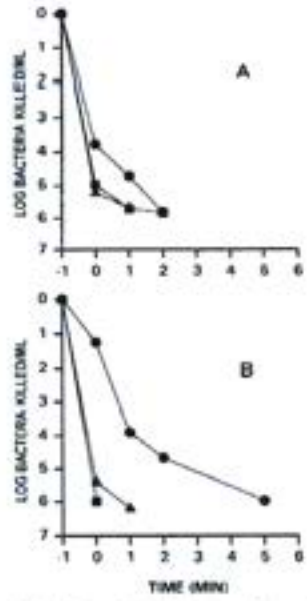

FIG. 2. Killing of viable cells of *S. typhimurium* (A) and *E. coli* (B) by ozone in deionized water containing no added organic material (▲) or 20 ppm of SS (■) or BSA (●). The data are means for at least two replicate experiments.

obtained in ozonated water with or without SS were significantly greater ($P < 0.05$) than in ozonated water containing BSA. More than 5 log units each of *S. typhimurium* and *E. coli* cells per ml was killed instantaneously (time zero) after exposure to ozonated water or to ozonated water containing SS, whereas equivalent levels of death for *S. typhimurium* and *E. coli* in the presence of BSA occurred only after 2- and 5-min exposures, respectively (Fig. 2).

The antimicrobial effects of ozonated deionized water without added organic material against eight bacterial strains are presented in Fig. 3. With respect to the amount of death and the overall patterns of the death curves, no significant difference ($P > 0.05$) among the four gram-negative bacteria was observed (Fig. 3A). Among the gram-positive bacteria, the extent of death as well as the death rate curves for *S. aureus* and *E. faecalis* cells did not differ significantly ($P > 0.05$); however, *L. monocytogenes* displayed a significantly greater ($P < 0.05$) rate of death than *S. aureus* and *E. faecalis* (Fig. 3B). For *L. monocytogenes* cells, at time zero, more than 5 log units was killed by ozonated deionized water, whereas for *S. aureus*, *E. faecalis*, and *B. cereus*, 3 log units of bacteria or more was killed (Fig. 3B). Overall, except where instantaneous death occurred, most bacteria displayed biphasic death curves which were enhanced when effective ozone levels were reduced in the presence of BSA (Fig. 1 to 3).

The antimycotic effects of ozonated deionized water against yeasts of two genera and *S. niger* spores are shown in Fig. 4. Ozonated deionized water without added organic material caused more than 4.5 log units of killed cells per ml for the two yeasts, *C. albicans* and *Z. bailii*, at time zero. Less than 1 log unit of *A. niger* spores per ml was killed under the same conditions after 5 min of exposure.

Ozone concentrations in deionized water and deionized water containing 20 ppm of SS or BSA are presented in Table 1. Ozone concentrations were determined in two ways: at the outlet of the ozone apparatus (C_{out}) and over the whole system

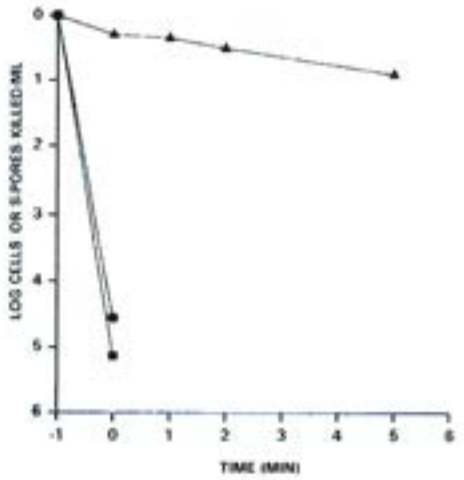

FIG. 4. Killing of fungal spores and viable yeast cells by ozone in deionized water with no added organic material. Symbols: ▲, *A. niger* spores; ●, *C. albicans*; ■, *Z. bailii*. The data are means for at least two replicate experiments.

(C_{avg}). No significant difference ($P > 0.05$) in the ozone levels (for C_{out} and C_{avg}) in deionized water and deionized water containing SS was observed. The ozone levels of C_{out} in deionized water and deionized water with SS added were 0.188 and 0.198 mg/liter, respectively, whereas C_{avg} levels were 0.064 and 0.068 mg/liter, respectively. The ozone levels for the deionized water containing BSA were significantly less ($P < 0.05$) than the ozone levels (C_{out} and C_{avg}) for deionized water and water containing SS. Average ozone concentrations in deionized water containing 20 ppm of BSA were 0.149 and 0.044 mg/liter for C_{out} and C_{avg}, respectively.

The results obtained in this study have shown that ozonated water is highly effective in killing both gram-positive and gram-negative food-associated bacteria. With the exception of *L. monocytogenes*, the gram-negative bacteria were substantially more sensitive to ozonated water than the gram-positive bacteria either in the absence or in the presence of added organic material. Yeast cells displayed sensitivity to ozonated water, whereas fungal spores were highly resistant.

Previous studies on the effects of ozone on microbes have involved the use of pure cultures and organisms naturally contaminating foods and water. Broadwater et al. (5), studying the effects of ozone on washed vegetative cells, reported that 0.12 mg/liter for *B. cereus* and 0.19 mg/liter for *E. coli* and *B. megaterium* were the minimal lethal threshold concentrations after 5 min of exposure. Fetner and Ingols (10) reported 0.4 to 0.5 mg/liter as the threshold concentration for *E. coli* after 1 min at 1°C. Both studies used varying ozone concentrations at a single time period and suggested that ozone killed microbes via an all-or-none phenomenon. Thus, in these studies either high ozone concentrations for a short period (1 min) or lower ozone concentrations for a single extended period (5 min) provided sufficient activity to reach the minimal threshold for complete killing. In the present study, however, ozone effectiveness determined by repeated sampling over a 5-min period at a single ozone concentration (0.15 to 0.20 mg/liter) indicated that an all-or-none killing phenomenon does not occur. Finch et al. (13) showed that *E. coli* in ozone demand-free phosphate water exhibited a disinfection rate consisting of an initial rapid stage followed by a slower inactivation stage. Several other studies using ozone have also shown that death rate kinetics for a variety of bacteria and viruses exhibit a biphasic process over an extended time period (6, 16, 20). In this study, biphasic death curves were observed for the majority of the gram-positive and gram-negative bacteria ozonated in the absence of added organic material (Fig. 3). This phenomenon was even more apparent wherever residual ozone levels were reduced by the presence of BSA (Fig. 1 and 2).

The sensitivity of microorganisms to ozone is profoundly affected by the organic nature of the medium, with protection caused both by physical factors, as in the case of agar, and by reduced ozone levels due to ozone demand of organic nutrients in the medium or in environmental waters (2, 8, 15, 16). This study shows that the type of organic material present during ozonation is more important than the amount present. Residual ozone levels in deionized water were significantly reduced only in the presence of 20 ppm of BSA, whereas 20 ppm of SS was without effect (Table 1). Consequently, death rates in the presence of BSA were reduced substantially but were not significantly affected in the presence of SS (Fig. 1 and 2).

The potential uses of ozone in the food industry include reduction of microorganisms on meat and poultry carcasses and in chilling water (19, 28), extension of shelf life of marine fish (14), reduction of atmospheric mold levels in meat and in small fruit storage rooms (9), and antimicrobial effects in bulk food items such as shelled eggs, bacon, beef, bananas, butter, mushrooms, cheese, and fruits (19). Additionally, ozone has been used synergistically with other antimicrobial agents (7, 14–16). The present study shows that ozonated water can effectively kill spoilage organisms (*P. aeruginosa* and *Z. bailii*), fecal contaminants (*E. faecalis* and *E. coli*), and food-borne pathogens (*L. monocytogenes*, *B. cereus*, *S. typhimurium*, *Y. enterocolitica*, and *S. aureus*). The sensitivity of the gram-negative pathogens and *L. monocytogenes* suggests that ozonated water might be especially applicable for killing these organisms on food surfaces such as fruits and vegetables where interference by organics may be minimal. Additionally, gaseous ozone might be effective in controlling *L. monocytogenes* in food environments. Although pure cultures of various food-borne pathogens and spoilage bacteria were used in this investigation, the ozone sensitivity data obtained on pure cultures used in this study should provide guidelines for further studies on ozone applications in the food and environmental industries.

TABLE 1. Mean concentrations and ranges of ozone in deionized water in the absence and presence of organic material

Additive (20 ppm)	Ozone (ppm) [mean (range)]	
	C_{out}	C_{avg}
None	0.188 (0.166–0.225)	0.064 (0.043–0.084)
SS	0.198 (0.166–0.246)	0.068 (0.052–0.092)
BSA	0.149[a] (0.131–0.168)	0.044[b] (0.036–0.053)

[a] Significantly less ($P < 0.05$) than the other C_{out} values.
[b] Significantly less ($P < 0.05$) than the other C_{avg} values.

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