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.

Template Revision 02/2020

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

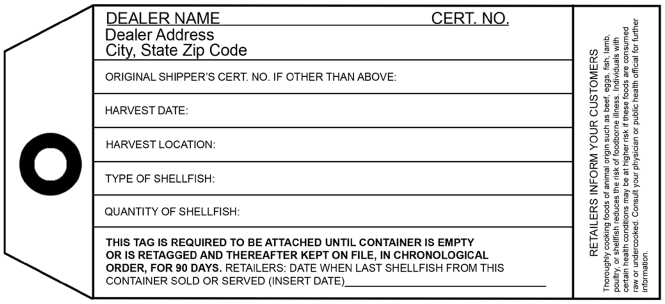
****Never mix shellstock from different containers****

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.



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

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

HARVEST DATE:

HARVEST LOCATION:

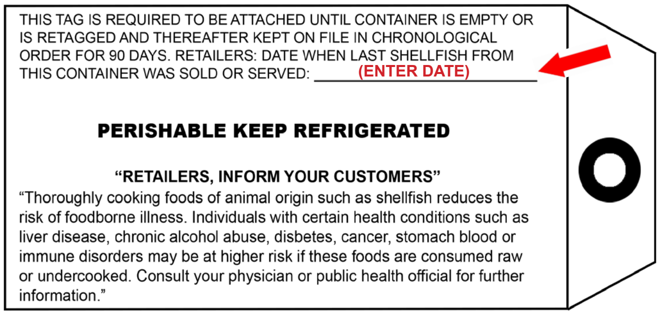
TYPE OF SHELLFISH:

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, 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.

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



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."

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

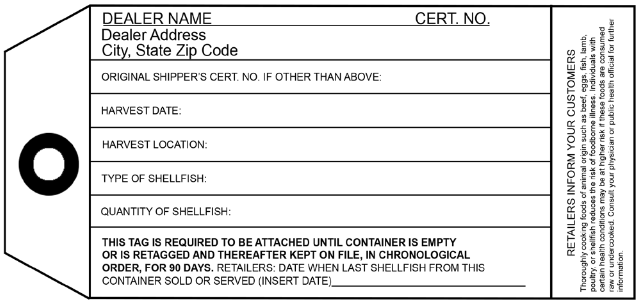
****Nunca combine los mariscos de diferentes contenedores****

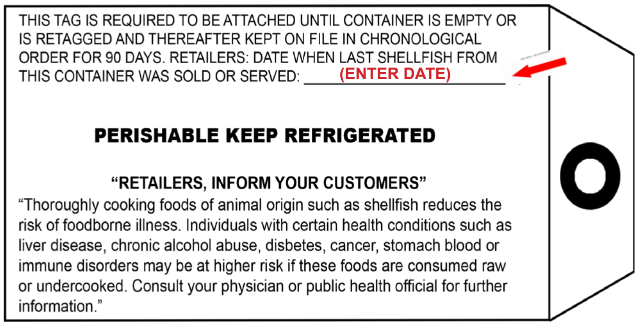
REGISTRAR

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.



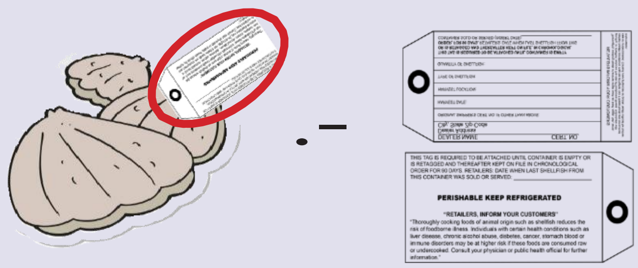


****Si se produce una enfermedad transmitida por los alimentos**, las etiquetas que se completaron correctamente brindan información crítica que puede minimizar futuras enfermedades y proteger a sus clientes y su negocio.**

SHELLSTOCK TAG PROCEDURES
Procedimientos de etiquetado de mariscos
(Oysters, Scallops, Mussels, & Clams)
(Ostras, Vieiras, Mejillones y Almejas)

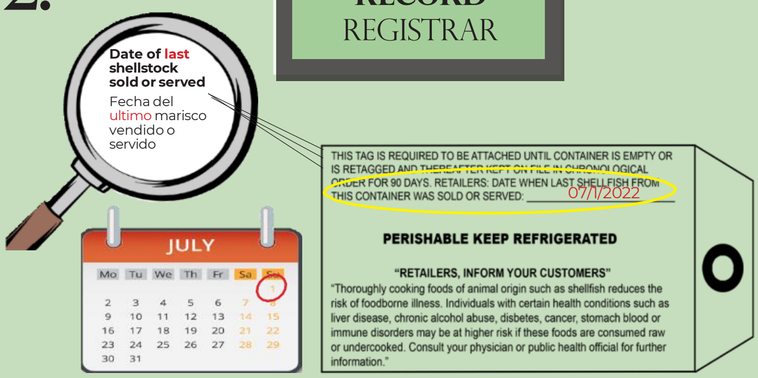
1.

KEEP
MANTENER



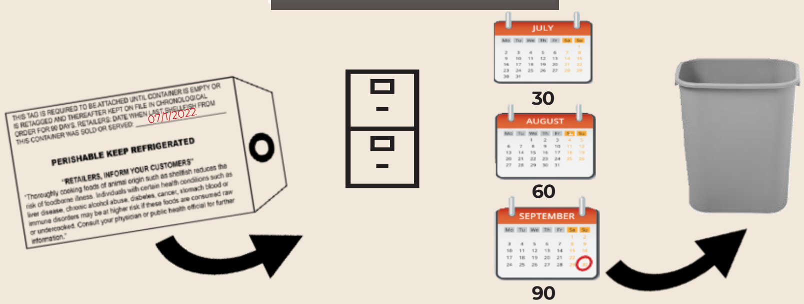
2.

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

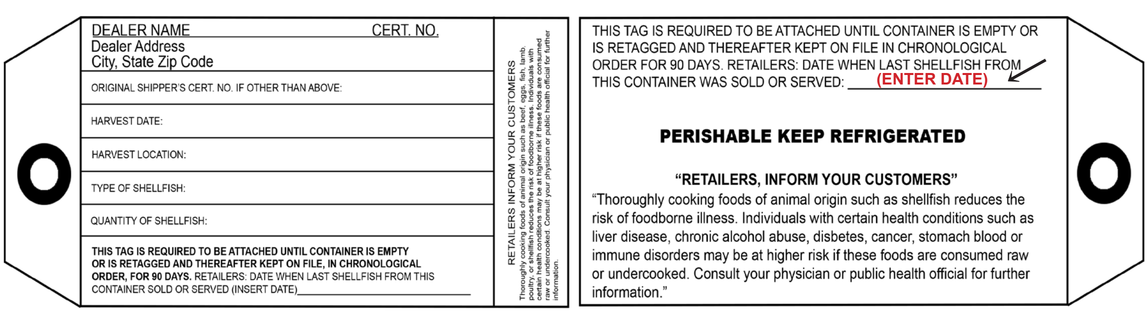
- **Write** the date on the blank line / space on the tag when the last shellstock from the bag / box has been sold, served, or thrown away
  - **Use** a permanent marker to record the date
  - **Record** the date anywhere on the tag if there is no line / space

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!

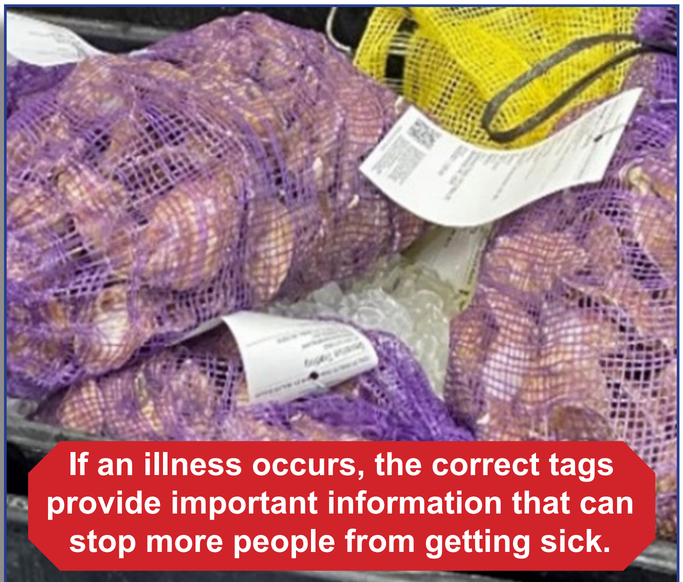
Commingling, or mixing shellstock collected on different days, packed on different days, or collected from different growing areas is not allowed.



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

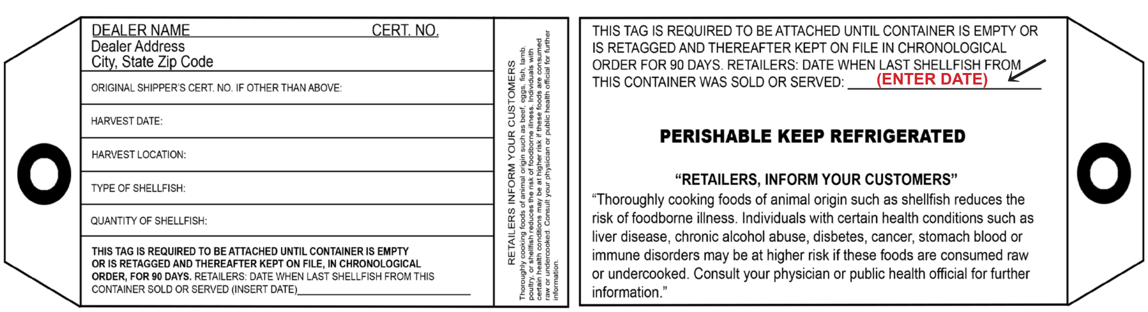
- **Escriba** la fecha en la línea/espacio en blanco de la etiqueta cuando se vendió, sirvió o se desecho el ultimo marisco de la bolsa/caja
  - **Use** un marcador permanente para poner la fecha
  - **Escriba** la fecha en cualquier lugar de la etiqueta si no hay línea o espacio en blanco

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!

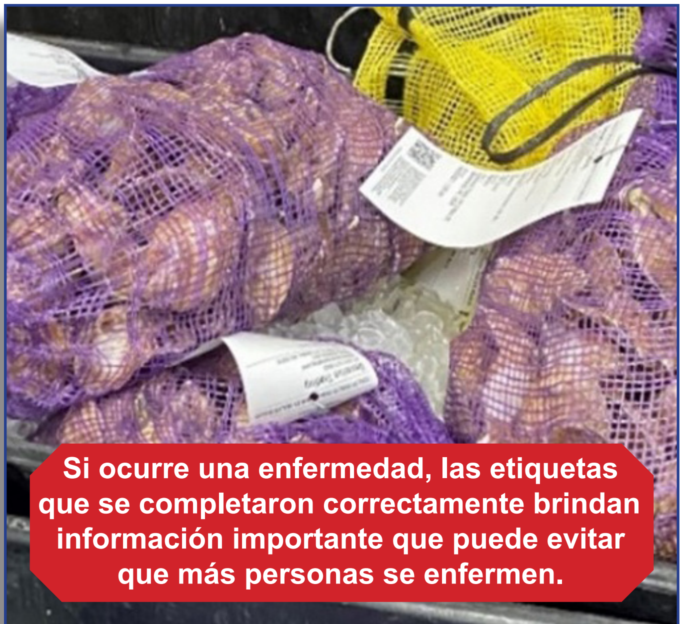
No se permite mezclar o combinar los mariscos recolectados en diferentes días, empacados en diferentes días o recolectados de diferentes áreas de cultivo



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)



Si ocurre una enfermedad, las etiquetas que se completaron correctamente brindan información importante que puede evitar que más personas se enfermen.

¿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

DEALER NAME: A person who is certified by the state regulatory authority to handle shellfish

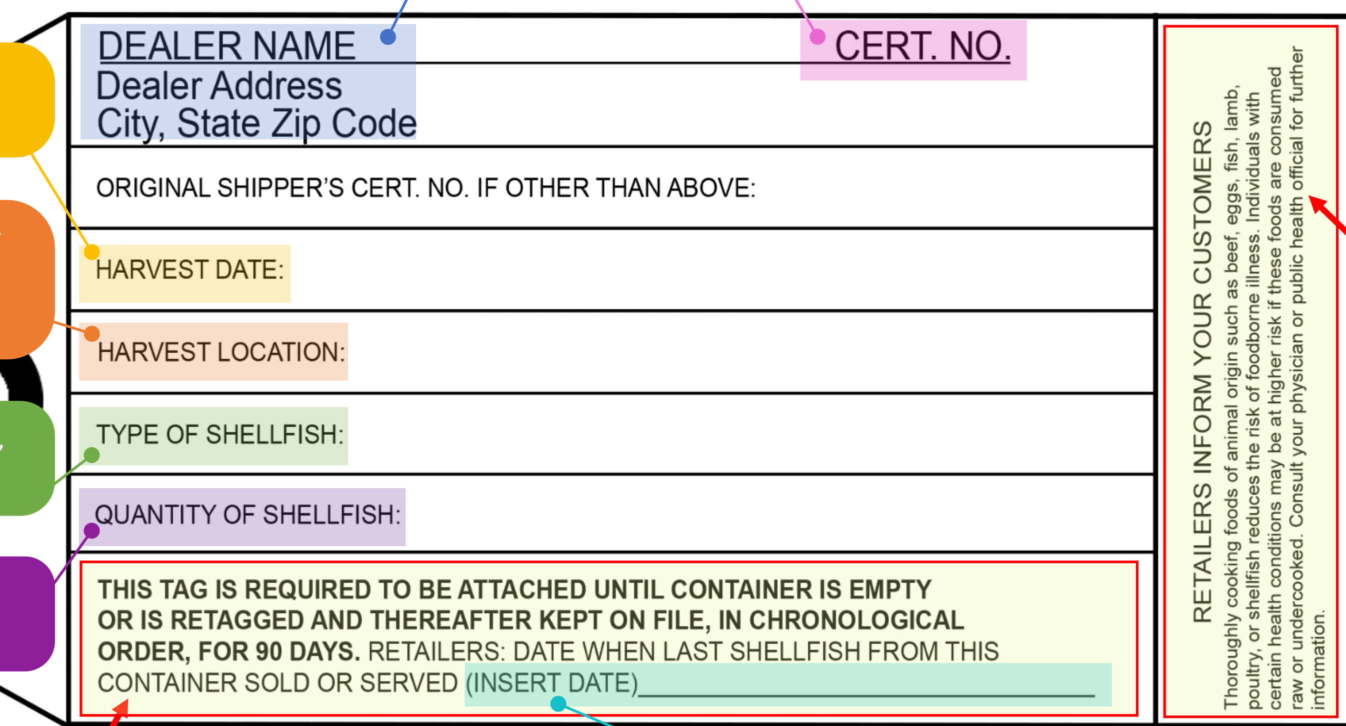
CERT NO: A combination of letters/numbers assigned by the state regulatory authority to a dealer

HARVEST DATE: Date shellstock was removed from water

HARVEST LOCATION: Identification of the water body, including the two letter state abbreviation

TYPE OF SHELLFISH: Such as "oysters", "PEI mussels", "littleneck clams"

QUANTITY OF SHELLFISH: Such as "100 count", "5 x 50 count"



The **CONSUMER ADVISORY** is required on all shellstock tags

This statement shall be on every tag exactly as it appears here

INSERT DATE: The last date this shellfish was sold or served, which is essential for traceback in case of illness

*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

	2022 Food Code Reference	SPECIFIC STANDARDS 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

TOXINS	FIELD FOCUS
☐ Paralytic shellfish poisoning ☐ Diarrhetic shellfish poisoning ☐ Neurotoxic shellfish poisoning ☐ Amnesic shellfish poisoning	S

BACTERIAL INFECTIONS	FIELD FOCUS
☐ *Vibrio cholerae O1* ☐ *Vibrio cholerae non-O1*	S Ill FW BHC HW CH XC CA

BACTERIAL INFECTIONS*	FIELD FOCUS
☐ *Vibrio parahaemolyticus* ☐ *Vibrio vulnificus* *Not typically transmitted person to person	S CH XC CA

RISK FACTORS & INTERVENTIONS FIELD FOCUS

SOURCE (S)
- ☐ Copies of delivery receipts/invoices
- ☐ Shellfish tags, ICSSL (Interstate Certified Shellfish Shippers List)

ILL FOOD WORKERS (ILL FW)
- ☐ Exclusion policy
- ☐ Check work schedules (employee list)
- ☐ Determine employee health status
- ☐ Determine roles of food workers for suspected meals and ingredients

BARE HAND CONTACT (BHC)
- ☐ Gloves/utensils available & indications of usage
- ☐ History of BHC control in facility

HANDWASHING (HW)
- ☐ Handwash sinks available & have soap/towels
- ☐ Observe proper HW

COLD HOLDING (CH)
- ☐ Proper CH
- ☐ History of proper temperature control practices
- ☐ Discussion of food prep steps
- ☐ Advanced preparation

CROSS-CONTAMINATION (XC)
- ☐ Proper storage during cold-holding, display
- ☐ Separation of utensils used for raw product
- ☐ Cleaning/sanitizing of equipment/utensils
- ☐ Shells used for other entrees
- ☐ Shucking gloves, towels, sanitizer buckets

CONSUMER ADVISORY (CA)
- ☐ Menu disclosure and reminder

METHODS, REMEDIATION & CONTROL MEASURES

Consider items and check each used.

INVESTIGATION METHODS
- ☐ Food, Environmental Samples
- ☐ Stool Samples
- ☐ Photographs
- ☐ Suspect Meal Menu
- ☐ Reservation Lists, Receipts
- ☐ Special Events, Parties
- ☐ Invoices, Inventory, Traceback
- ☐ Multiple Establishments Investigated
- ☐ Additional Case Finding

CONTROL MEASURES
- ☐ Behavior Change
- ☐ Procedure Change
- ☐ Exclude Ill FW
- ☐ Food Destruction
- ☐ Detention Order
- ☐ Cleaning & Sanitizing
- ☐ Suspension/Closure

MOVING FORWARD
- ☐ Follow-up Visit Scheduled
- ☐ Follow-up Visit with Interpreter
- ☐ Increased Inspections
- ☐ Menu Reduction
- ☐ Required Education/Training
- ☐ Office Conference

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

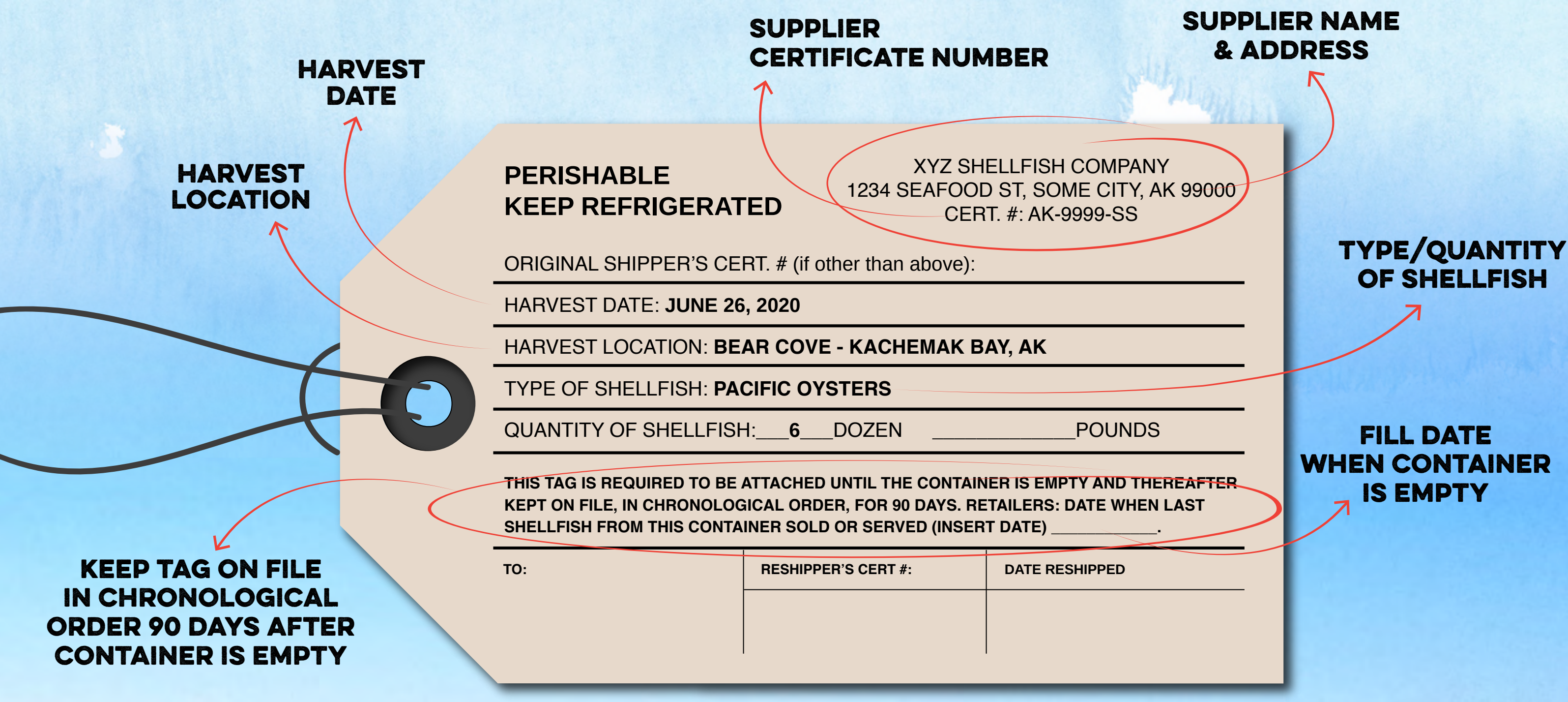
ADEC Food Safety & Sanitation Program

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. <u>ILL FOOD WORKERS (</u>

- **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. SEPARATION OF RAW ANIMAL FOODS FROM READY-TO-EAT FOODS

- 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. SEPARATION OF RAW ANIMAL FOODS OF DIFFERENT SPECIES

- 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. <u>CLEANING & SANITIZING OF FOOD CONTACT SURFACES</u>

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 $\geq$ 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

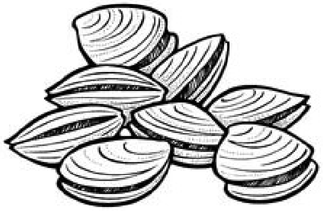
Raw, in-shell molluscan shellfish.

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.

For more information contact us: FOOD SAFETY BRANCH • (808)586-8000 • http://health.hawaii.gov/san

food code facts

Alaska Food Code Guidance

Food Safety & Sanitation Program

Alaska Department of Environmental Conservation

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

Molluscan Shellfish at Retail

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

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.

food code facts

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

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

Molluscan Shellfish at Retail

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

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.

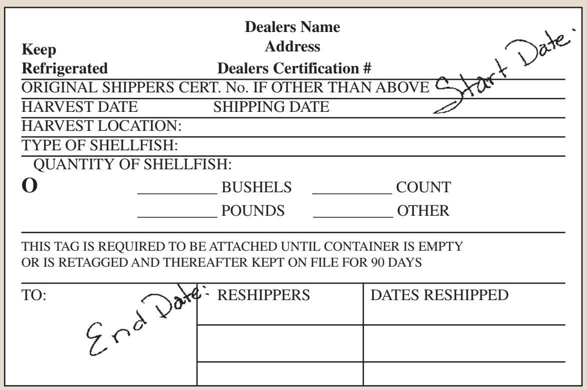
TEMPERATURE AND TIME CONTROL
SHUCKED SHELLFISH or SHELLSTOCK must be received and held at 41˚ F

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:
   - "Regarding the safety of these foods, written information is available upon request."
   - Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness." OR
   - "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.

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
Dealers Certification #
Keep Refrigerated
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:	RESHIPPERS	DATES RESHIPPED
End Date:		

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

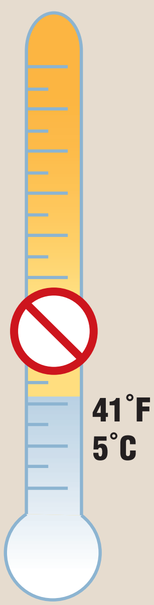
U.S. Food and Drug Administration

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)

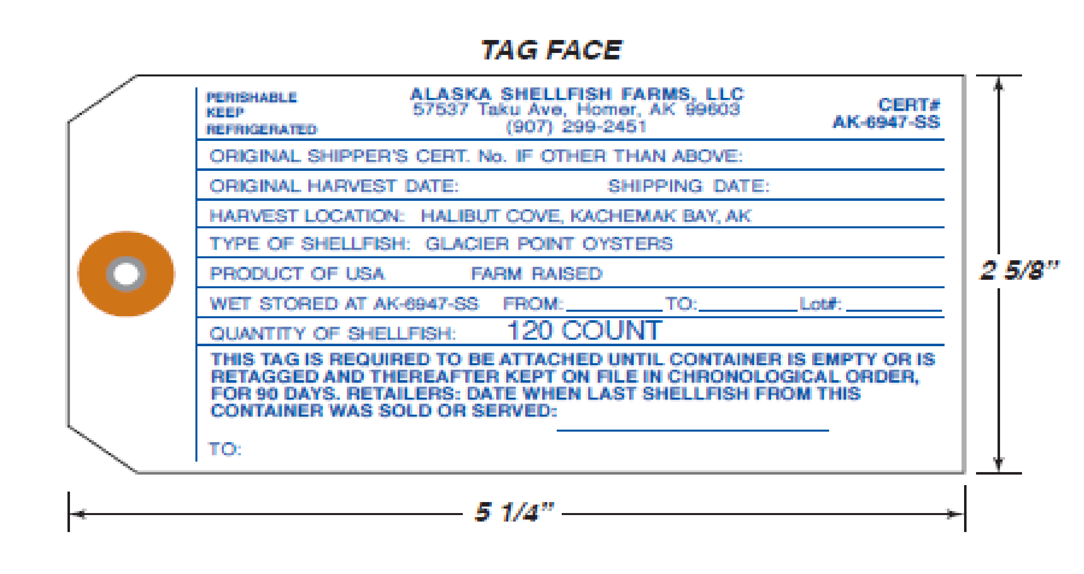
Harvester

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.

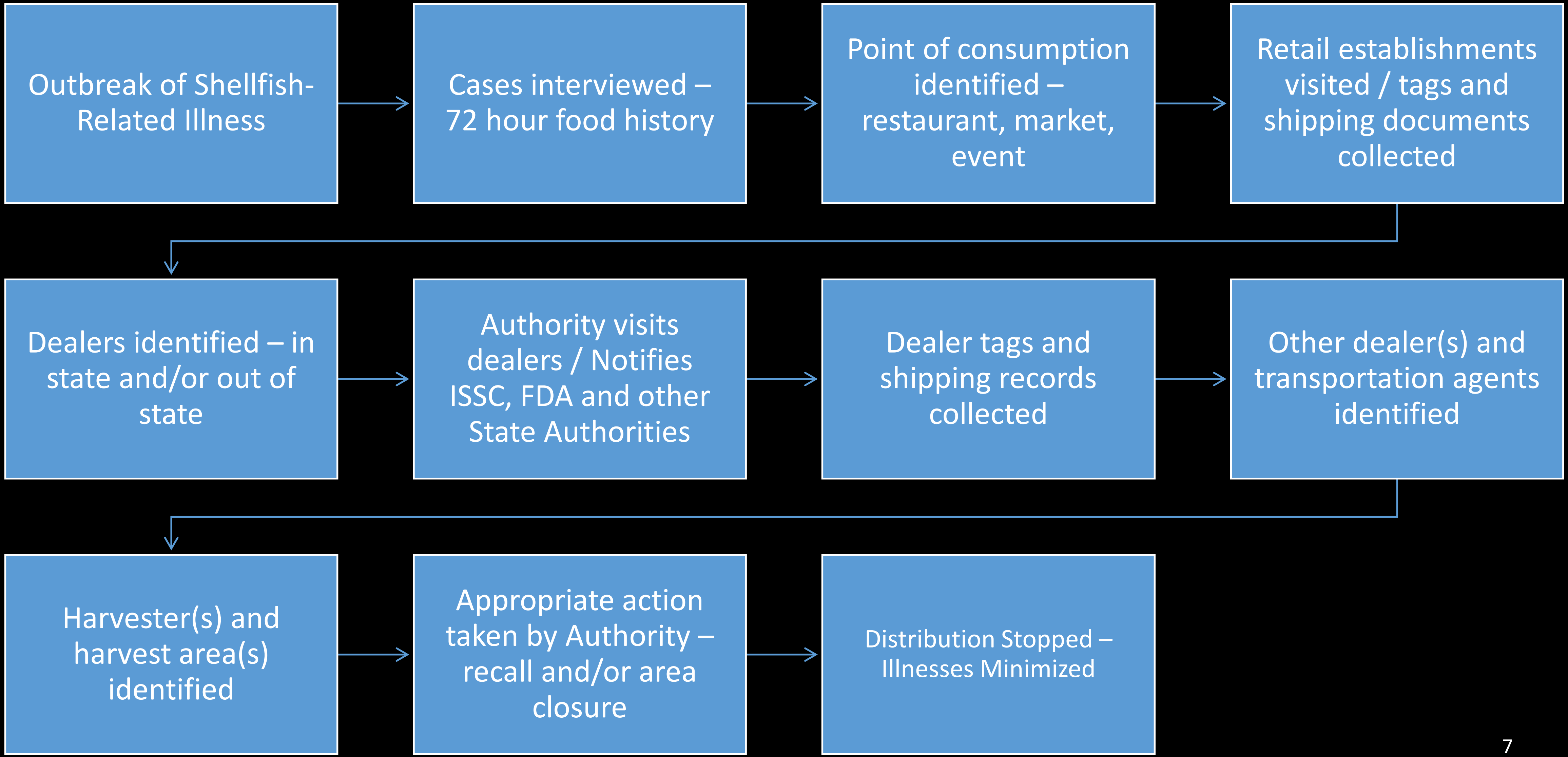
Recall

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

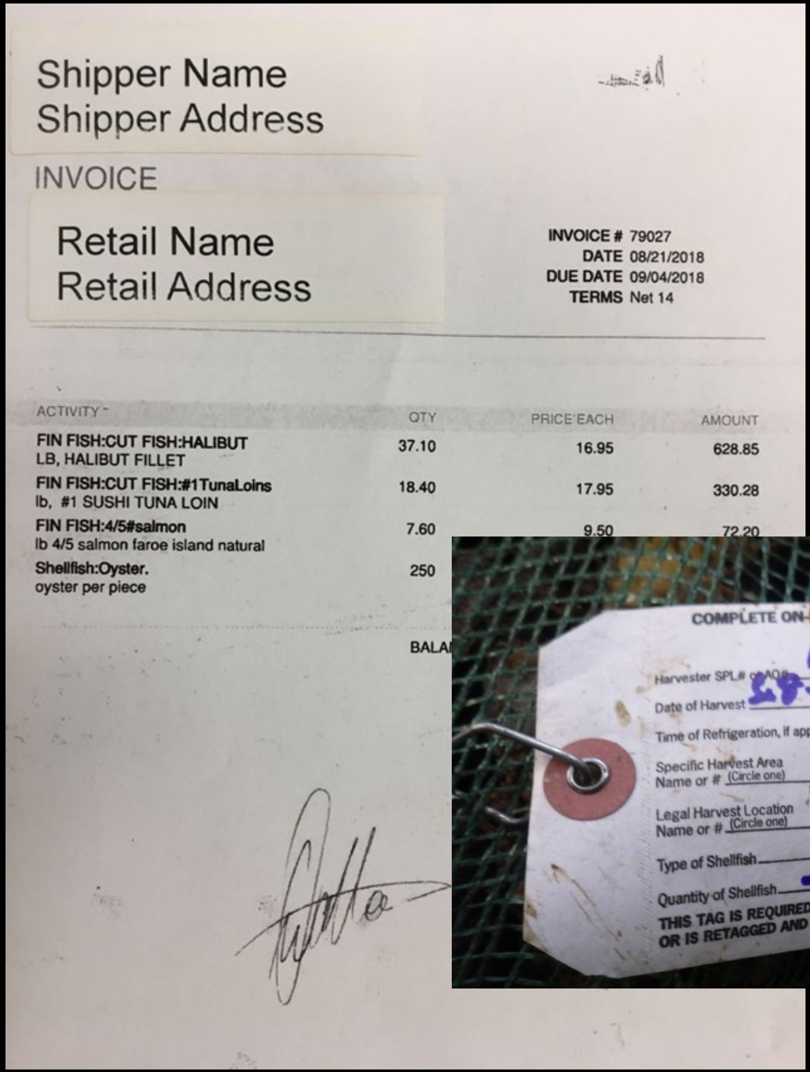
Traceback Objectives

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

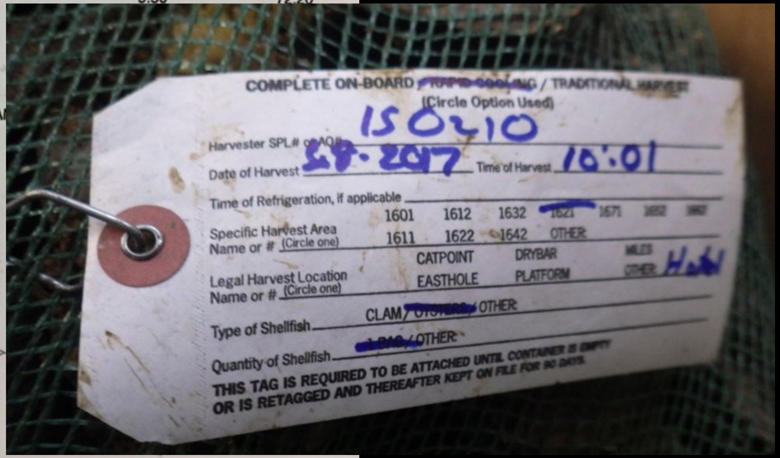
INVOICE

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

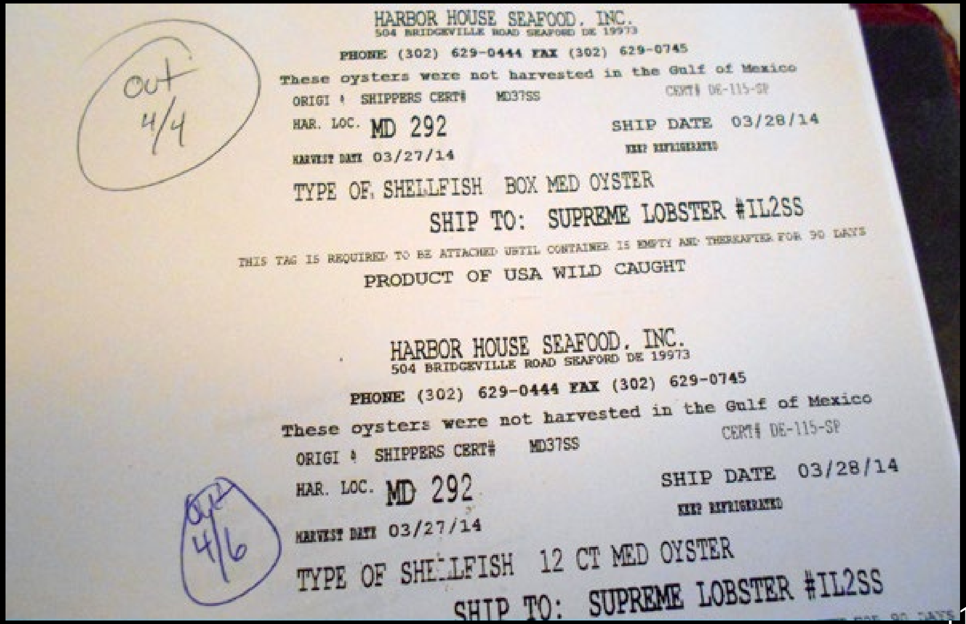
Retail

Retail Requirements

Every package has required tag

When last shellstock sold, date, and keep 90 days

No commingling during display



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):

Not required if depurated

HARVEST DATE: *November 17, 2010*

If depurated, date of depuration and cycle or lot number

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

TYPE OF SHELLFISH: *Manila Clams*

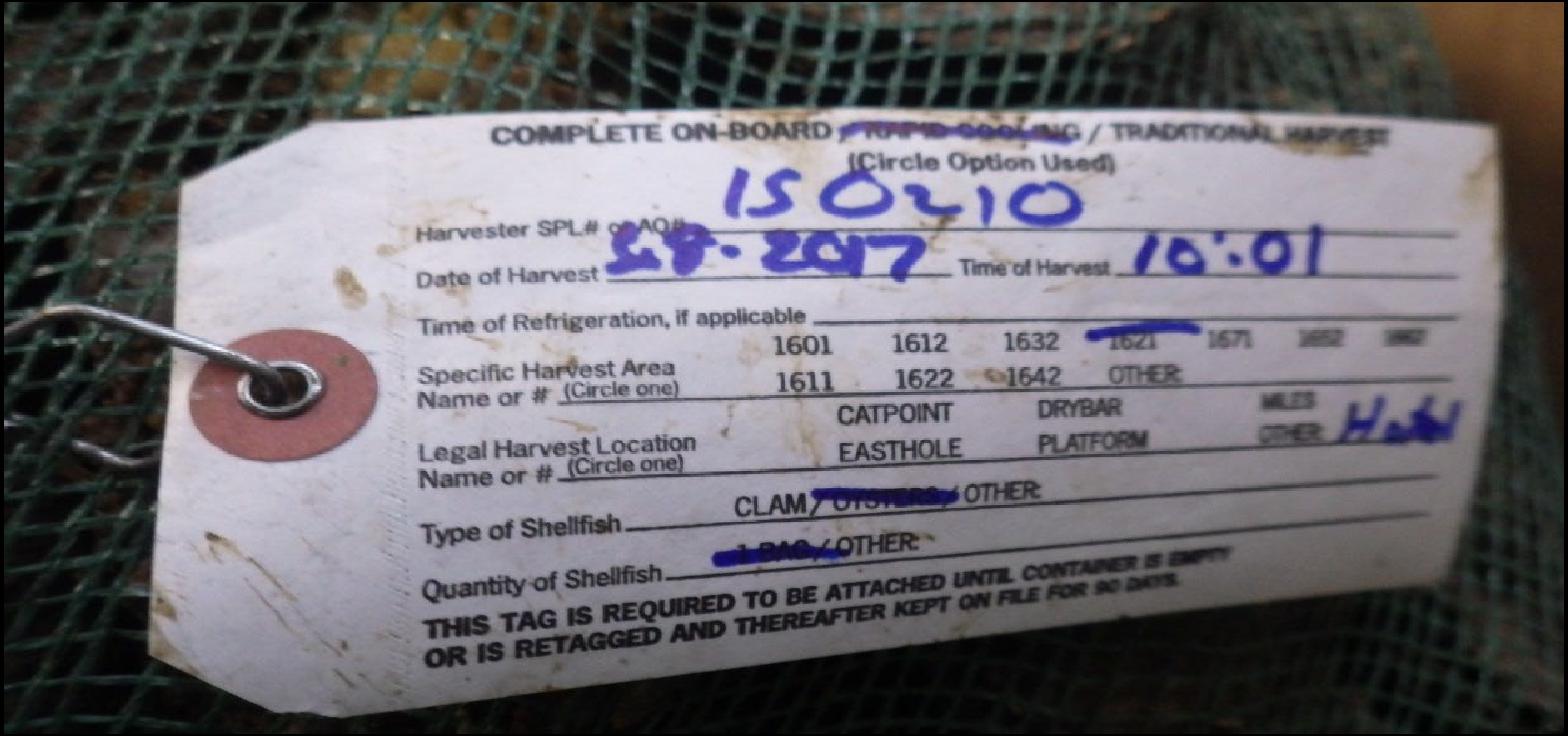
QUANTITY OF SHELLFISH: ________ dozen ________ pounds

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

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

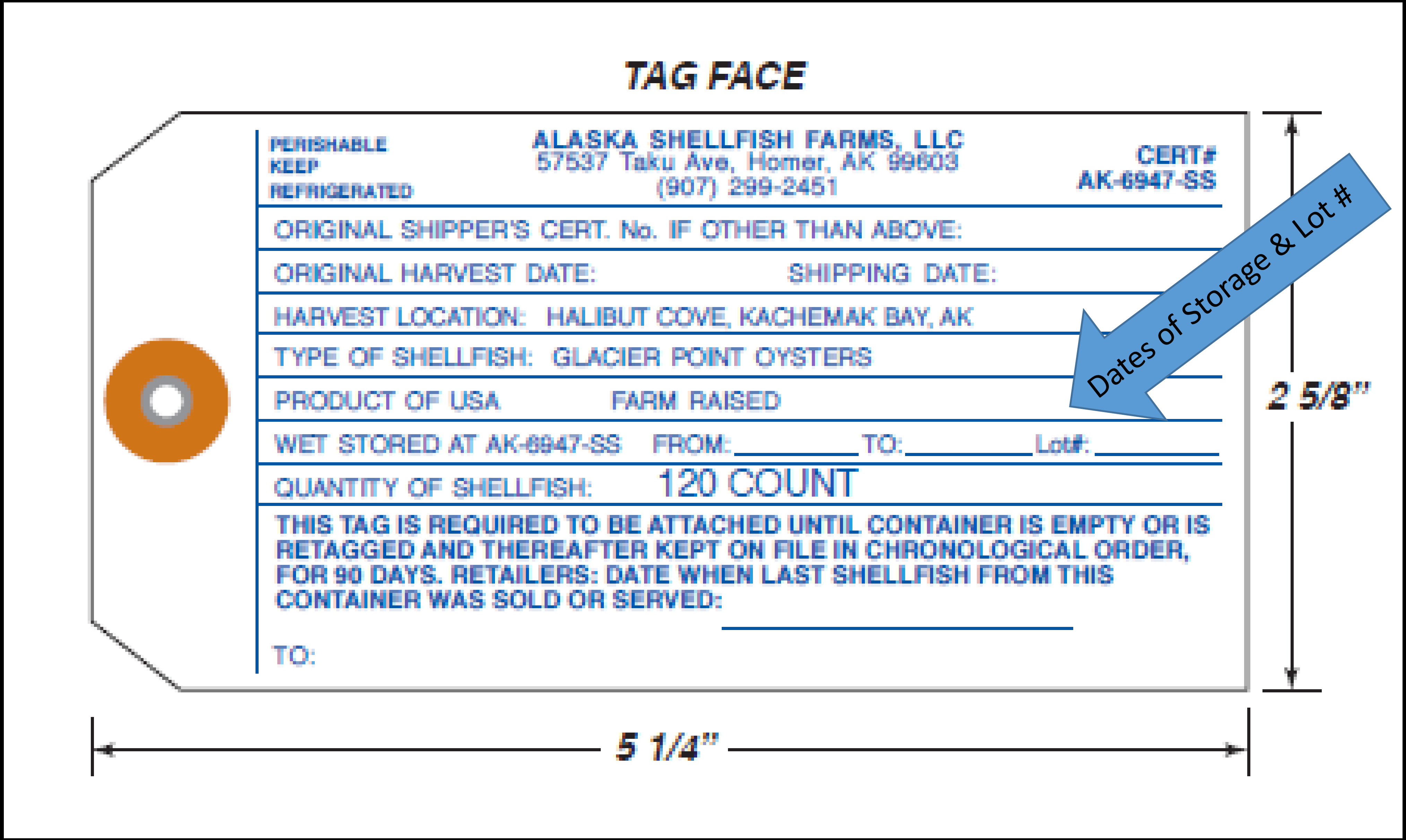
Harvester



COMPLETE ON-BOARD / TRADITIONAL HARVEST
(Circle Option Used)
Harvester SPL# or AQ# 150210
Date of Harvest
Time of Harvest 10:01
Time of Refrigeration, if applicable
Specific Harvest Area Name or # (Circle one)
1601 1612 1632 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



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**

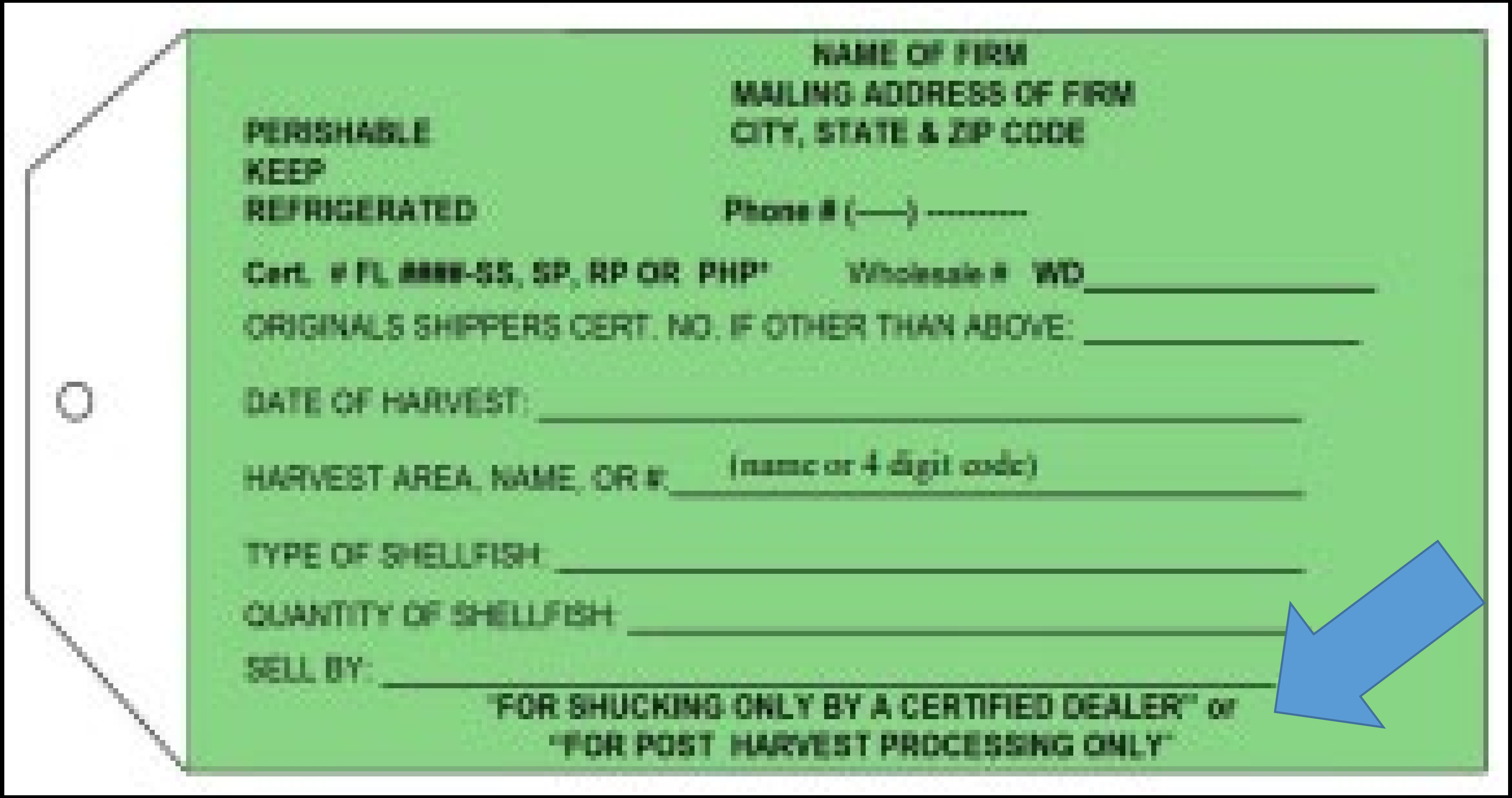
QUANTITY OF SHELLFISH: __________ dozen __________ pounds

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


NAME OF FIRM
MAILING ADDRESS OF FIRM
CITY, STATE & ZIP CODE

PERISHABLE
KEEP
REFRIGERATED

Phone # (----) ---------

Cert. # FL ####-SS, SP, RP OR PHP* Wholesale # WD ____________

ORIGINALS SHIPPERS CERT. NO. IF OTHER THAN ABOVE: ____________

DATE OF HARVEST: ____________

HARVEST AREA, NAME, OR #: (name or 4 digit code) ____________

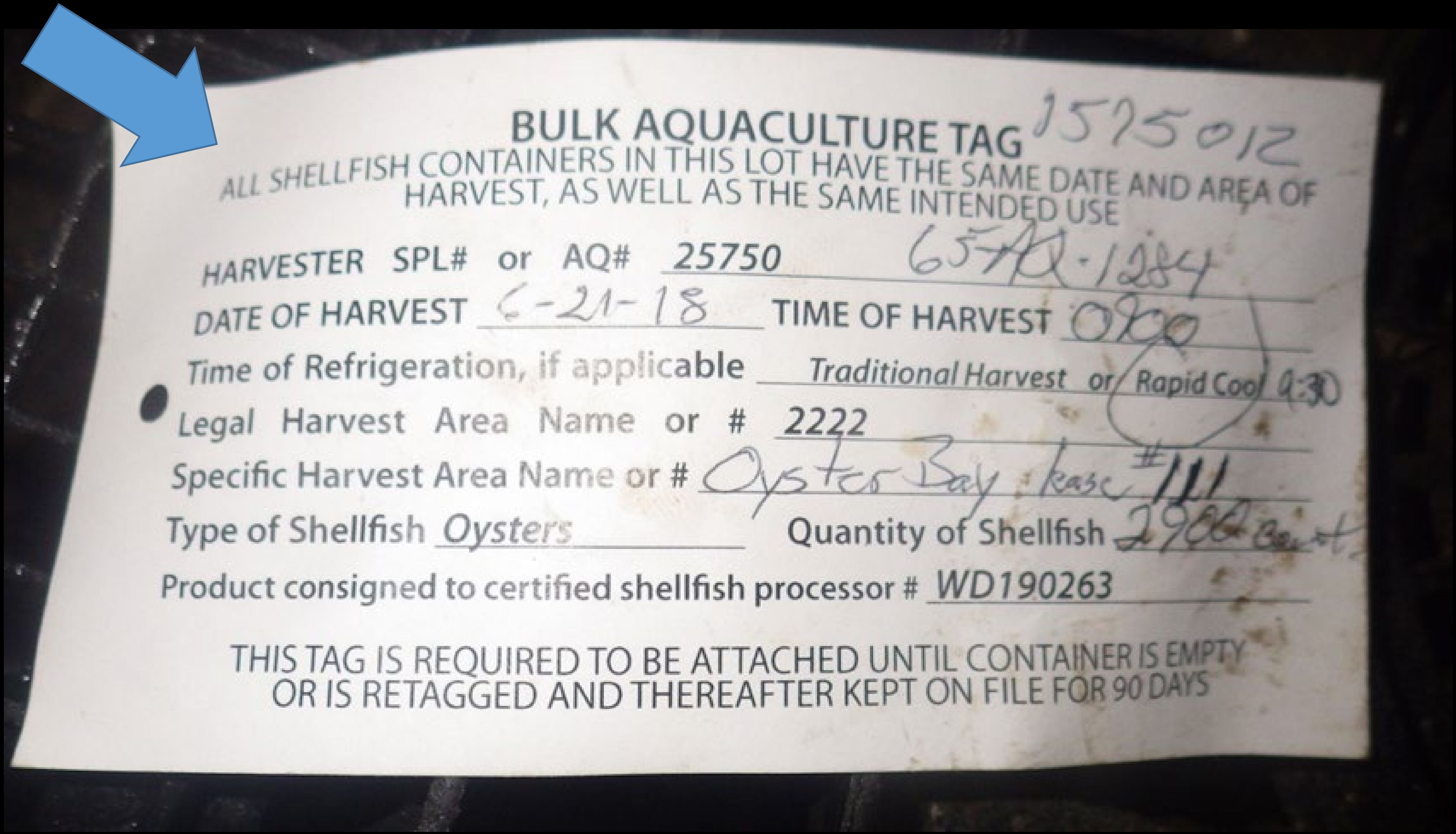
TYPE OF SHELLFISH: ____________

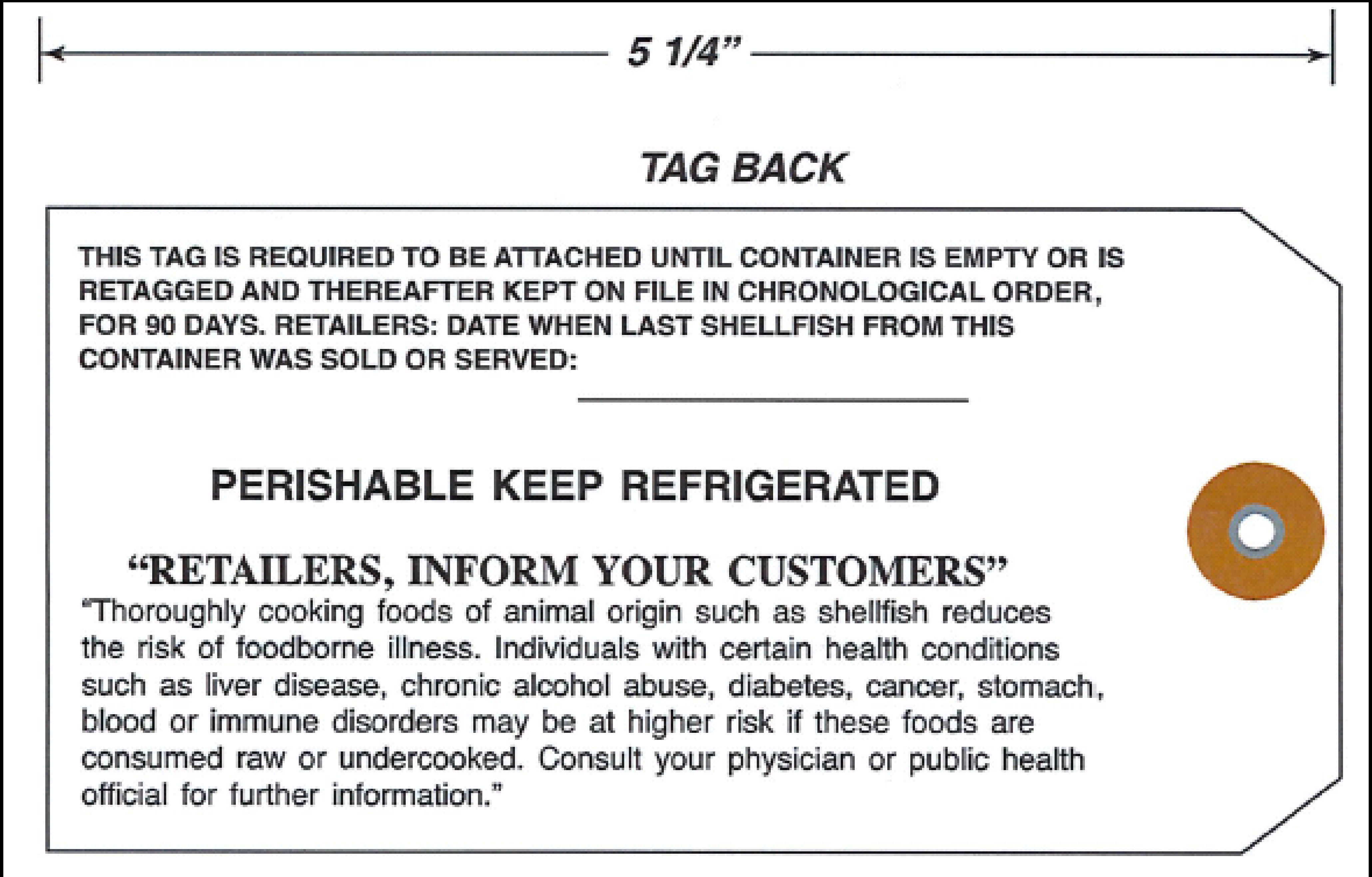
QUANTITY OF SHELLFISH: ____________

SELL BY: ____________

"FOR SHUCKING ONLY BY A CERTIFIED DEALER" or
"FOR POST HARVEST PROCESSING ONLY"

Bulk


BULK AQUACULTURE TAG
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
DATE OF HARVEST 6-21-18
TIME OF HARVEST
Time of Refrigeration, if applicable
Traditional Harvest or Rapid Cool
Legal Harvest Area Name or # 2222
Specific Harvest Area Name or # Oyster Bay
Type of Shellfish Oysters
Quantity of Shellfish
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


5 1/4”

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.”

2 5/8”

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

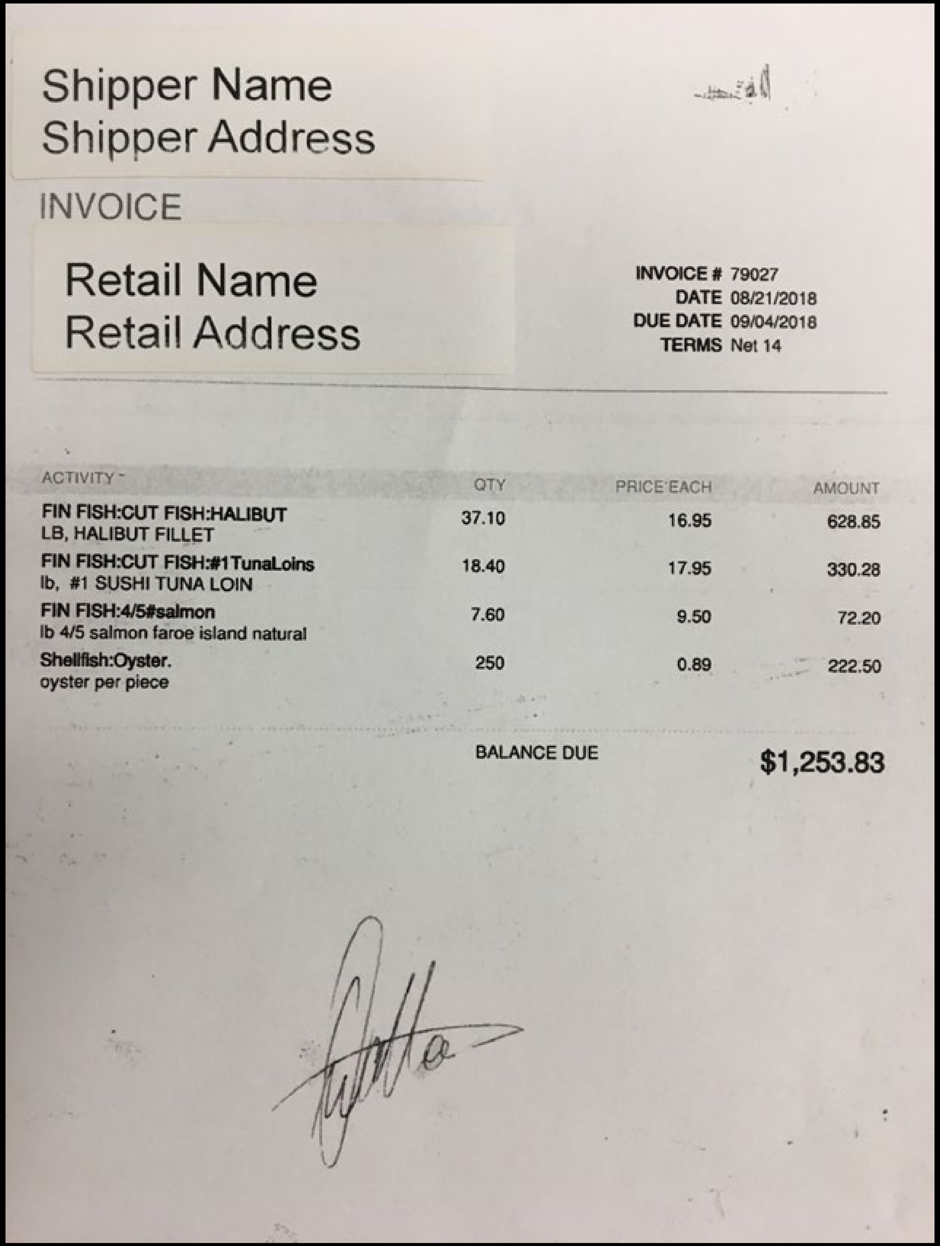
Transaction & Shipping Records

- 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

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

- Form(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.**”

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.

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

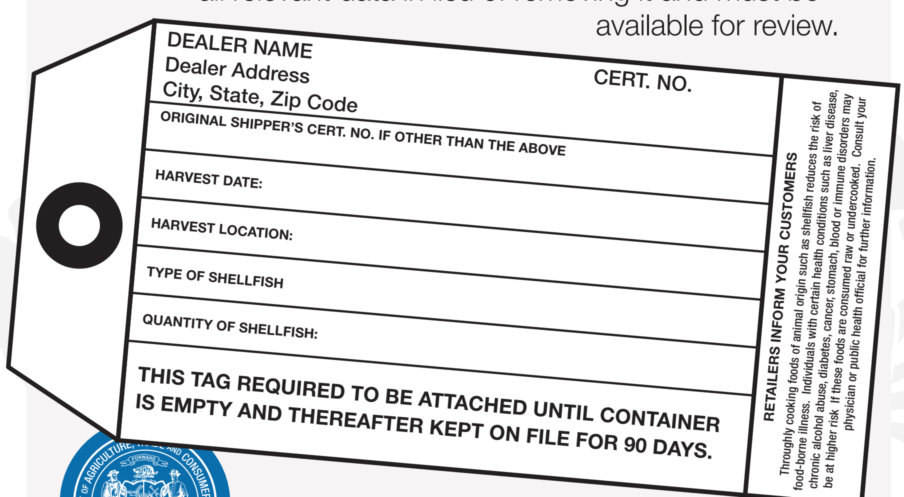
Molluscan shellfish that have one or both shells removed.

Shucker-packer

A person certified to shuck and pack shellfish.

Recordkeeping Requirements

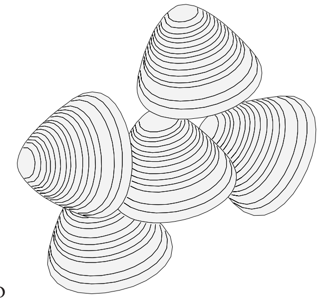
Tags must remain on the **SHELLSTOCK** container until the container is empty. The tags must then be retained for 90 calendar days, kept chronologically and available for review by the regulatory authority. If the label is printed on the container itself, the establishment may take a picture of the container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

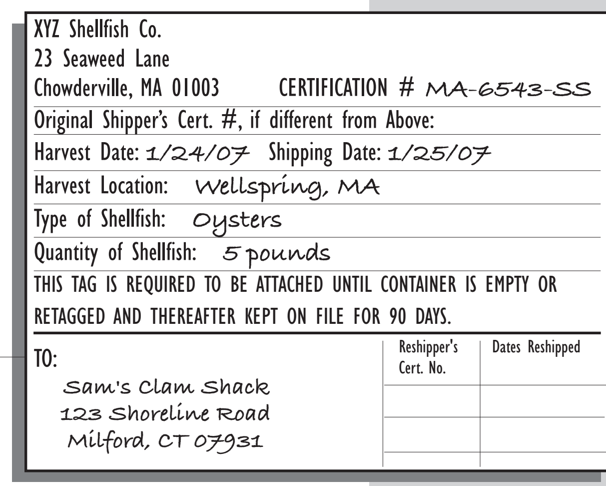
A Massachusetts Guide for
SAFE HANDLING OF SHELLFISH AT RETAIL



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****

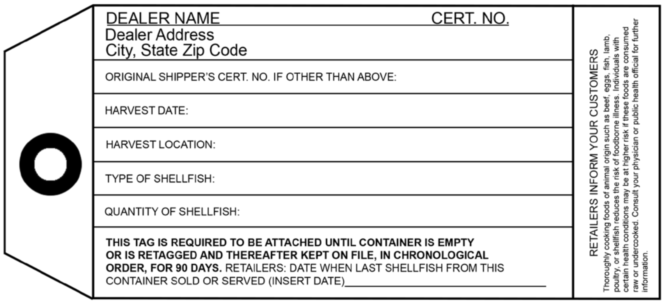
RECORD

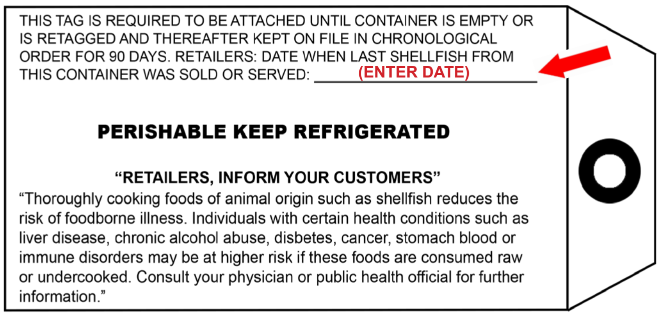
When the last shellstock from the bag / box has been sold, served, or discarded, **record the date** on the blank line / space on the tag with a permanent marker. If no line / space is provided, place the date anywhere on the tag.

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****

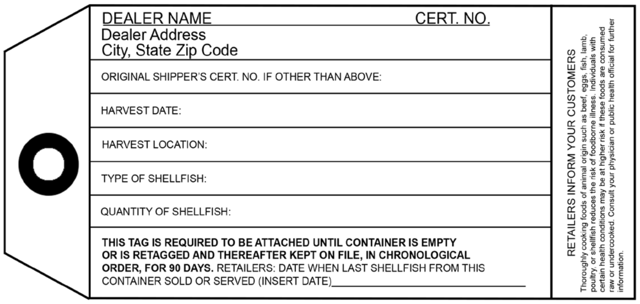
REGISTRAR

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.

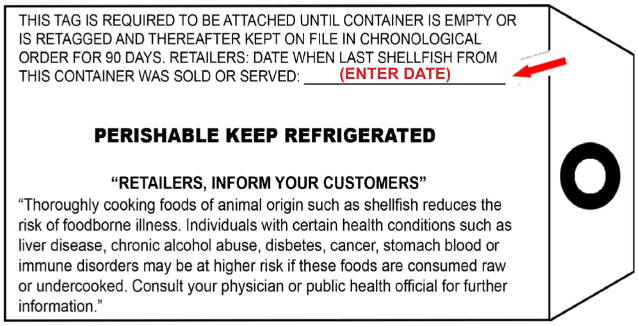
ARCHIVAR

- 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.

****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.**


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, 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."

SHELLSTOCK TAG PROCEDURES

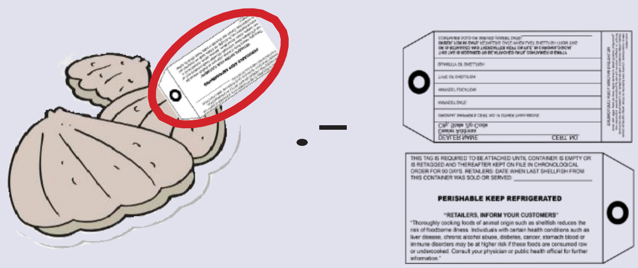
Procedimientos de etiquetado de mariscos

(Oysters, Scallops, Mussels, & Clams)

(Ostras, Vieiras, Mejillones y Almejas)

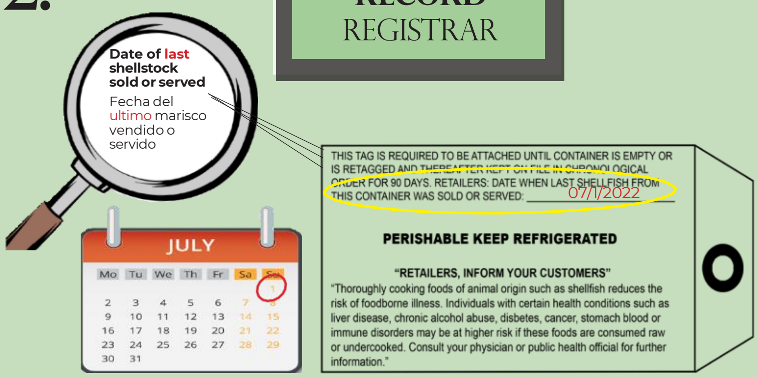
1.

KEEP
MANTENER



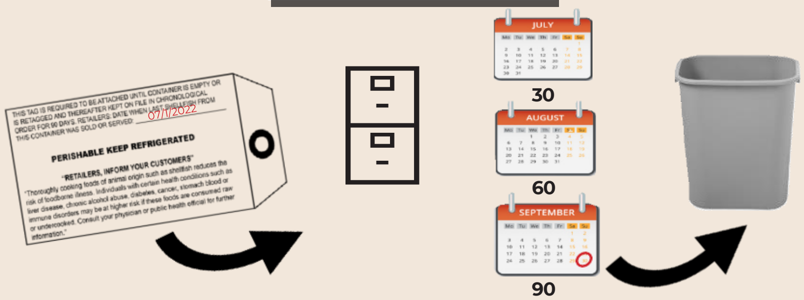
2.

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

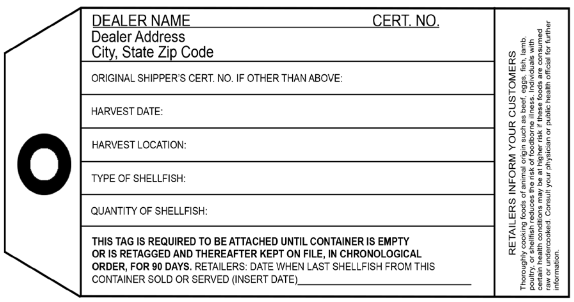
RECORD

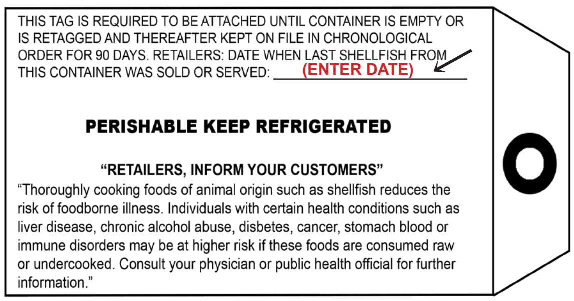
- **Write** the date on the blank line / space on the tag when the last shellstock from the bag / box has been sold, served, or thrown away
  - **Use** a permanent marker to record the date
  - **Record** the date anywhere on the tag if there is no line / space

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

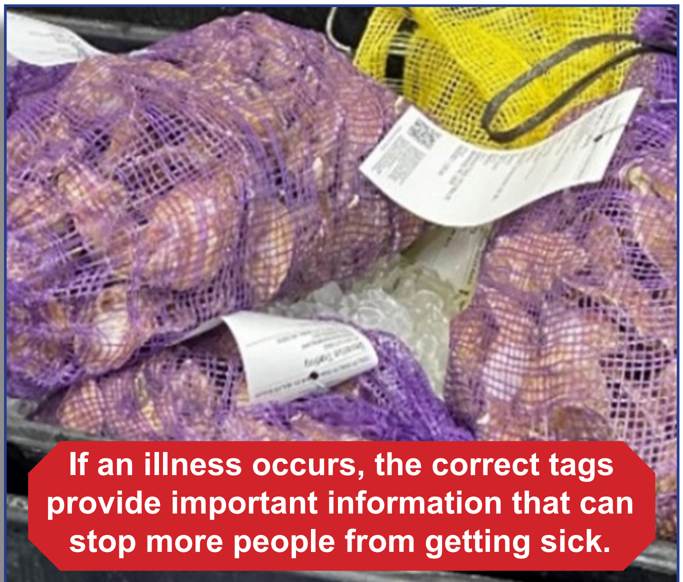
DO NOT MIX SHELLSTOCK!
Commingling, or mixing shellstock collected on different days, packed on different days, or collected from different growing areas is not allowed.





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)



If an illness occurs, the correct tags provide important information that can stop more people from getting sick.

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

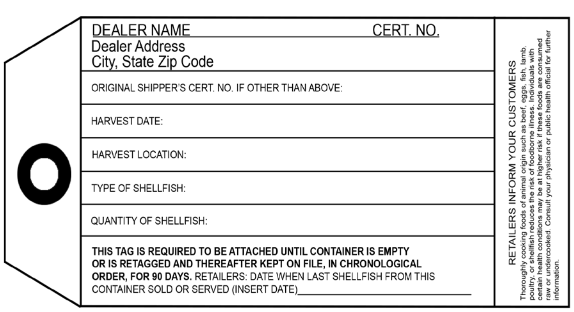
REGISTRAR

- **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

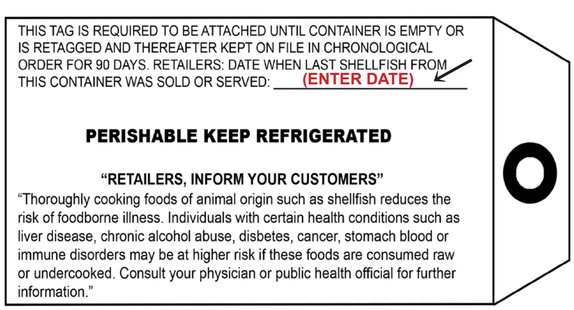
ARCHIVAR

- **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, 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.

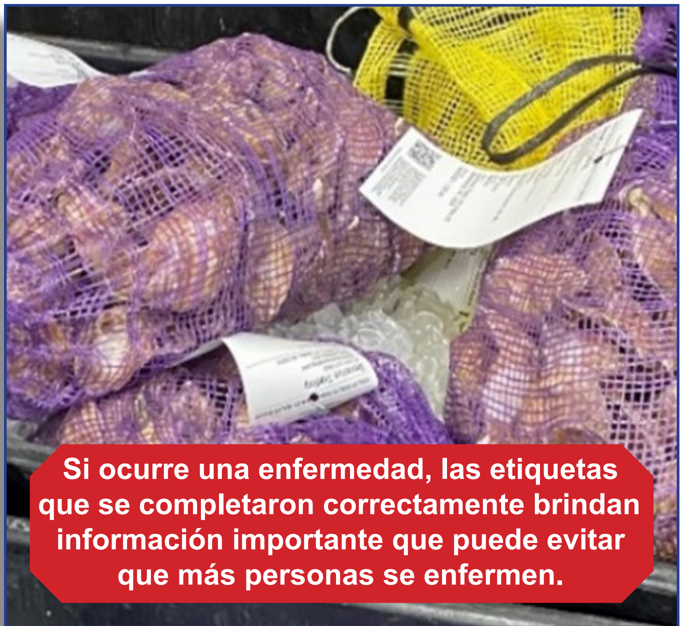

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE IN CHRONOLOGICAL ORDER FOR 90 DAYS. RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER WAS SOLD OR SERVED: ____(ENTER DATE)____

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)



Si ocurre una enfermedad, las etiquetas que se completaron correctamente brindan información importante que puede evitar que más personas se enfermen.

¿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

DEALER NAME: A person who is certified by the state regulatory authority to handle shellfish

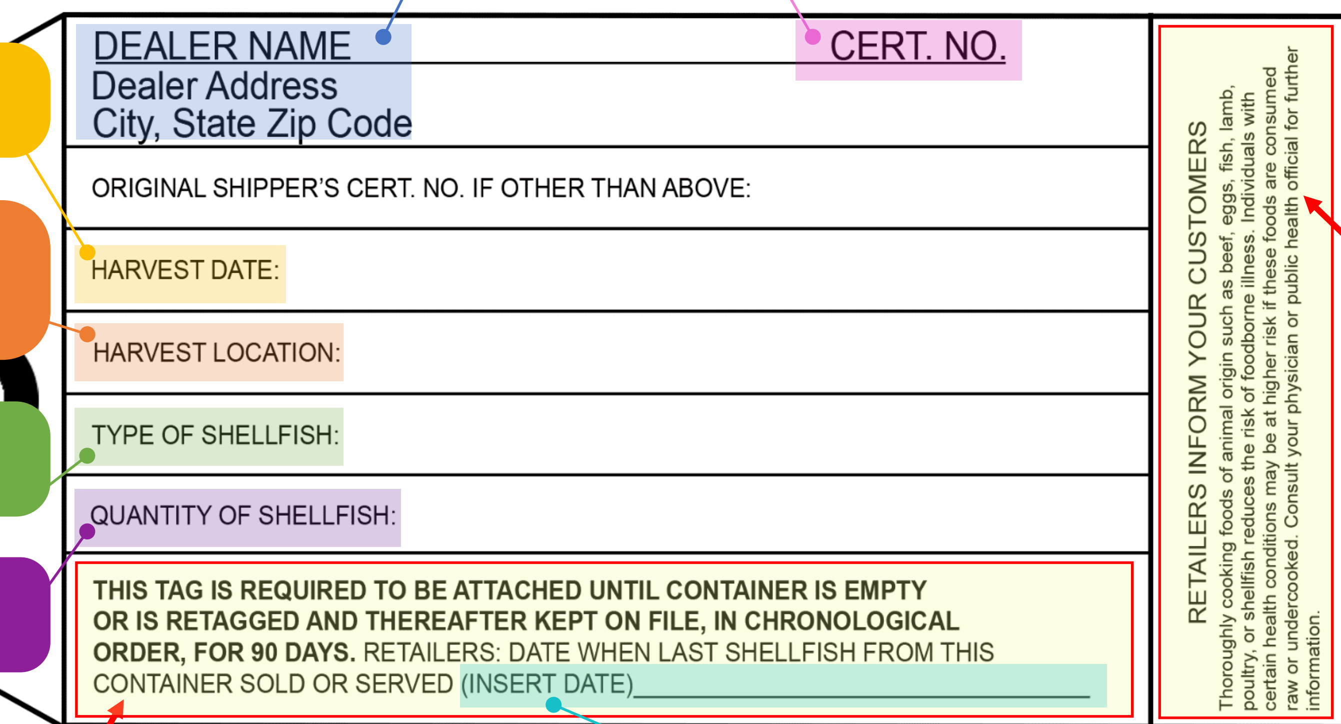
CERT NO: A combination of letters/numbers assigned by the state regulatory authority to a dealer

HARVEST DATE: Date shellstock was removed from water

HARVEST LOCATION: Identification of the water body, including the two letter state abbreviation

TYPE OF SHELLFISH: Such as "oysters", "PEI mussels", "littleneck clams"

QUANTITY OF SHELLFISH: Such as "100 count", "5 x 50 count"



The **CONSUMER ADVISORY** is required on all shellstock tags

This statement shall be on every tag exactly as it appears here

INSERT DATE: The last date this shellfish was sold or served, which is essential for traceback in case of illness

*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

	2022 Food Code Reference	SPECIFIC STANDARDS 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

SUSPECT AGENT/PATHOGEN OF CONCERN & CORRESPONDING FIELD FOCUS

TOXINS	FIELD FOCUS
☐ Paralytic shellfish poisoning ☐ Diarrhetic shellfish poisoning ☐ Neurotoxic shellfish poisoning ☐ Amnesic shellfish poisoning	S

BACTERIAL INFECTIONS	FIELD FOCUS
☐ *Vibrio cholerae O1* ☐ *Vibrio cholerae non-O1*	S Ill FW BHC HW CH XC CA

BACTERIAL INFECTIONS*	FIELD FOCUS
☐ *Vibrio parahaemolyticus* ☐ *Vibrio vulnificus*	S CH XC CA

*Not typically transmitted person to person

RISK FACTORS & INTERVENTIONS FIELD FOCUS

SOURCE (S)
- ☐ Copies of delivery receipts/invoices
- ☐ Shellfish tags, ICSSL (Interstate Certified Shellfish Shippers List)

ILL FOOD WORKERS (ILL FW)
- ☐ Exclusion policy
- ☐ Check work schedules (employee list)
- ☐ Determine employee health status
- ☐ Determine roles of food workers for suspected meals and ingredients

BARE HAND CONTACT (BHC)
- ☐ Gloves/utensils available & indications of usage
- ☐ History of BHC control in facility

HANDWASHING (HW)
- ☐ Handwash sinks available & have soap/towels
- ☐ Observe proper HW

COLD HOLDING (CH)
- ☐ Proper CH
- ☐ History of proper temperature control practices
- ☐ Discussion of food prep steps
- ☐ Advanced preparation

CROSS-CONTAMINATION (XC)
- ☐ Proper storage during cold-holding, display
- ☐ Separation of utensils used for raw product
- ☐ Cleaning/sanitizing of equipment/utensils
- ☐ Shells used for other entrees
- ☐ Shucking gloves, towels, sanitizer buckets

CONSUMER ADVISORY (CA)
- ☐ Menu disclosure and reminder

METHODS, REMEDIATION & CONTROL MEASURES

Consider items and check each used.

INVESTIGATION METHODS
- ☐ Food, Environmental Samples
- ☐ Stool Samples
- ☐ Photographs
- ☐ Suspect Meal Menu
- ☐ Reservation Lists, Receipts
- ☐ Special Events, Parties
- ☐ Invoices, Inventory, Traceback
- ☐ Multiple Establishments Investigated
- ☐ Additional Case Finding

CONTROL MEASURES
- ☐ Behavior Change
- ☐ Procedure Change
- ☐ Exclude Ill FW
- ☐ Food Destruction
- ☐ Detention Order
- ☐ Cleaning & Sanitizing
- ☐ Suspension/Closure

MOVING FORWARD
- ☐ Follow-up Visit Scheduled
- ☐ Follow-up Visit with Interpreter
- ☐ Increased Inspections
- ☐ Menu Reduction
- ☐ Required Education/Training
- ☐ Office Conference

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

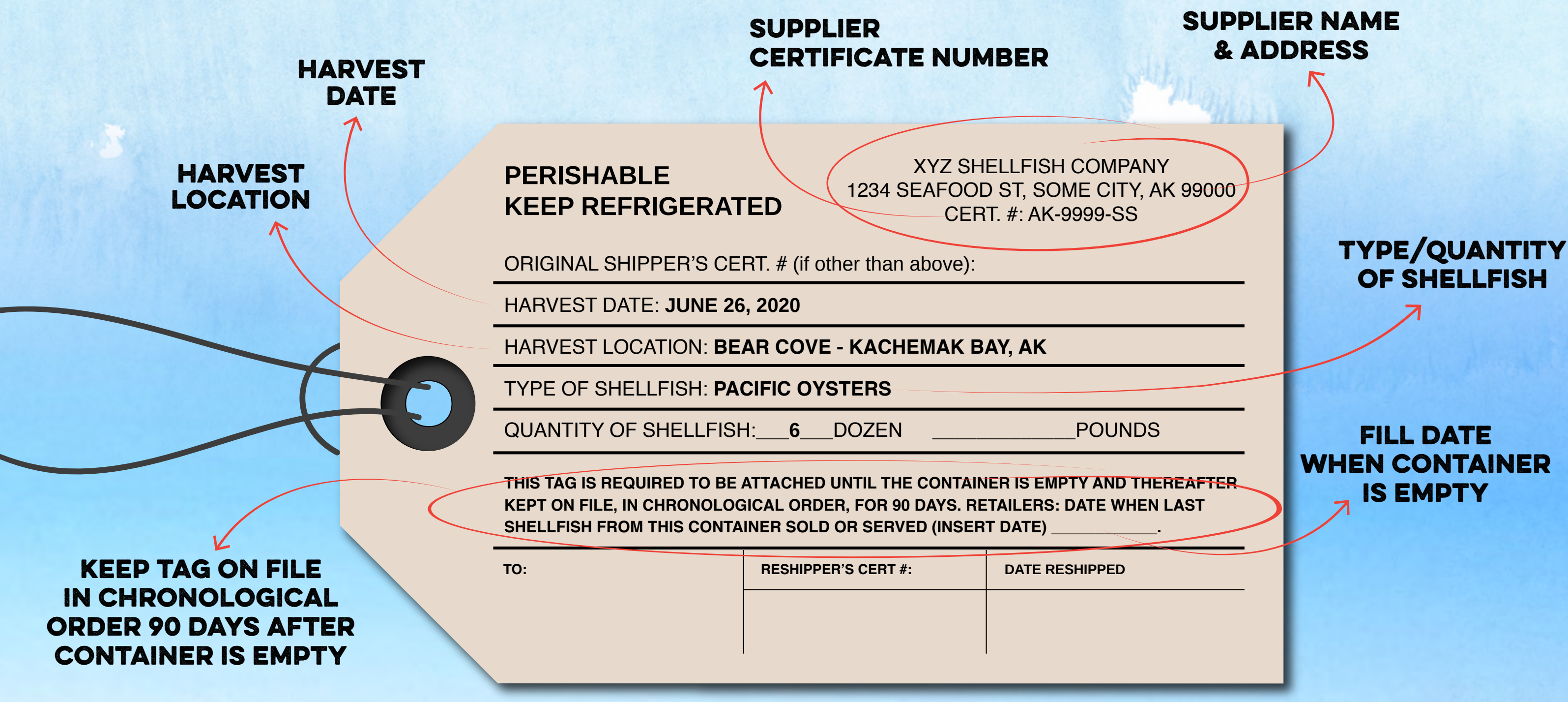
ADEC Food Safety & Sanitation Program

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. <u>ILL FOOD WORKERS (</u>

- **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. <u>HANDWASHING Critical Limits</u>

- 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. SEPARATION OF RAW ANIMAL FOODS FROM READY-TO-EAT FOODS

- 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. SEPARATION OF RAW ANIMAL FOODS OF DIFFERENT SPECIES

- 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. <u>CLEANING & SANITIZING OF FOOD CONTACT SURFACES</u>

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 $\geq$ 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

<u>DEFINITIONS:</u>

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

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

Molluscan Shellfish at Retail

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

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.

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."

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
Keep Address
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:	RESHIPPERS	DATES RESHIPPED
End Date:		

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

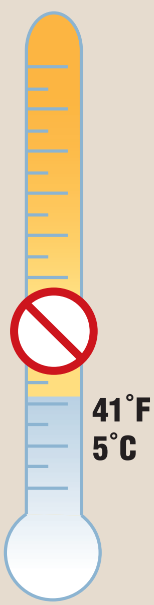
MOLLUSCAN SHELLFISH HANDLING

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)

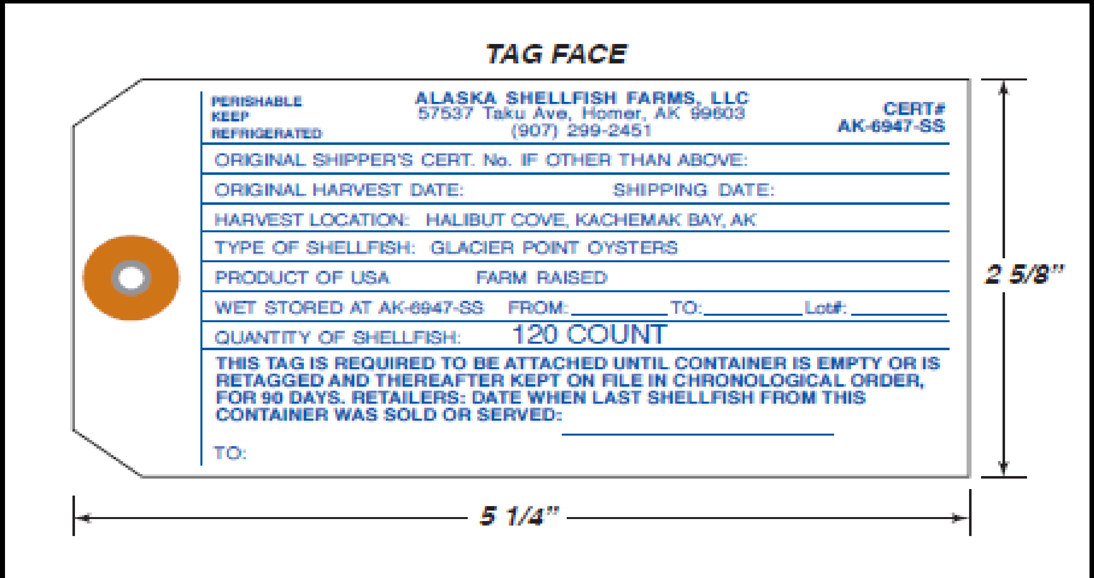
Harvester

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.

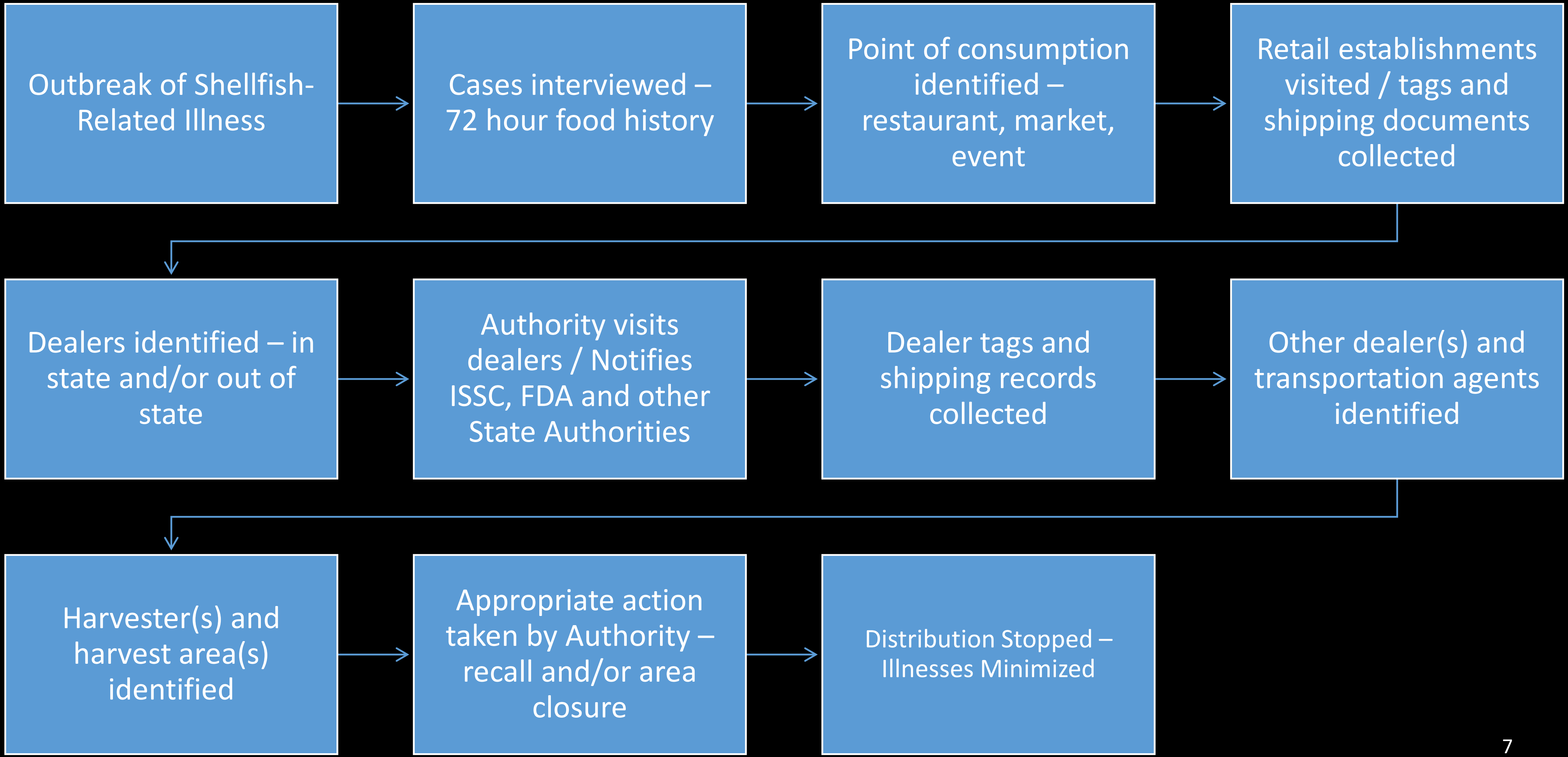
Recall

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

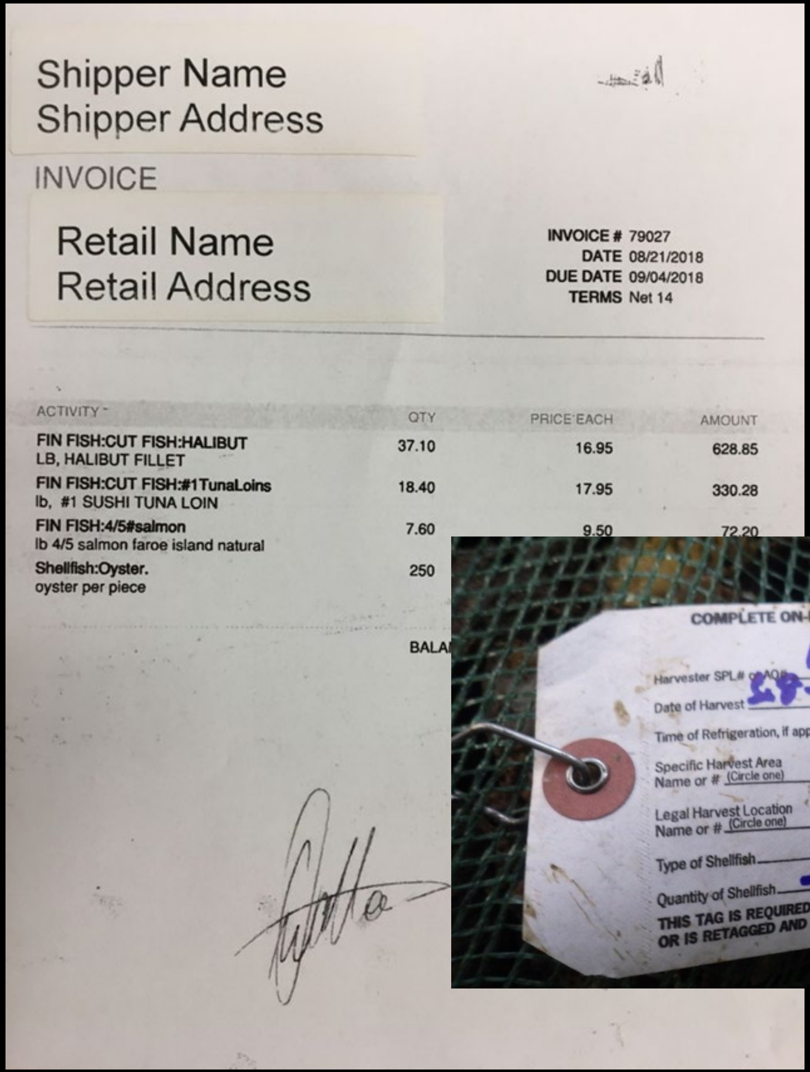
Traceback Objectives

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

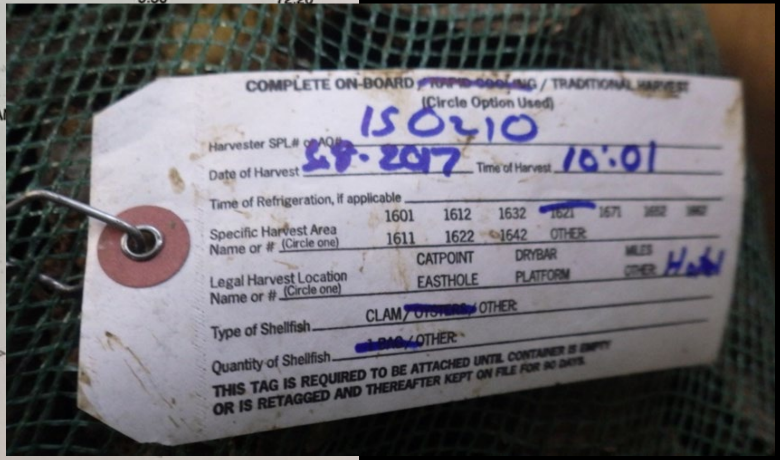
INVOICE

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


COMPLETE ON-BOARD / ~~RAPID COOLING~~ / TRADITIONAL HARVEST
(Circle Option Used)

Harvester SPL# or AQ# 150410
Date of Harvest
Time of Harvest 10:01
Time of Refrigeration, if applicable
Specific Harvest Area Name or # (Circle one) 1601 1612 1632 1621 1671 1652 1662 1611 1622 1642 OTHER
Legal Harvest Location Name or # (Circle one) CATPOINT DRYBAR MILES EASTHOLE PLATFORM OTHER
Type of Shellfish CLAM / OYSTERS / OTHER
Quantity of Shellfish 1 BAG / OTHER
THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS

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

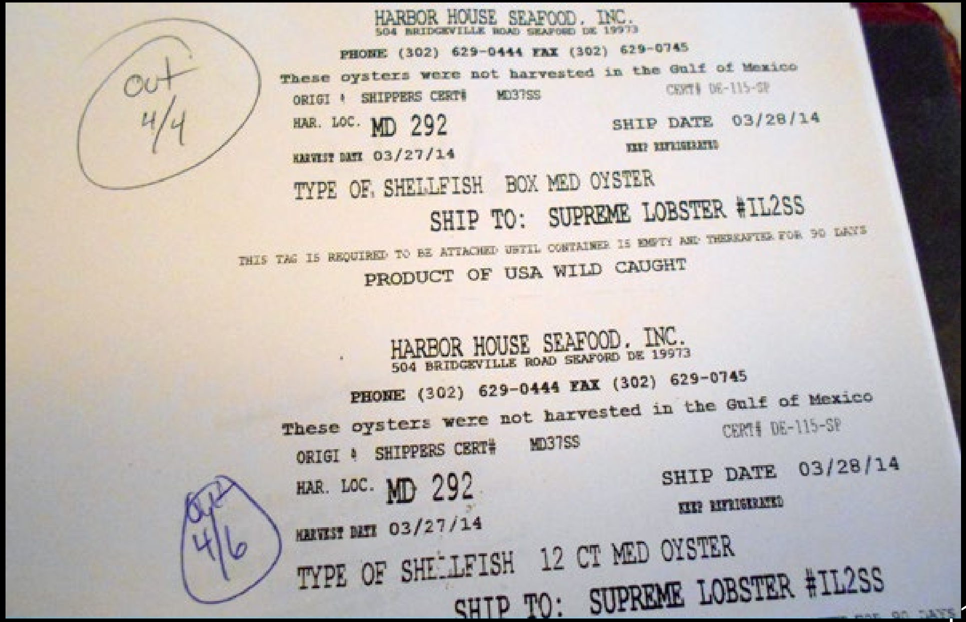
Retail

Retail Requirements

Every package has required tag

When last shellstock sold, date, and keep 90 days

No commingling during display



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):

Not required if depurated

HARVEST DATE: *November 17, 2010*

If depurated, date of depuration and cycle or lot number

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

TYPE OF SHELLFISH: *Manila Clams*

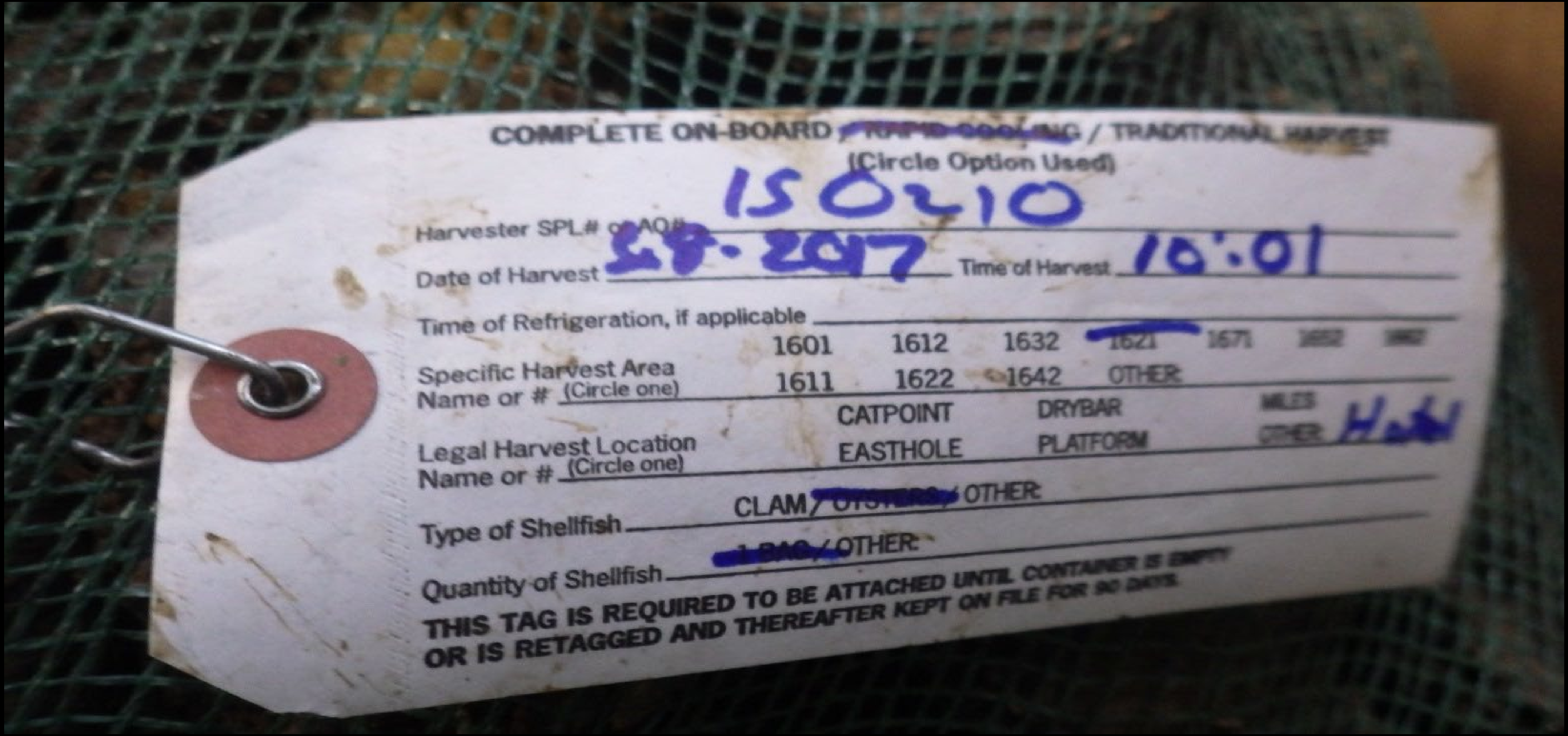
QUANTITY OF SHELLFISH: ________ dozen ________ pounds

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

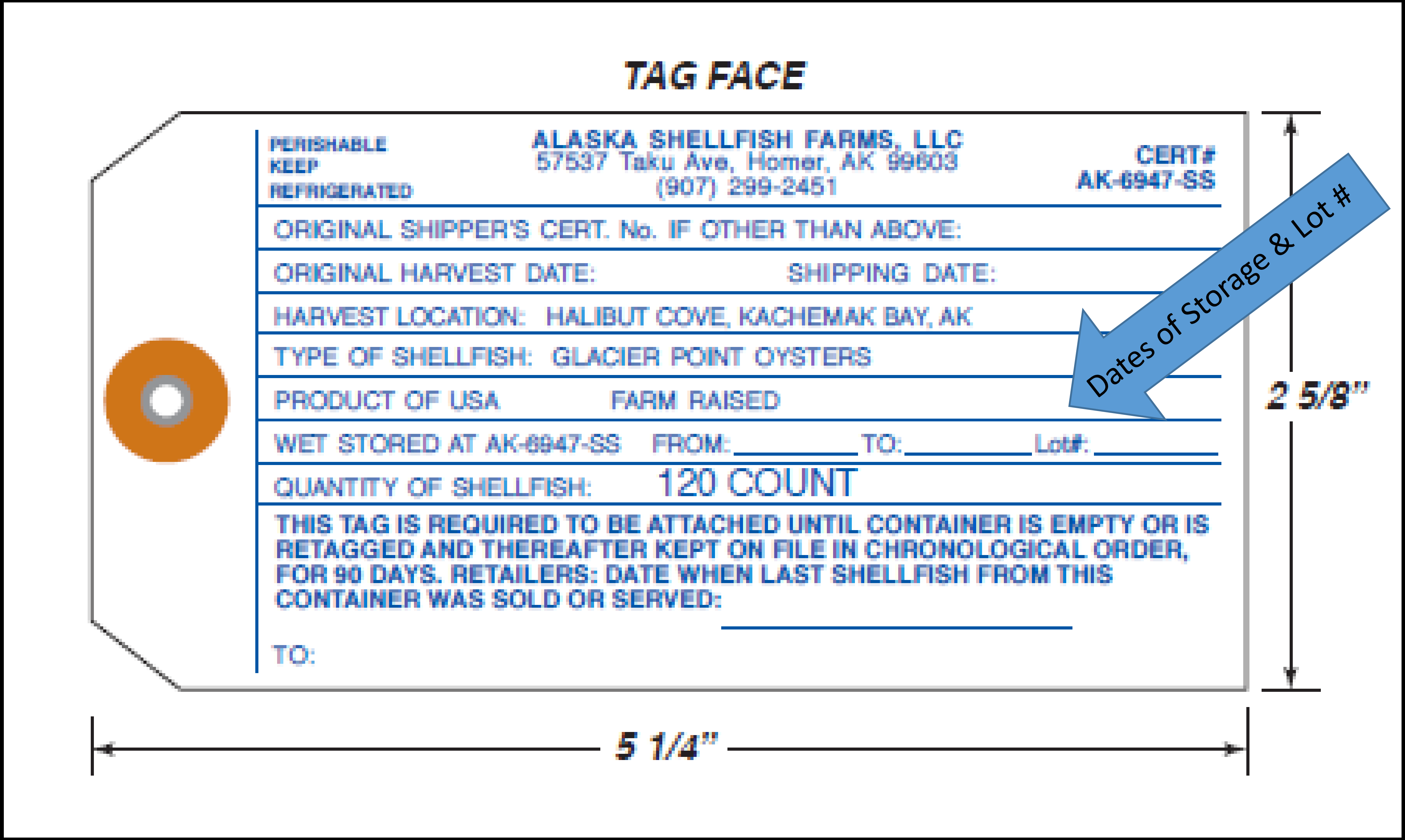
https://www.doh.wa.gov/Portals/1/Documents/4400/332-128-Dealer-Tag-Example.pdf

Harvester


COMPLETE ON-BOARD / TRADITIONAL HARVEST
(Circle Option Used)
150210
Harvester SPL# or AQ#
Date of Harvest
Time of Harvest 10:01
Time of Refrigeration, if applicable
Specific Harvest Area Name or # (Circle one)
1601 1612 1632
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



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**

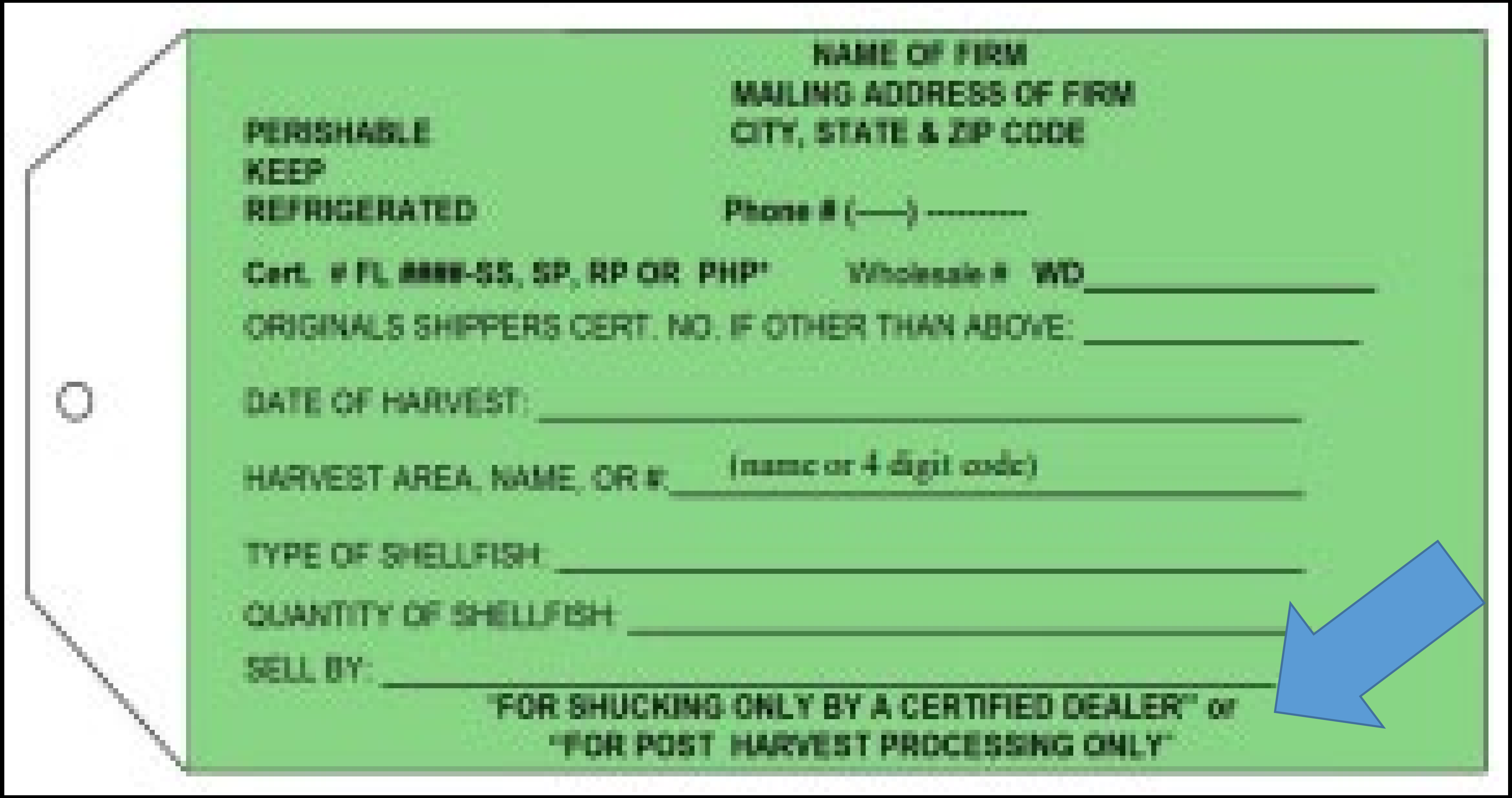
QUANTITY OF SHELLFISH: __________ dozen __________ pounds

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

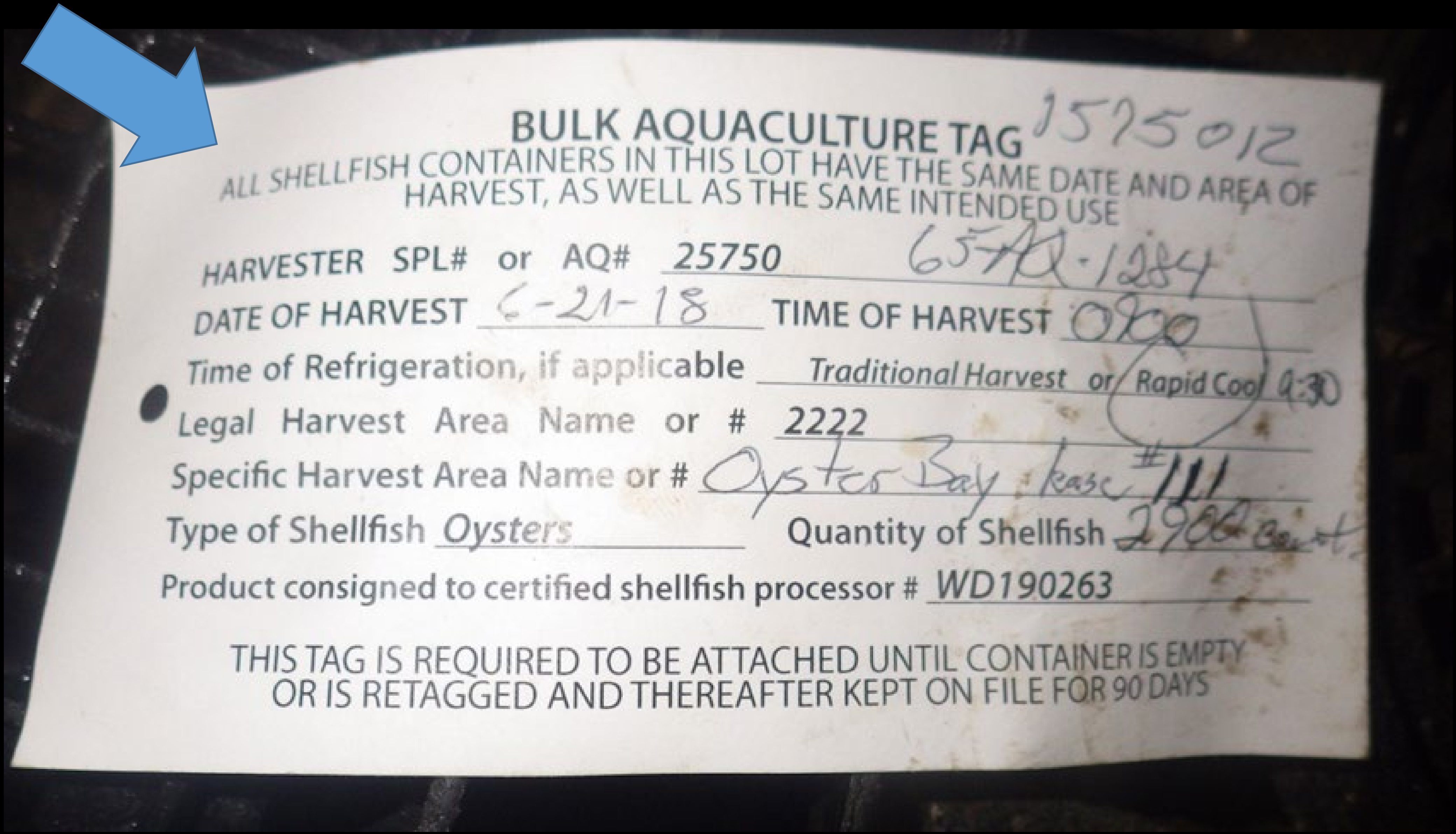
TO:	RESHIPPER'S CERT. No.	DATE RESHIPPED

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

Restricted Use



Bulk


BULK AQUACULTURE TAG
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
DATE OF HARVEST 6-21-18
TIME OF HARVEST
Time of Refrigeration, if applicable
Traditional Harvest or Rapid Cool
Legal Harvest Area Name or # 2222
Specific Harvest Area Name or # Oyster Bay
Type of Shellfish Oysters
Quantity of Shellfish
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

5 1/4"

TAG BACK

2 5/8"

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

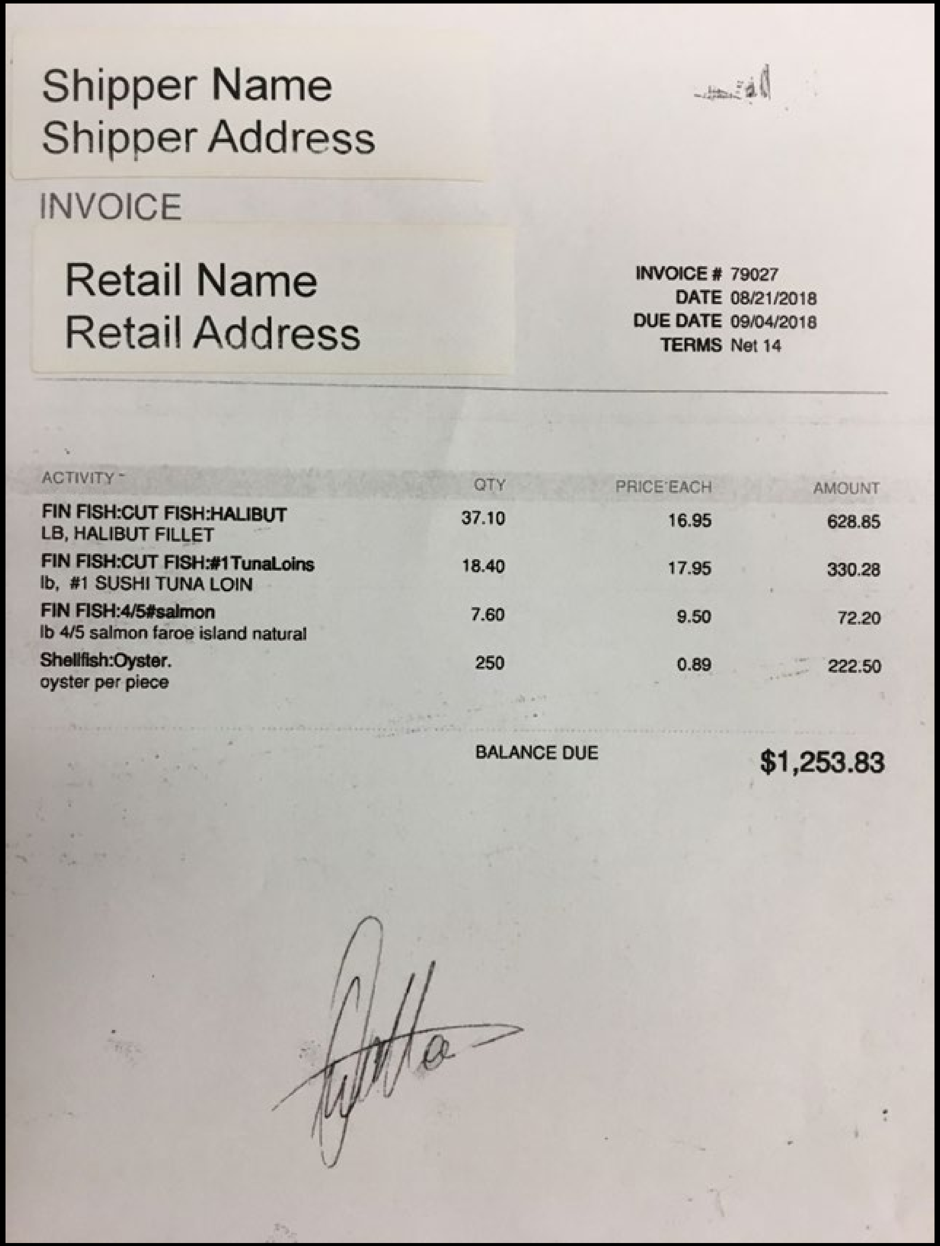
Transaction & Shipping Records

- 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

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.**"

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.

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.

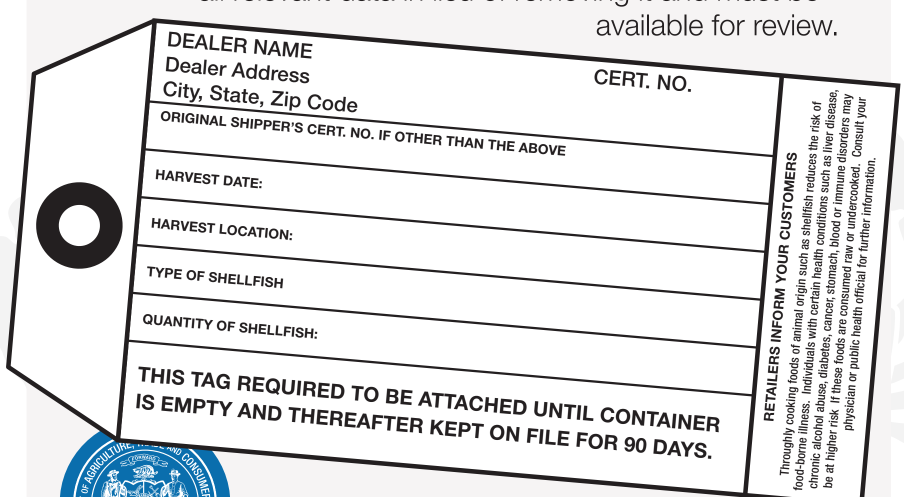
Shellstock
Raw, in-shell molluscan shellfish, such as an oyster or mollusk. This does not include shrimp, lobster, or scallop muscle.

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

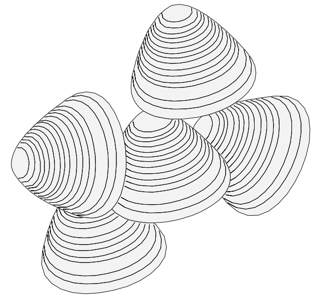
Shucker-packer
A person certified to shuck and pack shellfish.

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.



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

Massachusetts Food Safety Education Partnerships

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.

UMASS EXTENSION

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/

Journal of Food Protection, Vol. 83, No. 7, 2020, Pages 1248–1260
https://doi.org/10.4315/JFP-20-025
Published 2020 by the International Association for Food Protection

Research Paper

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

BINAIFER BEDFORD,[1] GIRVIN LIGGANS,[2] LAURIE WILLIAMS,[2] AND LAUREN JACKSON[1]*

[1]*Division of Food Processing Science and Technology, Office of Food Safety, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, 6502 South Archer Road, Bedford Park, Illinois 60501 (ORCID: https://orcid.org/0000-0001-6246-700X [L.J.])* [2]*Retail Food Protection Staff, Office of Food Safety, Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration, 5001 Campus Drive, College Park, Maryland 20740, USA*

MS 20-025: Received 17 January 2020/Accepted 19 March 2020/Published Online 23 June 2020

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

* Author for correspondence. Tel: 708-924-0616; Fax: 708-924-0690; E-mail: Lauren.Jackson@fda.hhs.gov.

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]

Coupon type	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 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]

Coupon type	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 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.

ACKNOWLEDGMENT

The authors appreciate the conversations and insights provided by Dr. Hal King and his suggestion on expanding the scope of the study to include alcohol quat sanitizer wipes (Table Turners) on the basis of current retail food establishment practices.

SUPPLEMENTAL MATERIAL

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

REFERENCES

1. Acker, W. W., J. Plasek, K. G. Blumenthal, K. H. Lai, M. Topaz, D. L. Seger, F. R. Goss, S. P. Slight, P. G. Dip, D. W. Bates, and L. Zhou. 2017. Prevalence of food allergies and intolerances documented in electronic health records. *J. Allergy Clin. Immunol*. 140:1587–1591.
2. Ak, N. O., D. O. Cliver, and C. W. Kaspar. 1994. Cutting boards of plastic and wood contaminated experimentally with bacteria. *J. Food Prot*. 57:16–22.
3. Ak, N. O., D. O. Cliver, and C. W. Kaspar. 1994. Decontamination of plastic and wooden cutting boards for kitchen use. *J. Food Prot*. 57:23–30.
4. Aviat, F., and C. Gerhards. 2016. Microbial safety of wood in contact with food: a review. *Compr. Rev. Food Sci. Food Saf*. 15:491–506.
5. Boyce, J. A., A. Assa'ad, A. W. Burks, S. M. Jones, H. A. Sampson, R. A. Wood, M. Plaut, S. F. Cooper, M. J. Fenton, S. H. Arshad, S. L. Bahna, L. A. Beck, C. Byrd-Bredbenner, C. A. Camargo, Jr., L. Eichenfield, G. T. Furuta, J. M. Hanifin, C. Jones, M. Kraft, B. D. Levy, P. Lieberman, S. Luccioli, K. M. McCall, L. C. Schneider, R. A. Simon, F. E. Simons, S. J. Teach, B. P. Yawn, and J. M. Schwaninger. 2010. Guidelines for the diagnosis and management of food allergy in the United States: report of the NIAID-sponsored expert panel. *J. Allergy Clin. Immunol*. 126(Suppl):S1–58.
6. Brough, H. A., K. Makinson, M. Penagos, S. J. Maleki, H. Cheng, A. Douiri, A. C. Stephens, V. Turcanu, and G. Lack. 2013. Distribution of peanut protein in the home environment. *J. Allergy Clin. Immunol*. 132:623–629.
7. Gehrig, M., C. Schnell, E. Zurcher, and L. Kucera. 2000. Hygienic aspects of wood and polyethylene cutting boards regarding food contaminations. A comparison. *Holz Roh Werkst*. 58:265–269.
8. Gupta, R. S., E. E. Springston, M. R. Warrier, B. Smith, R. Kumar, J. Pongracic, and J. L. Holl. 2011. The prevalence, severity, and distribution of childhood food allergy in the United States. *Pediatrics* 128:e9–e17.
9. Jackson, L. S., F. M. Al-Taher, M. Moorman, J. W. DeVries, R. Tippett, K. M. J. Swanson, T.-J. Fu, R. Salter, G. Dunaif, S. Estes, S. Albillos, and S. M. Gendel. 2008. Cleaning and other control and validation strategies to prevent allergen cross-contact in food-processing operations. *J. Food Prot*. 71:445–458.
10. Little, C., and S. Sagoo. 2009. Evaluation of the hygiene of ready-to-eat food preparation areas and practices in mobile food vendors in the UK. *Int. J. Environ. Health Res*. 19:431–443.
11. Lucke, F., and A. Skowyrska. 2015. Hygienic aspects of using wooden and plastic cutting boards, assessed in laboratory and small gastronomy units. *J. Consum. Prot. Food Saf*. 10:317–322.
12. Miller K., N. McGough, and H. Urwin. 2016. Catering gluten-free when simultaneously using wheat flour. *J. Food Prot*. 79:282–287.
13. Ortiz, J. C., P. Galan-Malo, M. Garcia-Galvez, A. Mateos, M. Ortiz-Ramos, P. Razquin, and L. Mata. 2018. Survey on the occurrence of allergens on food-contact surfaces from school canteen kitchens. *Food Control* 84:449–454.
14. Perry, T. T., M. K. Conover-Walker, A. Pomés, M. D. Chapman, and R. A. Wood. 2004. Distribution of peanut allergen in the environment. *J. Allergy Clin. Immunol*. 113:973–976.
15. Röder, M., A. Ibach, I. Baltruweit, H. Gruyters, A. Janise, C. Suwelack, R. Matissek, S. Vieths, and T. Holzhauser. 2008. Pilot plant investigations on cleaning efficiencies to reduce hazelnut cross-contamination in industrial manufacture of cookies. *J. Food Prot*. 71:2263–2271.
16. Schmidt, R. H. 1997. Basic elements of equipment cleaning and sanitizing in food processing and handling operations. University of Florida Cooperative Extension Service, Institute of Food and Agricultural Sciences. Available at: http://edis.ifas.ufl.edu/FS077. Accessed 16 October 2019.
17. Sicherer, S., and H. A. Sampson. 2014. Food allergy: epidemiology, pathogenesis, diagnosis, and treatment. *J. Allergy Clin. Immunol*. 133:291–307.
18. Sicherer, S., and H. A. Sampson. 2018. Food allergy: a review and update on epidemiology, pathogenesis, diagnosis, prevention, and management. *J. Allergy Clin. Immunol*. 141:41–58.
19. Tebbutt, G. M. 1991. An assessment of cleaning and sampling methods for food-contact surfaces in premises preparing and selling high-risk foods. *Epidemiol. Infect*. 106:319–327.
20. U.S. Department of Agriculture, Economic Research Service. 2019. U.S. food-away-from-home spending continued to outpace food-at-home spending in 2018. Available at: www.ers.usda.gov/data-products/chart-gallery/chart-detail/?chartid=58364. Accessed 23 September 2019.
21. U.S. Department of Agriculture, Food Safety and Inspection Service. 2013. Cutting boards and food safety. Available at: www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/cutting-boards-and-food-safety. Accessed 15 January 2019.
22. U.S. Food and Drug Administration. 2004. Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). Public law 108-282. Title II. U.S. Food and Drug Administration, Silver Spring, MD. Available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm. Accessed 12 January 2017.
23. U.S. Food and Drug Administration. 2017. Food Code. Available at: https://www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/ucm595139.htm. Accessed 10 October 2019.
24. Wang, X., O. A. Young, and D. P. Karl. 2010. Evaluation of cleaning procedures for allergen control in a food industry environment. *J. Food Sci*. 75:T149–T155.
25. Watrous, G. H. 1975. Food soils, water hardness, and alkaline cleaner formulations. *J. Milk Food Technol*. 38:163–165.
26. Watson, W. T. A., A. Woodrow, and A. W. Stadnyk. 2015. Removal of peanut allergen Ara h 1 from common hospital surfaces, toys and books using standard cleaning methods. *Allergy Asthma Clin. Immunol.* 11:1–4. https://doi.org/doi:10.1186/s13223-015-0069-x
27. Welker, C., N. Faiola, S. Davis, I. Maffatore, and C. A. Batt. 1997. Bacterial retention and cleanability of plastic and wood cutting boards with commercial food service maintenance practices. *J. Food Prot*. 60:407–413.

Proceedings of the Nutrition Society (2005), **64**, 475–480 DOI:10.1079/PNS2005453

Review of statutory and voluntary labelling of food allergens*

Mark Boden, Ruth Dadswell and Sue Hattersley†
Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH, UK

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

*The opinions expressed in the present paper represent the opinions of the authors and do not represent the views of the Food Standards Agency.
†**Corresponding author:** Mrs Sue Hattersley, fax +44 20 7276 8513, email sue.hattersley@foodstandards.gsi.gov.uk

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),

https://doi.org/10.1079/PNS2005453 Published online by Cambridge University Press

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

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

https://doi.org/10.1079/PNS2005453 Published online by Cambridge University Press

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.

References

Anaphylaxis Campaign (2001) ‘May contain’ labelling – The consumer’s perspective. http://www.food.gov.uk/multimedia/pdfs/maycontainreport.pdf

COI Communications (2002) Nut allergy labelling: Report of research into the consumer response. http://www.food.gov.uk/multimedia/pdfs/nutallergyresearch.pdf

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (2002) Adverse reactions to food and food ingredients. http://www.food.gov.uk/science/ouradvisors/toxicity/reports/food reactions

Department of Health and Human Services (2001) Food code. http://www.cfsan.fda.gov/~dms/foodcode.html

European Commission (1979) Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer. *Official Journal of the European Commission* L**033**, 1–14.

European Commission (2000) Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. *Official Journal of the European Commission* L**109**, 29–42.

European Commission (2003) Directive 2003/89/EC of the European Parliament and of the Council of 10 November 2003 amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs. *Official Journal of the European Communities* L**308**, 15–18.

European Commission (2005) Commission Directive 2005/26/EC of 21 March 2005 establishing a list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council. *Official Journal of the European Commission* L**075**, 33–34.

European Food Safety Authority (2004) Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission relating to the evaluation of allergenic foods for labelling purposes (EFSA-Q-2003–016). http://www.efsa.eu.int/science/nda/nda_opinions/341_en.html

European Food Safety Authority (2004–5) Opinions of the Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA). http://www.efsa.eu.int/science/nda/nda_opinions/catindex_en.html

Food and Agriculture Organization (1995) *Report of the FAO Technical Consultation on Food Allergies*. Rome: FAO.

Food Standards Agency (2004) Advice for caterers on allergy and intolerance, May 2004. http://food/gov.uk/safereating/allergyintol/caterers/

Food Standards Agency (2005) Strategic Plan 2005–2010 – Putting consumers first. http://www.food.gov.uk/multimedia/pdfs/stratplan0510.pdf

Food Standards Australia New Zealand (2002) The Australia New Zealand Food Standards Code. http://www.foodstandards.gov.au/foodstandardscode/

Helm RM & Burks AW (2000) Mechanisms of food allergy. *Current Opinion in Immunology* **12**, 647–653.

Hourihane J (1998) Prevalence and severity of food allergy – need for control. *Allergy* **53**, Suppl. 46, 84–88.

Howarth PH (1998) Is allergy increasing? Early life influences. *Clinical and Experimental Allergy* **28**, Suppl. 6, 2–7.

Johansson SG, Bieber T, Dahl R, Friedmann PS, Lanier BQ, Lockey RF *et al.* (2004) Revised nomenclature for allergy for global use: Report of the Nomenclature Review Committee of the World Allergy Organisation, October 2003. *Journal of Allergy and Clinical Immunology* **113**, 832–836.

National Assembly of Wales (2004) Welsh Statutory Instrument 2004 No. 3022 (W.261). The Food Labelling (Amendment) (No. 2) (Wales) Regulations 2004 http://www.opsi.gov.uk/legislation/wales/wsi2004/20043022e.htm

Northern Ireland Assembly (2004) Statutory Rule 2004 No. 469. Food Labelling (Amendment No. 2) Regulations (Northern Ireland) 2004. http://www.opsi.gov.uk/sr/sr2004/20040469.htm

Scottish Parliament (2004) Scottish Statutory Instrument 2004 No. 472. The Food Labelling Amendment (No. 2) (Scotland) Regulations 2004. http://www.opsi.gov.uk/legislation/scotland/ssi2004/20040472.htm

Taylor SL (1987) Allergic and sensitivity reactions to food components. In *Nutritional Toxicology*, vol. II, pp. 173–197 [JN Hathcock, editor]. Orlando, FL: Academic Press.

UK Parliament (1990) Food Safety Act 1990 (c. 16). http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900016_en_1.htm

UK Parliament (1996) Statutory Instrument 1996 No. 1499. The Food Labelling Regulations 1996. http://www.opsi.gov.uk/si/si1996/Uksi_19961499_en_1.htm

UK Parliament (2004) Statutory Instrument 2004 No. 2824. The Food Labelling (Amendment) (England) (No. 2) Regulations 2004. http://www.opsi.gov.uk/si/si2004/20042824.htm

UK Parliament Health Committee (2004) Health Committee Report, 2004. The provision of allergy services. http://www.publications.parliament.uk/pa/cm200304/cmselect/cmhealth/696/69602.htm

US Congress (2004) Food Allergen Labelling and Consumer Protection Act of 2004. http://www.cfsan.fda.gov/~dms/alrgact.html

Woods RK, Stoney RM, Raven J, Walters EH, Abramson M & Thien FC (2002) Reported adverse reactions overestimate true food allergy in the community. *European Journal of Clinical Nutrition* **56**, 31–36.

Young E, Stoneham MD, Petruckevitch A, Barton J & Rona R (1994) A population study of food intolerance. *Lancet* **343**, 1127–1130.

MARIE BOYD*

Serving Up Allergy Labeling: Mitigating Food Allergen Risks in Restaurants

Introduction 111
I. Restaurants, Food Allergies, and The Limitations of Existing Law 115
  A. Food Allergies and Restaurants 115
  B. The Gap in Federal Law 121
  C. Other Limitations of the Law 124
    1. The Food Code 124
    2. State and Local Allergen Awareness Laws 129
    3. Tort Law 131
    4. Disability Law 134
II. Menu Labeling 137
  A. Local and State 137
    1. New York City 137
      a. 2006 Menu Labeling Regulation 137
      b. 2008 Menu Labeling Regulation 139
    2. Others 141
  B. Federal 143
    1. Legislation 143
    2. Regulations 146
    3. Compliance Date 148

* Assistant Professor, University of South Carolina School of Law. A.B., Harvard University. J.D., Yale Law School. Thanks to Rita Barnett-Rose, Derek W. Black, Thomas P. Crocker, Kurt Eggert, Jacqueline R. Fox, and Jaime R. Harrison for their comments and suggestions. I benefited greatly from presenting an early version of this article at the Chapman University Dale E. Fowler School of Law Junior Faculty Works-in-Progress Conference. Thanks to Candle M. Wester, Clermon E. Acklin III, Wesley Martin, and Mary C. Stamato for their research assistance, and to Vanessa McQuinn and Shannon Palmore for their administrative support.

III. Creating a Framework for the Regulation of Food Allergen Labeling and Management in Restaurants 150
A. A Proposed Framework for Food Allergen Regulation. 151
1. Using Menu Labeling as a Model 151
2. Labeling Food Allergens... 154
3. Preventing Cross Contact.. 156
4. Training Employees 158
5. Recognizing the Role of Consumers........................ 158
B. Discussion 159
1. Potential Benefits 159
2. Response to Anticipated Critiques 162
a. Coverage 162
b. Market.. 164
c. Information Access 165
d. Cost and Feasibility 167
e. Potential Liability 169
IV. Implementing Food Allergen Labeling and Management Requirements.. 170
A. Federal Action.. 170
B. State and Local Action... 176
1. State and Local Powers 176
2. Potential Benefits and Limitations of State and Local Action.. 177
3. Anticipated Challenges to State and Local Action .. 179
a. Preemption... 179
b. Dormant Commerce Clause 181
Conclusion 182

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

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

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).

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

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,*

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]

---

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.

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).

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]

---

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

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,

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).

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]

---

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

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

---

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).

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

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).

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

---

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,

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).

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

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.

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

---

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).

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

---

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).

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

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).

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

---

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).

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]

---

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).

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

---

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).

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

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.

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

[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).

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

---

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.

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

---

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.

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

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).

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

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.

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).

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

---

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).

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

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

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

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].

> 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

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.

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

---

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).

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

[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).

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.

---

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)).

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

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.

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

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).

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

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.

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

---

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").

"[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

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

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

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]

---

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

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

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.

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

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.

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]

---

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").

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

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)).

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

---

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).

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

[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.).

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

---

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.*

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.

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

---

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).

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]

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);

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

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.").

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.

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.

[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.

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,

---

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.").

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.

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.

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]

---

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.

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]

---

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*

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

---

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.*

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

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

---

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 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

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.

"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,

---

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).

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

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).

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.

---

[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).

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

---

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).

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.

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.

---

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").

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

---

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).

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

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.

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.

"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.

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.

JAMA Network Open

Original Investigation | Allergy

Prevalence and Severity of Food Allergies Among US Adults

Ruchi S. Gupta, MD, MPH; Christopher M. Warren, BA; Bridget M. Smith, PhD; Jialing Jiang, BA; Jesse A. Blumenstock, BS; Matthew M. Davis, MD, MAPP; Robert P. Schleimer, PhD; Kari C. Nadeau, MD, PhD

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.

JAMA Network Open. 2019;2(1):e185630. doi:10.1001/jamanetworkopen.2018.5630

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.

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

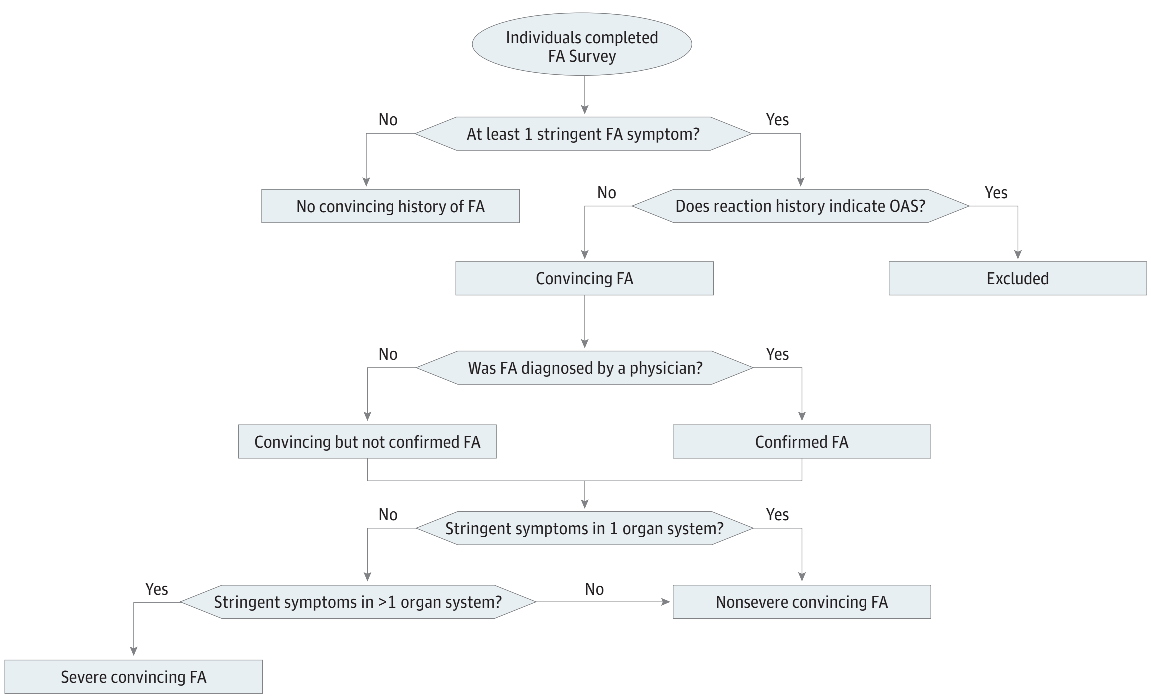
The surveys extended our national child food allergy survey, administered in 2009 to 2010, which was developed by pediatricians, allergists, health services researchers, and survey methodologists. Expert panel review and key informant cognitive interviews (N = 40) were conducted on the original survey 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 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.

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 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.

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)

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.

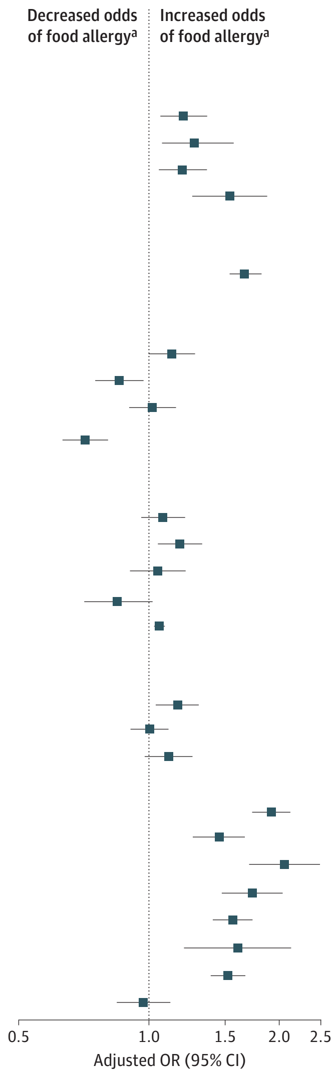
CI, 2.0-5.3), sesame (OR, 3.0; 95% CI, 1.4-6.2), or soy allergy (OR, 1.5; 95% CI, 1.0-2.1) or a comorbid insect sting allergy (OR, 2.0; 95% CI, 1.4-2.9). Adults 50 years or older also had significantly reduced odds of a current epinephrine prescription. Current epinephrine prescription rates varied considerably 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.

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, 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.

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

Accepted for Publication: October 19, 2018.

Published: January 4, 2019. doi:10.1001/jamanetworkopen.2018.5630

Corresponding Author: Ruchi S. Gupta, MD, MPH, Institute for Public Health and Medicine, Northwestern University Feinberg School of Medicine, 750 N Lake Shore Dr, Ste 680, Chicago, IL 60611 (r-gupta@northwestern.edu).

Author Affiliations: Institute for Public Health and Medicine, Northwestern University Feinberg School of Medicine, Chicago, Illinois (Gupta, Smith, Jiang, Blumenstock, Davis); Department of Pediatrics, Northwestern University Feinberg School of Medicine, Chicago, Illinois (Gupta, Davis); Mary Ann & J. Milburn Smith Child Health Research, Outreach, and Advocacy Center, Ann & Robert H. Lurie Children's Hospital, Chicago, Illinois (Gupta, Davis); Department of Medicine, Northwestern University Feinberg School of Medicine, Chicago, Illinois (Gupta, Davis, Schleimer); Department of Preventive Medicine, University of Southern California Keck School of Medicine, Los Angeles (Warren); Center for Innovation for Complex Chronic Healthcare, Edward J. Hines Jr Veterans Affairs Hospital, Hines, Illinois (Smith); Department of Medical Social Sciences, Northwestern University Feinberg School of Medicine, Chicago, Illinois (Davis); Department of Preventive Medicine, Northwestern University Feinberg School of Medicine, Chicago, Illinois (Davis); Sean N. Parker Center for Allergy and Asthma Research, Stanford University School of Medicine, Stanford, California (Nadeau).

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.

Concept and design: Gupta, Warren, Smith, Jiang, Blumenstock, Nadeau.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Gupta, Warren, Smith, Jiang, Blumenstock, Nadeau.

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.

Administrative, technical, or material support: Gupta, Jiang, Blumenstock, Davis.

Supervision: Gupta, Smith, Nadeau.

Conflict of Interest Disclosures: Dr Gupta reports receiving grants from the National Institutes of Health (NIH), Stanford University, and Aimmune Therapeutics during the conduct of the study; serving as a medical consultant/advisor for DBV, Aimmune, Before Brands, Pfizer, Mylan, and Kaleo, Inc, over the past 3 years; and receiving grants from the NIH, Allergy and Asthma Network, Food Allergy Research & Education, Rho Inc, Northwestern University Clinical and Translational Sciences Institute, Thermo Fisher, United Health Group, Mylan, and the National Confectioners Association outside the submitted work. Mr Warren reports grants from the NIH during the conduct of the study. Dr Smith reports grants from Aimmune and the NIH during the conduct of the study and grants from Mylan outside the submitted work. Ms Jiang reports grants from the NIH, Aimmune Therapeutics, and Stanford University during the conduct of the study. Mr Blumenstock reports grants from Aimmune during the conduct of the study. Dr Schleimer reports grants from the NIH during the conduct of the study; personal fees from Allakos, Sanofi, Genentech, ActoBio Therapeutics, and Lyra Therapeutics outside the submitted work; is a shareholder in Allakos, BioMarck, Aurasense, Exicure Inc, and Aqualung Therapeutics Corp outside the submitted work; and is inventor on patents pertaining to desloratadine, Siglec-8, and Siglec-8 ligand that have been licensed. Dr Nadeau reported grants from the National Institute of Allergy and Infectious Diseases, Food Allergy Research and

Education (FARE), and EAT; personal fees from Regeneron; and other support from Novartis, Sanofi, Astellas, Nestle, BeforeBrands, Alladapt, ForTra, Genentech, AImmune Therapeutics, and DBV Technologies outside the submitted work. No other disclosures were reported.

Funding/Support: This study was funded by grant R21AI135702 from the National Institute of Allergy and Infectious Diseases (Dr Gupta, principal investigator), the Sean N. Parker Center for Allergy and Asthma Research at Stanford University, Aimmune Therapeutics, and Denise and Dave Bunning.

Role of the Funder/Sponsor: The funding sources had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and the decision to submit the manuscript for publication.

Additional Contributions: The members of our expert panel provided input on the study design. Bruce S. Bochner, MD, Department of Medicine, Northwestern University Feinberg School of Medicine, Chicago, Illinois, Ozge Aktas, MD, Institute for Public Health and Medicine, Northwestern University Feinberg School of Medicine, Chicago, Illinois, and Lauren Kao, MA, Institute for Public Health and Medicine, Northwestern University Feinberg School of Medicine, Chicago, Illinois, reviewed the manuscript. They were not compensated for their work. Nadarajasundaram Ganesh, PhD, Statistics and Methodology Department, NORC at the University of Chicago, Chicago, Illinois, contributed to the survey weighting approach used in this study and received compensation for his help.

REFERENCES

1. Gupta R, Holdford D, Bilaver L, Dyer A, Holl JL, Meltzer D. The economic impact of childhood food allergy in the United States. *JAMA Pediatr*. 2013;167(11):1026-1031. doi:10.1001/jamapediatrics.2013.2376

2. Bock SA, Muñoz-Furlong A, Sampson HA. Further fatalities caused by anaphylactic reactions to food, 2001-2006. *J Allergy Clin Immunol*. 2007;119(4):1016-1018. doi:10.1016/j.jaci.2006.12.622

3. Warren CM, Otto AK, Walkner MM, Gupta RS. Quality of life among food allergic patients and their caregivers. *Curr Allergy Asthma Rep*. 2016;16(5):38. doi:10.1007/s11882-016-0614-9

4. Walkner M, Warren C, Gupta RS. Quality of life in food allergy patients and their families. *Pediatr Clin North Am*. 2015;62(6):1453-1461. doi:10.1016/j.pcl.2015.07.003

5. Gupta RS, Springston EE, Warrier MR, et al. The prevalence, severity, and distribution of childhood food allergy in the United States. *Pediatrics*. 2011;128(1):e9-e17. doi:10.1542/peds.2011-0204

6. Jackson KD, Howie LD, Akinbami OJ. Trends in allergic conditions among children: United States, 1997-2011. *NCHS Data Brief*. 2013;(121):1-8.

7. Sicherer SH, Muñoz-Furlong A, Godbold JH, Sampson HA. US prevalence of self-reported peanut, tree nut, and sesame allergy: 11-year follow-up. *J Allergy Clin Immunol*. 2010;125(6):1322-1326. doi:10.1016/j.jaci.2010.03.029

8. Sicherer SH, Muñoz-Furlong A, Sampson HA. Prevalence of seafood allergy in the United States determined by a random telephone survey. *J Allergy Clin Immunol*. 2004;114(1):159-165. doi:10.1016/j.jaci.2004.04.018

9. McGowan EC, Keet CA. Prevalence of self-reported food allergy in the National Health and Nutrition Examination Survey (NHANES) 2007-2010. *J Allergy Clin Immunol*. 2013;132(5):1216-1219.e5. doi:10.1016/j.jaci.2013.07.018

10. Verrill L, Bruns R, Luccioli S. Prevalence of self-reported food allergy in U.S. adults: 2001, 2006, and 2010. *Allergy Asthma Proc*. 2015;36(6):458-467. doi:10.2500/aap.2015.36.3895

11. Savage J, Sicherer S, Wood R. The natural history of food allergy. *J Allergy Clin Immunol Pract*. 2016;4(2):196-203. doi:10.1016/j.jaip.2015.11.024

12. Jones SM, Burks AW. Food Allergy. *N Engl J Med*. 2017;377(23):2294-2295. doi:10.1056/NEJMc1713844

13. Kamdar TA, Peterson S, Lau CH, Saltoun CA, Gupta RS, Bryce PJ. Prevalence and characteristics of adult-onset food allergy. *J Allergy Clin Immunol Pract*. 2015;3(1):114-5.e1. doi:10.1016/j.jaip.2014.07.007

14. Hochstadter E, Clarke A, De Schryver S, et al. Increasing visits for anaphylaxis and the benefits of early epinephrine administration: a 4-year study at a pediatric emergency department in Montreal, Canada. *J Allergy Clin Immunol*. 2016;137(6):1888-1890.e4. doi:10.1016/j.jaci.2016.02.016

15. Lin RY, Anderson AS, Shah SN, Nurruzzaman F. Increasing anaphylaxis hospitalizations in the first 2 decades of life: New York State, 1990 -2006. *Ann Allergy Asthma Immunol*. 2008;101(4):387-393. doi:10.1016/S1081-1206(10)60315-8

16. Branum AM, Lukacs SL. Food allergy among children in the United States. *Pediatrics*. 2009;124(6):1549-1555. doi:10.1542/peds.2009-1210

17. Gupta RS, Kim JS, Springston EE, Pongracic JA, Wang X, Holl J. Development of the Chicago Food Allergy Research Surveys: assessing knowledge, attitudes, and beliefs of parents, physicians, and the general public. *BMC Health Serv Res*. 2009;9:142. doi:10.1186/1472-6963-9-142

18. Mercer AW, Kreuter F, Keeter S, Stuart EA. Theory and practice in nonprobability surveys: parallels between causal inference and survey inference. *Public Opin Q*. 2017;81(S1):250-271. doi:10.1093/poq/nfw060

19. Elliott MN, Haviland AM. Use of a web-based convenience sample to supplement a probability sample. *Surv Methodol*. 2007;33(2):211-215.

20. Jiang J, Lahiri P. Mixed model prediction and small area estimation. *Test*. 2006;15(1):1. doi:10.1007/BF02595419

21. Rao J, Molina I. *Small Area Estimation*. 2nd ed. Hoboken, NJ: Wiley; 2015. doi:10.1002/9781118735855

22. Stata Statistical Software. Release 14 [computer program]. College Station, TX: StataCorp LP; 2015.

23. Rao JNK, Scott AJ. The analysis of categorical data from complex sample surveys: χ^2 tests for goodness of fit and independence in two-way tables. *J Am Stat Assoc*. 1981;76(374):221-230. doi:10.1080/01621459.1981.10477633

24. Jones SM, Burks AW. Food allergy. *N Engl J Med*. 2017;377(12):1168-1176. doi:10.1056/NEJMcp1611971

25. Gupta RS, Lau CH, Sita EE, Smith B, Greenhawt MJ. Factors associated with reported food allergy tolerance among US children. *Ann Allergy Asthma Immunol*. 2013;111(3):194-198.e4. doi:10.1016/j.anai.2013.06.026

26. Lopata AL, Kleine-Tebbe J, Kamath SD. Allergens and molecular diagnostics of shellfish allergy: part 22 of the Series Molecular Allergology. *Allergo J Int*. 2016;25(7):210-218. doi:10.1007/s40629-016-0124-2

27. Wood RA. The natural history of food allergy. *Pediatrics*. 2003;111(6 pt 3):1631-1637.

28. Dunlop JH, Keet CA. Epidemiology of food allergy. *Immunol Allergy Clin North Am*. 2018;38(1):13-25. doi:10.1016/j.iac.2017.09.002

29. Dutmer CM, Kim H, Searing DA, Zoratti EM, Liu AH. Asthma in inner city children: recent insights: United States. *Curr Opin Allergy Clin Immunol*. 2018;18(2):139-147.

30. Shaw TE, Currie GP, Koudelka CW, Simpson EL. Eczema prevalence in the United States: data from the 2003 National Survey of Children's Health. *J Invest Dermatol*. 2011;131(1):67-73. doi:10.1038/jid.2010.251

31. Greenhawt M, Weiss C, Conte ML, Doucet M, Engler A, Camargo CA Jr. Racial and ethnic disparity in food allergy in the United States: a systematic review. *J Allergy Clin Immunol Pract*. 2013;1(4):378-386. doi:10.1016/j.jaip.2013.04.009

32. Joseph CL, Zoratti EM, Ownby DR, et al. Exploring racial differences in IgE-mediated food allergy in the WHEALS birth cohort. *Ann Allergy Asthma Immunol*. 2016;116(3):219-224.e1. doi:10.1016/j.anai.2015.12.019

33. Boyce JA, Assa'ad A, Burks AW, et al; NIAID-Sponsored Expert Panel. Guidelines for the diagnosis and management of food allergy in the United States: summary of the NIAID-sponsored expert panel report. *J Allergy Clin Immunol*. 2010;126(6):1105-1118. doi:10.1016/j.jaci.2010.10.008

34. Sicherer SH, Simons FER; Section on Allergy and Immunology. Epinephrine for first-aid management of anaphylaxis. *Pediatrics*. 2017;139(3):e20164006. doi:10.1542/peds.2016-4006

35. Sicherer SH, Sampson HA. Food allergy: epidemiology, pathogenesis, diagnosis, and treatment. *J Allergy Clin Immunol*. 2014;133(2):291-307. doi:10.1016/j.jaci.2013.11.020

36. Sicherer SH, Muñoz-Furlong A, Sampson HA. Prevalence of peanut and tree nut allergy in the United States determined by means of a random digit dial telephone survey: a 5-year follow-up study. *J Allergy Clin Immunol*. 2003;112(6):1203-1207. doi:10.1016/S0091-6749(03)02026-8

37. Eller E, Hansen TK, Bindslev-Jensen C. Clinical thresholds to egg, hazelnut, milk and peanut: results from a single-center study using standardized challenges. *Ann Allergy Asthma Immunol*. 2012;108(5):332-336. doi:10.1016/j.anai.2012.03.010

38. Worm M, Edenharter G, Ruëff F, et al. Symptom profile and risk factors of anaphylaxis in Central Europe. *Allergy*. 2012;67(5):691-698. doi:10.1111/j.1398-9995.2012.02795.x

39. Brown SG, Stone SF, Fatovich DM, et al. Anaphylaxis: clinical patterns, mediator release, and severity. *J Allergy Clin Immunol*. 2013;132(5):1141-1149.e5. doi:10.1016/j.jaci.2013.06.015

40. Summers CW, Pumphrey RS, Woods CN, McDowell G, Pemberton PW, Arkwright PD. Factors predicting anaphylaxis to peanuts and tree nuts in patients referred to a specialist center. *J Allergy Clin Immunol*. 2008;121(3):632-638.e2. doi:10.1016/j.jaci.2007.12.003

41. Smith PK, Hourihane JO, Lieberman P. Risk multipliers for severe food anaphylaxis. *World Allergy Organ J*. 2015;8(1):30. doi:10.1186/s40413-015-0081-0

42. Togias A, Cooper SF, Acebal ML, et al. Addendum guidelines for the prevention of peanut allergy in the United States: report of the National Institute of Allergy and Infectious Diseases–Sponsored Expert Panel. *Pediatr Dermatol*. 2017;34(1):e1-e21. doi:10.1111/pde.13093

43. National Academies of Sciences E, and Medicine. In: Oria MP, Stallings VA, eds. *Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management, and Public Policy*. Washington, DC: The National Academies Press; 2016.

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)

The Prevalence, Severity, and Distribution of Childhood Food Allergy in the United States

AUTHORS: Ruchi S. Gupta, MD, MPH,[a,b,c] Elizabeth E. Springston, BA,[a,b] Manoj R. Warrier, MD,[d,e] Bridget Smith, PhD,[f,g] Rajesh Kumar, MD,[b,c] Jacqueline Pongracic, MD,[c,h] and Jane L. Holl, MD, MPH[a,c]

[a]Institute for Healthcare Studies and [c]Department of Pediatrics, Northwestern University Feinberg School of Medicine, Chicago, Illinois; [b]Smith Child Health Research Program and [h]Division of Allergy and Immunology, Children's Memorial Hospital, Chicago, Illinois; [d]Division of Allergy and Immunology, St Louis University School of Medicine, St Louis, Missouri; [e]Allergy, Asthma and Sinus Care Center, St Louis, Missouri; [f]Program in Health Services Research, Loyola Stritch School of Medicine, Maywood, Illinois; and [g]Center for Management of Complex Chronic Care, Edward Hines Jr VA Hospital, Hines, Illinois

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.

www.pediatrics.org/cgi/doi/10.1542/peds.2011-0204

doi:10.1542/peds.2011-0204

Accepted for publication Apr 15, 2011

Address correspondence to Ruchi S. Gupta, MD, MPH, Children's Memorial Hospital, 2300 Children's Plaza, Box 157, Chicago, IL 60640. E-mail: rugupta@childrensmemorial.org

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: *The authors have indicated they have no financial relationships relevant to this article to disclose.*

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

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

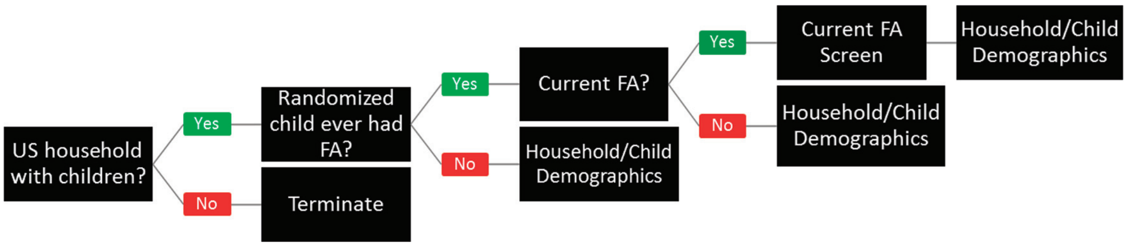


FIGURE 1
Survey scheme based on participant response. FA indicates food allergy.

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),

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-

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 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 certain 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 ≥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.

ACKNOWLEDGMENTS

We thank the Food Allergy Initiative and Dave and Denise Bunning for their support of this research. In addition, special thanks to Xiaobin Wang, MD, MPH, ScD, of the Smith Child Health Research Program at Children's Memorial Hospital for valuable guidance in data analysis and manuscript preparation.

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.

REFERENCES

1. Avery NJ, King RM, Knight S, Hourihane JO. Assessment of quality of life in children with peanut allergy. *Pediatr Allergy Immunol*. 2003;14(5):378–382
2. Primeau MN, Kagan R, Joseph L, et al. The psychological burden of peanut allergy as perceived by adults with peanut allergy and the parents of peanut-allergic children. *Clin Exp Allergy*. 2000;30(8):1135–1143
3. Branum AM, Lukacs SL. Food allergy among children in the United States. *Pediatrics*. 2009;124(6):1549–1555
4. Springston EE, Smith B, Shulruff J, et al. Variations in quality of life among caregivers of food-allergic children. *Ann Allergy Asthma Immunol*. 2010;105(4):287–294
5. Gupta RS, Kim JS, Barnathan JA, Amsden LB, Tummala LS, Holl JL. Food allergy knowledge, attitudes and beliefs: focus groups of parents, physicians and the general public. *BMC Pediatr*. 2008;8:36
6. Gupta RS, Springston EE, Smith B, et al. Food allergy knowledge, attitudes, and beliefs of parents with food-allergic children in the United States. *Pediatr Allergy Immunol*. 2010;21(6):927–934
7. Lin RY, Anderson AS, Shah SN, Nurruzzaman F. Increasing anaphylaxis hospitalizations in the first 2 decades of life: New York State, 1990–2006. *Ann Allergy Asthma Immunol*. 2008;101(4):387–393
8. Sicherer SH. Epidemiology of food allergy. *J Allergy Clin Immunol*. 2011;127(3):594–602
9. Bock SA. Prospective appraisal of complaints of adverse reactions to foods in children during the first 3 years of life. *Pediatrics*. 1987;79(5):683–688
10. Liu AH, Jaramillo R, Sicherer SH, et al. National prevalence and risk factors for food allergy and relationship to asthma: results from the National Health and Nutrition Examination Survey 2005–2006. *J Allergy Clin Immunol*. 2010;126(4):798–806 e13
11. Boyce JA, Assa'ad A, Burks AW, et al, and the NIAID-Sponsored Expert Panel. Guidelines for the Diagnosis and Management of Food Allergy in the United States: summary of the NIAID-Sponsored Expert Panel Report. *J Allergy Clin Immunol*. 2010;126(6):1105–1118
12. Chafen JJ, Newberry SJ, Riedl MA, et al. Diagnosing and managing common food allergies: a systematic review. *JAMA*. 2010;303(18):1848–1856
13. Sicherer SH, Sampson HA. Food allergy. *J Allergy Clin Immunol*. 2010;125(2 suppl 2):S116–S125
14. Gupta RS, Kim JS, Springston EE, Pongracic JA, Wang X, Holl J. Development of the Chicago Food Allergy Research Surveys: as-

sessing knowledge, attitudes, and beliefs of parents, physicians, and the general public. *BMC Health Serv Res*. 2009;9:142

15. Dennis JM. *KnowledgePanel: Processes & Procedures Contributing to Sample Representativeness & Tests for Self-Selection Bias*. Menlo Park, CA: Knowledge Networks, Inc; 2010:1–9. Available at: www.knowledgenetworks.com/ganp/docs/KnowledgePanelR-Statistical-Methods-Note.pdf. Accessed June 7, 2011
16. Dennis JM, Chatt C, Li R, Motta-Stanko A, Pulliam P. *Data Collection Mode Effects Controlling for Sample Origins in a Panel Survey: Telephone Versus Internet*. Menlo Park, CA: Knowledge Networks, Inc; 2005: 1–26. Available at: www.knowledgenetworks.com/ganp/docs/Research-0105.pdf. Accessed June 7, 2011
17. Heeringa SG, West BT, Berglud PA. *Applied Survey Data Analysis*. Boca Raton, FL: Taylor and Francis Group; 2010
18. Rona RJ, Keil T, Summers C, et al. The prevalence of food allergy: a meta-analysis. *J Allergy Clin Immunol*. 2007; 120(3):638–646
19. Hourihane JO, Aiken R, Briggs R, et al. The impact of government advice to pregnant mothers regarding peanut avoidance on the prevalence of peanut allergy in United Kingdom children at school entry. *J Allergy Clin Immunol*. 2007;119(5):1197–1202
20. Ben-Shoshan M, Harrington DW, Soller L, et al. A population-based study on peanut, tree nut, fish, shellfish, and sesame allergy prevalence in Canada. *J Allergy Clin Immunol*. 2010;125(6):1327–1335
21. Shah E, Pongracic J. Food-induced anaphylaxis: who, what, why, and where? *Pediatr Ann*. 2008;37(8):536–541

JAMA Network Open

Original Investigation | Allergy

Prevalence and Severity of Food Allergies Among US Adults

Ruchi S. Gupta, MD, MPH; Christopher M. Warren, BA; Bridget M. Smith, PhD; Jialing Jiang, BA; Jesse A. Blumenstock, BS; Matthew M. Davis, MD, MAPP; Robert P. Schleimer, PhD; Kari C. Nadeau, MD, PhD

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.

JAMA Network Open. 2019;2(1):e185630. doi:10.1001/jamanetworkopen.2018.5630

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.

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

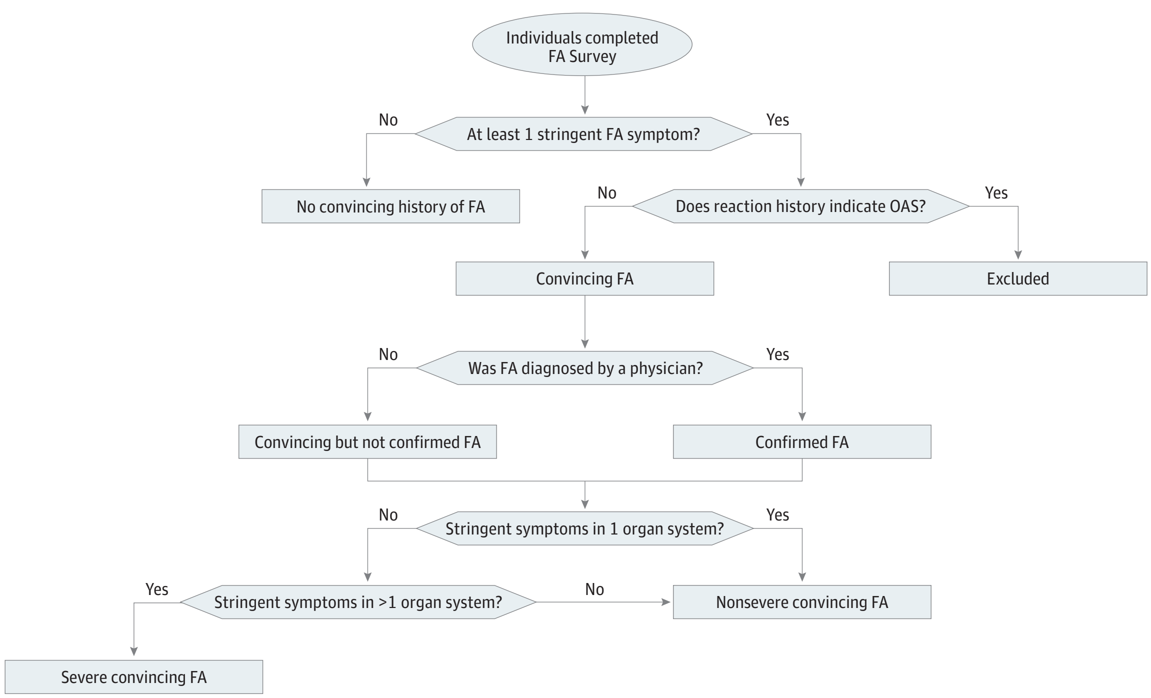
The surveys extended our national child food allergy survey, administered in 2009 to 2010, which was developed by pediatricians, allergists, health services researchers, and survey methodologists. Expert panel review and key informant cognitive interviews (N = 40) were conducted on the original survey 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 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.

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 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.

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)

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.

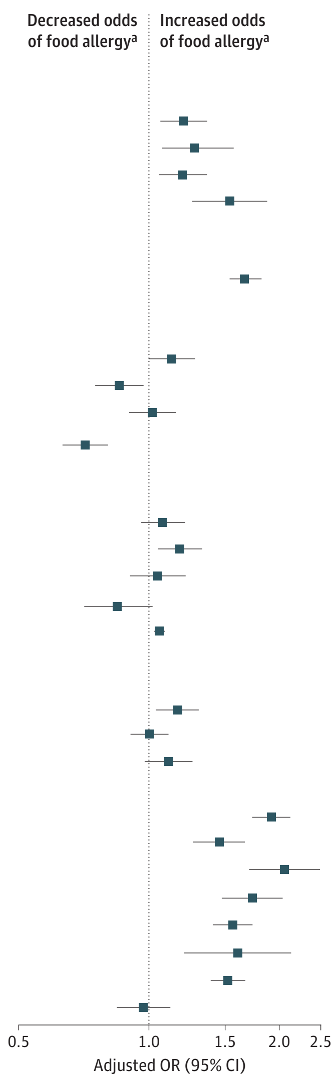
CI, 2.0-5.3), sesame (OR, 3.0; 95% CI, 1.4-6.2), or soy allergy (OR, 1.5; 95% CI, 1.0-2.1) or a comorbid insect sting allergy (OR, 2.0; 95% CI, 1.4-2.9). Adults 50 years or older also had significantly reduced odds of a current epinephrine prescription. Current epinephrine prescription rates varied considerably 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.

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, 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.

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

Accepted for Publication: October 19, 2018.

Published: January 4, 2019. doi:10.1001/jamanetworkopen.2018.5630

Corresponding Author: Ruchi S. Gupta, MD, MPH, Institute for Public Health and Medicine, Northwestern University Feinberg School of Medicine, 750 N Lake Shore Dr, Ste 680, Chicago, IL 60611 (r-gupta@northwestern.edu).

Author Affiliations: Institute for Public Health and Medicine, Northwestern University Feinberg School of Medicine, Chicago, Illinois (Gupta, Smith, Jiang, Blumenstock, Davis); Department of Pediatrics, Northwestern University Feinberg School of Medicine, Chicago, Illinois (Gupta, Davis); Mary Ann & J. Milburn Smith Child Health Research, Outreach, and Advocacy Center, Ann & Robert H. Lurie Children's Hospital, Chicago, Illinois (Gupta, Davis); Department of Medicine, Northwestern University Feinberg School of Medicine, Chicago, Illinois (Gupta, Davis, Schleimer); Department of Preventive Medicine, University of Southern California Keck School of Medicine, Los Angeles (Warren); Center for Innovation for Complex Chronic Healthcare, Edward J. Hines Jr Veterans Affairs Hospital, Hines, Illinois (Smith); Department of Medical Social Sciences, Northwestern University Feinberg School of Medicine, Chicago, Illinois (Davis); Department of Preventive Medicine, Northwestern University Feinberg School of Medicine, Chicago, Illinois (Davis); Sean N. Parker Center for Allergy and Asthma Research, Stanford University School of Medicine, Stanford, California (Nadeau).

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.

Concept and design: Gupta, Warren, Smith, Jiang, Blumenstock, Nadeau.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Gupta, Warren, Smith, Jiang, Blumenstock, Nadeau.

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.

Administrative, technical, or material support: Gupta, Jiang, Blumenstock, Davis.

Supervision: Gupta, Smith, Nadeau.

Conflict of Interest Disclosures: Dr Gupta reports receiving grants from the National Institutes of Health (NIH), Stanford University, and Aimmune Therapeutics during the conduct of the study; serving as a medical consultant/advisor for DBV, Aimmune, Before Brands, Pfizer, Mylan, and Kaleo, Inc, over the past 3 years; and receiving grants from the NIH, Allergy and Asthma Network, Food Allergy Research & Education, Rho Inc, Northwestern University Clinical and Translational Sciences Institute, Thermo Fisher, United Health Group, Mylan, and the National Confectioners Association outside the submitted work. Mr Warren reports grants from the NIH during the conduct of the study. Dr Smith reports grants from Aimmune and the NIH during the conduct of the study and grants from Mylan outside the submitted work. Ms Jiang reports grants from the NIH, Aimmune Therapeutics, and Stanford University during the conduct of the study. Mr Blumenstock reports grants from Aimmune during the conduct of the study. Dr Schleimer reports grants from the NIH during the conduct of the study; personal fees from Allakos, Sanofi, Genentech, ActoBio Therapeutics, and Lyra Therapeutics outside the submitted work; is a shareholder in Allakos, BioMarck, Aurasense, Exicure Inc, and Aqualung Therapeutics Corp outside the submitted work; and is inventor on patents pertaining to desloratadine, Siglec-8, and Siglec-8 ligand that have been licensed. Dr Nadeau reported grants from the National Institute of Allergy and Infectious Diseases, Food Allergy Research and

Education (FARE), and EAT; personal fees from Regeneron; and other support from Novartis, Sanofi, Astellas, Nestle, BeforeBrands, Alladapt, ForTra, Genentech, AImmune Therapeutics, and DBV Technologies outside the submitted work. No other disclosures were reported.

Funding/Support: This study was funded by grant R21AI135702 from the National Institute of Allergy and Infectious Diseases (Dr Gupta, principal investigator), the Sean N. Parker Center for Allergy and Asthma Research at Stanford University, Aimmune Therapeutics, and Denise and Dave Bunning.

Role of the Funder/Sponsor: The funding sources had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and the decision to submit the manuscript for publication.

Additional Contributions: The members of our expert panel provided input on the study design. Bruce S. Bochner, MD, Department of Medicine, Northwestern University Feinberg School of Medicine, Chicago, Illinois, Ozge Aktas, MD, Institute for Public Health and Medicine, Northwestern University Feinberg School of Medicine, Chicago, Illinois, and Lauren Kao, MA, Institute for Public Health and Medicine, Northwestern University Feinberg School of Medicine, Chicago, Illinois, reviewed the manuscript. They were not compensated for their work. Nadarajasundaram Ganesh, PhD, Statistics and Methodology Department, NORC at the University of Chicago, Chicago, Illinois, contributed to the survey weighting approach used in this study and received compensation for his help.

REFERENCES

1. Gupta R, Holdford D, Bilaver L, Dyer A, Holl JL, Meltzer D. The economic impact of childhood food allergy in the United States. *JAMA Pediatr*. 2013;167(11):1026-1031. doi:10.1001/jamapediatrics.2013.2376

2. Bock SA, Muñoz-Furlong A, Sampson HA. Further fatalities caused by anaphylactic reactions to food, 2001-2006. *J Allergy Clin Immunol*. 2007;119(4):1016-1018. doi:10.1016/j.jaci.2006.12.622

3. Warren CM, Otto AK, Walkner MM, Gupta RS. Quality of life among food allergic patients and their caregivers. *Curr Allergy Asthma Rep*. 2016;16(5):38. doi:10.1007/s11882-016-0614-9

4. Walkner M, Warren C, Gupta RS. Quality of life in food allergy patients and their families. *Pediatr Clin North Am*. 2015;62(6):1453-1461. doi:10.1016/j.pcl.2015.07.003

5. Gupta RS, Springston EE, Warrier MR, et al. The prevalence, severity, and distribution of childhood food allergy in the United States. *Pediatrics*. 2011;128(1):e9-e17. doi:10.1542/peds.2011-0204

6. Jackson KD, Howie LD, Akinbami OJ. Trends in allergic conditions among children: United States, 1997-2011. *NCHS Data Brief*. 2013;(121):1-8.

7. Sicherer SH, Muñoz-Furlong A, Godbold JH, Sampson HA. US prevalence of self-reported peanut, tree nut, and sesame allergy: 11-year follow-up. *J Allergy Clin Immunol*. 2010;125(6):1322-1326. doi:10.1016/j.jaci.2010.03.029

8. Sicherer SH, Muñoz-Furlong A, Sampson HA. Prevalence of seafood allergy in the United States determined by a random telephone survey. *J Allergy Clin Immunol*. 2004;114(1):159-165. doi:10.1016/j.jaci.2004.04.018

9. McGowan EC, Keet CA. Prevalence of self-reported food allergy in the National Health and Nutrition Examination Survey (NHANES) 2007-2010. *J Allergy Clin Immunol*. 2013;132(5):1216-1219.e5. doi:10.1016/j.jaci.2013.07.018

10. Verrill L, Bruns R, Luccioli S. Prevalence of self-reported food allergy in U.S. adults: 2001, 2006, and 2010. *Allergy Asthma Proc*. 2015;36(6):458-467. doi:10.2500/aap.2015.36.3895

11. Savage J, Sicherer S, Wood R. The natural history of food allergy. *J Allergy Clin Immunol Pract*. 2016;4(2):196-203. doi:10.1016/j.jaip.2015.11.024

12. Jones SM, Burks AW. Food Allergy. *N Engl J Med*. 2017;377(23):2294-2295. doi:10.1056/NEJMc1713844

13. Kamdar TA, Peterson S, Lau CH, Saltoun CA, Gupta RS, Bryce PJ. Prevalence and characteristics of adult-onset food allergy. *J Allergy Clin Immunol Pract*. 2015;3(1):114-5.e1. doi:10.1016/j.jaip.2014.07.007

14. Hochstadter E, Clarke A, De Schryver S, et al. Increasing visits for anaphylaxis and the benefits of early epinephrine administration: a 4-year study at a pediatric emergency department in Montreal, Canada. *J Allergy Clin Immunol*. 2016;137(6):1888-1890.e4. doi:10.1016/j.jaci.2016.02.016

15. Lin RY, Anderson AS, Shah SN, Nurruzzaman F. Increasing anaphylaxis hospitalizations in the first 2 decades of life: New York State, 1990 -2006. *Ann Allergy Asthma Immunol*. 2008;101(4):387-393. doi:10.1016/S1081-1206(10)60315-8

16. Branum AM, Lukacs SL. Food allergy among children in the United States. *Pediatrics*. 2009;124(6):1549-1555. doi:10.1542/peds.2009-1210

17. Gupta RS, Kim JS, Springston EE, Pongracic JA, Wang X, Holl J. Development of the Chicago Food Allergy Research Surveys: assessing knowledge, attitudes, and beliefs of parents, physicians, and the general public. *BMC Health Serv Res*. 2009;9:142. doi:10.1186/1472-6963-9-142

18. Mercer AW, Kreuter F, Keeter S, Stuart EA. Theory and practice in nonprobability surveys: parallels between causal inference and survey inference. *Public Opin Q*. 2017;81(S1):250-271. doi:10.1093/poq/nfw060

19. Elliott MN, Haviland AM. Use of a web-based convenience sample to supplement a probability sample. *Surv Methodol*. 2007;33(2):211-215.

20. Jiang J, Lahiri P. Mixed model prediction and small area estimation. *Test*. 2006;15(1):1. doi:10.1007/BF02595419

21. Rao J, Molina I. *Small Area Estimation*. 2nd ed. Hoboken, NJ: Wiley; 2015. doi:10.1002/9781118735855

22. Stata Statistical Software. Release 14 [computer program]. College Station, TX: StataCorp LP; 2015.

23. Rao JNK, Scott AJ. The analysis of categorical data from complex sample surveys: χ^2 tests for goodness of fit and independence in two-way tables. *J Am Stat Assoc*. 1981;76(374):221-230. doi:10.1080/01621459.1981.10477633

24. Jones SM, Burks AW. Food allergy. *N Engl J Med*. 2017;377(12):1168-1176. doi:10.1056/NEJMcp1611971

25. Gupta RS, Lau CH, Sita EE, Smith B, Greenhawt MJ. Factors associated with reported food allergy tolerance among US children. *Ann Allergy Asthma Immunol*. 2013;111(3):194-198.e4. doi:10.1016/j.anai.2013.06.026

26. Lopata AL, Kleine-Tebbe J, Kamath SD. Allergens and molecular diagnostics of shellfish allergy: part 22 of the Series Molecular Allergology. *Allergo J Int*. 2016;25(7):210-218. doi:10.1007/s40629-016-0124-2

27. Wood RA. The natural history of food allergy. *Pediatrics*. 2003;111(6 pt 3):1631-1637.

28. Dunlop JH, Keet CA. Epidemiology of food allergy. *Immunol Allergy Clin North Am*. 2018;38(1):13-25. doi:10.1016/j.iac.2017.09.002

29. Dutmer CM, Kim H, Searing DA, Zoratti EM, Liu AH. Asthma in inner city children: recent insights: United States. *Curr Opin Allergy Clin Immunol*. 2018;18(2):139-147.

30. Shaw TE, Currie GP, Koudelka CW, Simpson EL. Eczema prevalence in the United States: data from the 2003 National Survey of Children's Health. *J Invest Dermatol*. 2011;131(1):67-73. doi:10.1038/jid.2010.251

31. Greenhawt M, Weiss C, Conte ML, Doucet M, Engler A, Camargo CA Jr. Racial and ethnic disparity in food allergy in the United States: a systematic review. *J Allergy Clin Immunol Pract*. 2013;1(4):378-386. doi:10.1016/j.jaip.2013.04.009

32. Joseph CL, Zoratti EM, Ownby DR, et al. Exploring racial differences in IgE-mediated food allergy in the WHEALS birth cohort. *Ann Allergy Asthma Immunol*. 2016;116(3):219-224.e1. doi:10.1016/j.anai.2015.12.019

33. Boyce JA, Assa'ad A, Burks AW, et al; NIAID-Sponsored Expert Panel. Guidelines for the diagnosis and management of food allergy in the United States: summary of the NIAID-sponsored expert panel report. *J Allergy Clin Immunol*. 2010;126(6):1105-1118. doi:10.1016/j.jaci.2010.10.008

34. Sicherer SH, Simons FER; Section on Allergy and Immunology. Epinephrine for first-aid management of anaphylaxis. *Pediatrics*. 2017;139(3):e20164006. doi:10.1542/peds.2016-4006

35. Sicherer SH, Sampson HA. Food allergy: epidemiology, pathogenesis, diagnosis, and treatment. *J Allergy Clin Immunol*. 2014;133(2):291-307. doi:10.1016/j.jaci.2013.11.020

36. Sicherer SH, Muñoz-Furlong A, Sampson HA. Prevalence of peanut and tree nut allergy in the United States determined by means of a random digit dial telephone survey: a 5-year follow-up study. *J Allergy Clin Immunol*. 2003;112(6):1203-1207. doi:10.1016/S0091-6749(03)02026-8

37. Eller E, Hansen TK, Bindslev-Jensen C. Clinical thresholds to egg, hazelnut, milk and peanut: results from a single-center study using standardized challenges. *Ann Allergy Asthma Immunol*. 2012;108(5):332-336. doi:10.1016/j.anai.2012.03.010

38. Worm M, Edenharter G, Ruëff F, et al. Symptom profile and risk factors of anaphylaxis in Central Europe. *Allergy*. 2012;67(5):691-698. doi:10.1111/j.1398-9995.2012.02795.x

39. Brown SG, Stone SF, Fatovich DM, et al. Anaphylaxis: clinical patterns, mediator release, and severity. *J Allergy Clin Immunol*. 2013;132(5):1141-1149.e5. doi:10.1016/j.jaci.2013.06.015

40. Summers CW, Pumphrey RS, Woods CN, McDowell G, Pemberton PW, Arkwright PD. Factors predicting anaphylaxis to peanuts and tree nuts in patients referred to a specialist center. *J Allergy Clin Immunol*. 2008;121(3):632-638.e2. doi:10.1016/j.jaci.2007.12.003

41. Smith PK, Hourihane JO, Lieberman P. Risk multipliers for severe food anaphylaxis. *World Allergy Organ J*. 2015;8(1):30. doi:10.1186/s40413-015-0081-0

42. Togias A, Cooper SF, Acebal ML, et al. Addendum guidelines for the prevention of peanut allergy in the United States: report of the National Institute of Allergy and Infectious Diseases–Sponsored Expert Panel. *Pediatr Dermatol*. 2017;34(1):e1-e21. doi:10.1111/pde.13093

43. National Academies of Sciences E, and Medicine. In: Oria MP, Stallings VA, eds. *Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management, and Public Policy*. Washington, DC: The National Academies Press; 2016.

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)

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**

Photo: Getty

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.”

“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?

NEWS

Home / News / Health News / Tough New Labeling Law for S...

Tough New Labeling Law for Sesame Prompts Companies to Add It to Their Products

By HealthDay

Dec. 22, 2022

Save Comment

LinkedIn
Reddit

By Cara Murez Foster 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.

Recommended Videos

Powered by AnyClip

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

HHS Public Access
Author manuscript
J Food Prot. Author manuscript; available in PMC 2017 February 23.

Published in final edited form as:
J Food Prot. 2016 September ; 79(9): 1588–1598. doi:10.4315/0362-028X.JFP-16-085.

Food Allergy Knowledge and Attitudes of Restaurant Managers and Staff: An EHS-Net Study

Taylor J. Radke[1,*], **Laura G. Brown**[1], **E. Rickamer Hoover**[1], **Brenda V. Faw**[2], **David Reimann**[3], **Melissa R. Wong**[4], **David Nicholas**[5], **Jonathan Barkley**[6], and **Danny Ripley**[7]

[1]Centers for Disease Control and Prevention, National Center for Environmental Health, 4770 Buford Highway, Mailstop F58, Atlanta, Georgia 30341

[2]California Department of Public Health, Sacramento, California 95899

[3]Minnesota Department of Health, Mankato, Minnesota 56001

[4]New York City Department of Health and Mental Hygiene, New York, New York 11101

[5]New York State Department of Health, Albany, New York 12237

[6]Rhode Island Department of Health, Providence, Rhode Island 02908

[7]Metro Nashville/Davidson County Public Health Department, Nashville, Tennessee 37209, USA

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.

*Author for correspondence. Tel: 770-488-7652; Fax: 770-488-7310; tradke@cdc.gov.

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.

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.

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) 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 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, $n = 156$).

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.

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.

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.

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, 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 positive attitudes. Food allergy training is also recommended for new and existing managers and staff.

Acknowledgments

We thank the restaurant managers, workers, and servers who participated in this study and the EHS-Net staff who assisted with study design and data collection. This publication is based on data collected and provided by CDC EHS-Net, which is supported by a CDC grant award funded under CDC-RFA-EH05-013. The findings and conclusions in this report are those of the authors and do not necessarily represent the views of CDC or the Agency for Toxic Substances and Disease Registry.

REFERENCES

1. Ahuja R, Sicherer S. Food-allergy management from the perspective of restaurant and food establishment personnel. Ann. Allergy Asthma Immunol. 2007; 98:344–348. [PubMed: 17458430]
2. American Academy of Allergy, Asthma and Immunology. Food allergy. 2015 [Accessed 29 December 2015] Available at http://www.aaaai.org/conditions-and-treatments/conditions-dictionary/food-allergies.aspx.
3. Bailey S, Kindratt TB, Smith H, Reading D. Food allergy training event for restaurant staff; a pilot evaluation. Clin. Transl. Allergy. 2014; 4:26. [PubMed: 25225607]
4. Borchgrevink CP, Elsworth JD, Taylor SE, Christensen KE. Food intolerances, food allergies, and restaurants. J. Culin. Sci. Techol. 2009; 7:259–284.
5. Common L, Corrigan C, Smith H, Bailey S, Harris S, Holloway JA. How safe is your curry? Food allergy awareness of restaurant staff. J. Allergy Ther. 2013; 4:1–4.
6. Dupuis R, Meisel Z, Grande D, Strupp E, Kounaves S, Graves A, Frasso R, Cannuscio CC. Food allergy management among restaurant workers in a large US city. Food Control. 2016; 63:147–157.
7. Food Allergy and Anaphylaxis Network. Welcoming guests with food allergies. 2010 [Accessed 5 November 2015] Available at: https://www.foodallergy.org/document.doc?id=143.
8. Food Allergy Research and Education. About food allergies. 2015 [Accessed 9 April 2015] Available at: http://www.foodallergy.org/about-food-allergies.
9. Furlong TJ, DeSimone J, Sicherer SH. Peanut and tree nut allergic reactions in restaurants and other food establishments. J. Allergy Clin. Immunol. 2001; 108:867–870. [PubMed: 11692117]
10. National Institute of Allergy and Infectious Diseases. [Accessed 9 April 2015] What is an allergic reaction to food?. 2010. Available at: http://www.niaid.nih.gov/topics/foodAllergy/understanding/Pages/allergicRxn.aspx
11. Shafie A, Azman A. Assessment of knowledge, attitude, and practice of food allergies among food handlers in the state of Penang, Malaysia. Public Health. 2015; 129:1278–1284. [PubMed: 25931434]
12. Sogut A, Kavut A, Kartal Ì, Beyhun EN, Çayir A, Mutlu M, Özkan B. Food allergy knowledge and attitude of restaurant personnel in Turkey. Int. Forum Allergy Rhinol. 2015; 5:157–161. [PubMed: 25312743]
13. U.S. Food and Drug Administration. [Accessed 9 April 2015] Food allergies: what you need to know. 2010. Available at http://www.fda.gov/downloads/Food/ResourcesForYou/Consumers/UCM220117.pdf
14. Wanich N, Weiss C, Furlong TJ, Sicherer SH. Food allergic customer (FAC) experience in restaurants and food establishments. J. Allergy Clin. Immunol. 2008; 121:S182.
15. Weiss C, Munoz-Furlong A. Fatal food allergy reactions in restaurants and food-service establishments: strategies for prevention. Food Prot. Trends. 2008; 28:657–661.

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

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

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.

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.

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

Question	Manager (N = 277)		Food worker (N = 211)		Server (N = 156)	
	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.

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 ($F_{2,636} = 6.31$, $P = 0.002$).

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, $P = 0.002$, $N = 149$.

TABLE 6

Descriptive data on restaurant manager and staff food allergy attitudes[a]

Statement	Manager (*N* = 277)		Food worker (*N* = 211)		Server (*N* = 156)	
	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

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.

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] $\chi 2 = 27.86$, df = 4, $P < 0.001$, $N = 196$.

[d] $\chi 2 = 24.43$, df = 4, $P < 0.001$, $N = 149$.

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

[a]Department of Pediatrics, Division of Allergy and Immunology, Icahn School of Medicine at Mount Sinai, New York, NY
[b]Division of Allergy and Immunology, Department of Pediatrics, Children's National Health System, Washington, DC
[c]George Washington University School of Medicine and Health Sciences, Washington, DC
[d]Division of Allergy and Immunology, Department of Medicine, University of South Florida, Tampa, FL
[e]Food Allergy Research & Education (FARE), Mclean, VA
No funding was received for this work.
Conflicts of interest: J. Wang received institutional research funding from Regeneron, DBV, and Aimmune; consultancy fees from DBV, ALK-Abelló, and Genentech; and is an UpToDate author. The rest of the authors declare that they have no relevant conflicts of interest.
Received for publication June 24, 2020; revised December 3, 2020; accepted for publication December 4, 2020.
Available online December 15, 2020.
Corresponding author: Roxanne C. Oriel, MD, Department of Pediatrics, Division of Allergy and Immunology, Icahn School of Medicine at Mount Sinai, One Gustave L. Levy Place, Box 1198, New York, NY 10029. E-mail: roxanne.oriel@mssm.edu.
2213-2198

https://doi.org/10.1016/j.jaip.2020.12.018

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

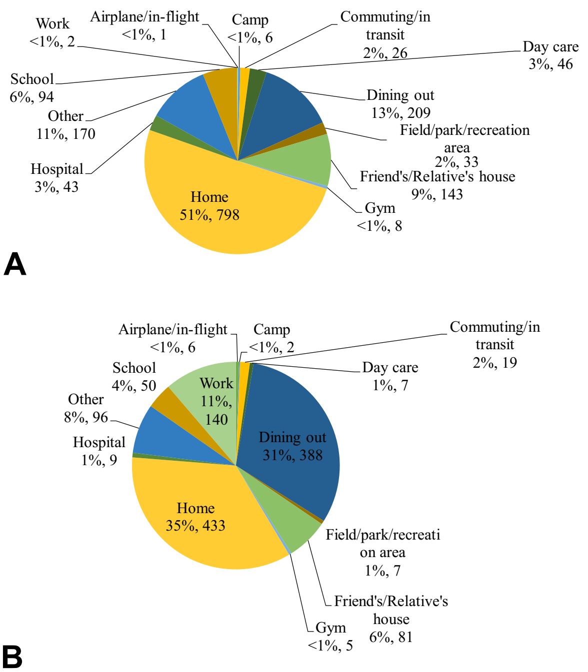


FIGURE 1. Most recent location for an allergic reaction reported as percentage, number of subjects. (**A**), Children <18 years (n = 1579). (**B**) Adults ≥18 years (n = 1243). Other refers to unsure or no response.

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

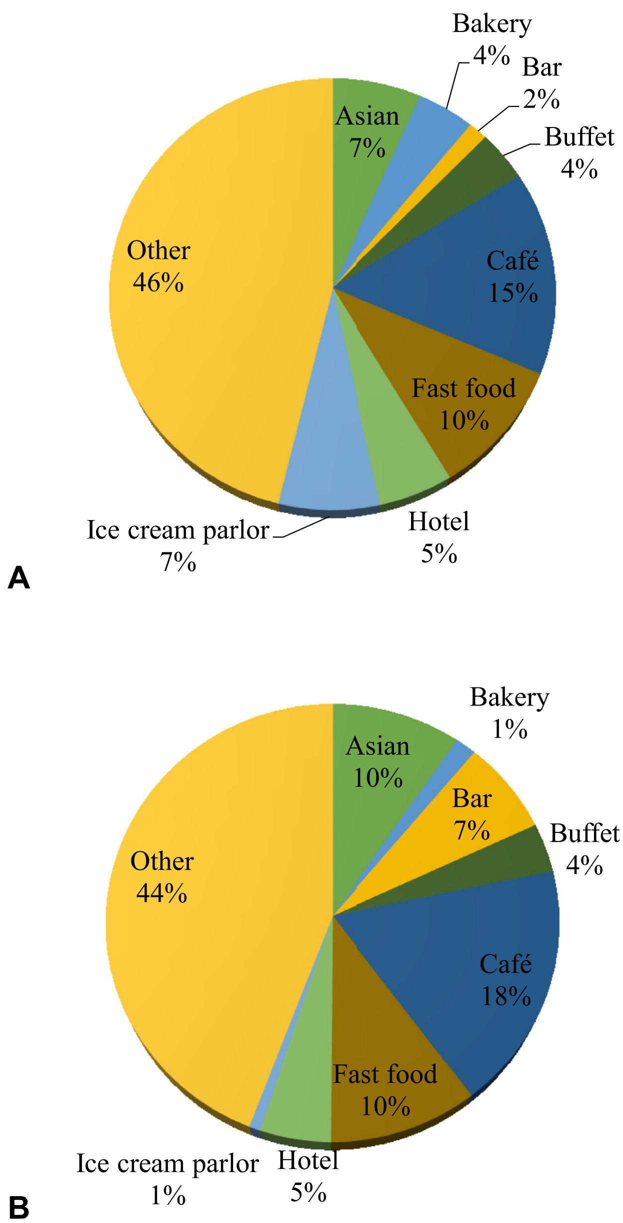


FIGURE 2. Type of food-serving establishment in which an allergic reaction occurred. (**A**), Children <18 years. (**B**), Adults ≥18 years.

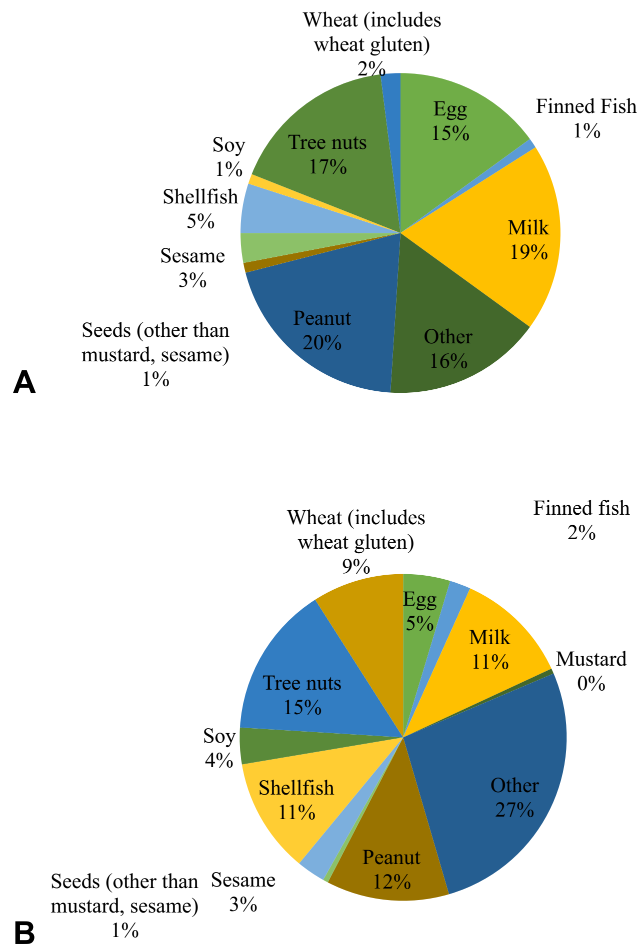


FIGURE 3. Culprit food allergens while dining out. (**A**), Children <18 years. Other refers to fruits, vegetables, herbs or spices, or unspecified by the survey respondent. (**B**), Adults ≥18 years. Other refers to fruits, vegetables, herbs or spices, cereals, and grains other than wheat, beans, legumes, 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.

REFERENCES

1. Bock SA, Munoz-Furlong A, Sampson HA. Fatalities due to anaphylactic reactions to foods. J Allergy Clin Immunol 2001;107:191-3.
2. Bock SA, Munoz-Furlong A, Sampson HA. Further fatalities caused by anaphylactic reactions to food, 2001-2006. J Allergy Clin Immunol 2007;119:1016-8.
3. Greenhawt MJ, Singer AM, Baptist AP. Food allergy and food allergy attitudes among college students. J Allergy Clin Immunol 2009;124:323-7.
4. Furlong TJ, McMorris MS, Greenhawt MJ. Self-reported allergic reactions to peanuts and tree nuts occurring in restaurants and food service establishments. J Allergy Clin Immunol 2008;121(Suppl 1):S248.
5. Wanich N, Weiss C, Furlong TJ, Sicherer SH. Food Allergic Consumer (FAC) experience in restaurants and food establishments. J Allergy Clin Immunol 2008;121(Suppl 1):S182.
6. Furlong TJ, DeSimone J, Sicherer SH. Peanut and tree nut allergic reactions in restaurants and other food establishments. J Allergy Clin Immunol 2001;108:867-70.
7. Eigenmann PA, Zamora SA. An internet-based survey on the circumstances of food-induced reactions following the diagnosis of IgE-mediated food allergy. Allergy 2002;57:449-53.
8. Versluis A, Knulst AC, Kruizinga AG, Michelsen A, Houben GF, Baumert JL, et al. Frequency, severity and causes of unexpected allergic reactions to food: a systematic literature review. Clin Exp Allergy 2015;45:347-67.
9. Radke TJ, Brown LG, Faw B, Hedeen N, Matis B, Perez P, et al. Restaurant food allergy practices—six selected sites, United States, 2014. MMWR Morb Mortal Wkly Rep 2017;66:404-7.
10. Radke TJ, Brown LG, Hoover ER, Faw BV, Reimann D, Wong MR, et al. Food allergy knowledge and attitudes of restaurant managers and staff: an EHS-Net study. J Food Prot 2016;79:1588-98.
11. Dupuis R, Meisel Z, Grande D, Strupp E, Kounaves S, Graves A, et al. Food allergy management among restaurant workers in a large U.S. city. Food Control 2016;63:147-57.
12. Ahuja R, Sicherer SH. Food-allergy management from the perspective of restaurant and food establishment personnel. Ann Allergy Asthma Immunol 2007;98:344-8.
13. Furlong TJ, Maloney JM, Sicherer SH. Seafood allergic reactions in restaurants. J Allergy Clin Immunol 2006;117(Suppl):S41.
14. U.S. Food and Drug Administration, U.S. Department of Health and Human Services. Food Code 2017. Available from: https://www.fda.gov/food/fda-food-code/food-code-2017. Accessed June 24, 2020.
15. Sicherer SH, Furlong TJ, Muñoz-Furlong A, Burks AW, Sampson HA. A voluntary registry for peanut and tree nut allergy: characteristics of the first 5149 registrants. J Allergy Clin Immunol 2001;108:128-32.
16. Beasley TM, Schumacker RE. Multiple regression approach to analyzing contingency tables: post hoc and planned comparison procedures. J Exp Educ 1995;64:79-93.
17. Centers for Disease Control and Prevention. Voluntary guidelines for managing food allergies in schools and early care and education programs. Washington, DC: US Department of Health and Human Services; 2013.
18. Carter CA, Pistiner M, Wang J, Sharma HP. Food allergy in restaurants work group report. J Allergy Clin Immunol Pract 2020;8:70-4.
19. Wen H, Kwon J. Food allergy risk communication in restaurants. Food Prot Trends 2016;36:372-83.
20. Leftwich J, Barnett J, Muncer K, Shepherd R, Raats MM, Gowland MH, et al. The challenges for nut-allergic consumers of eating out. Clin Exp Allergy 2011;41:243-9.
21. Food Allergy Research and Education. Food allergy and restaurants. Available from: https://www.foodallergy.org/food-allergies-and-restaurants. Accessed June 24, 2020.
22. Oria MP, Stallings VA, editors. Finding a path to safety in food allergy: assessment of the global burden, causes, prevention, management, and public policy. Washington, DC: National Academies Press; 2016.

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

References:

1. Center for Disease Control and Prevention, Water, Sanitation, and Environmentally Related Hygiene (WASH), Hygiene Fast Facts https://www.cdc.gov/hygiene/fast-facts.html, Last reviewed June 15, 2022.

2. Green, L., Selman, C. Self-Reported Factors impacting food workers' and managers' safe food preparation practices: A qualitative study**.** *Food Protection Trends*, 2005, Vol. 25, No. 12, Pages 981–990. https://www.cdc.gov/nceh/ehs/ehsnet/docs/factors_impacting_food_workers_food_prep_fpt_journal.pdf (See supporting attachment 2)

3. Persad, Geeta, Jose Pablo Ortiz Partida, Daniel Swain. 2020. Troubled Waters: Preparing for Climate Threats to California's Water System. Cambridge, MA: Union of Concerned Scientists. https://www.ucsusa.org/sites/default/files/2020-10/troubled-waters.pdf (file too large to attach to Issue)

4. Strohbehn, C., Sneed, J., Paola, P., Meyer, J. Hand Washing Frequencies and Procedures Used in Retail Food Service. *J Food Prot,* 1 August 2008; 71 (8): 1641–1650. https://doi.org/10.4315/0362-028X-71.8.1641 (See supporting attachment 3)

Food Protection Trends, Vol. 25, No. 12, Pages 981–990

6200 Aurora Ave., Suite 200W, Des Moines, IA 50322-2864

International Association for Food Protection

Factors Impacting Food Workers' and Managers' Safe Food Preparation Practices: A Qualitative Study

LAURA R. GREEN[1*] and CAROL SELMAN[2]

[1] Health, Social, and Economics Research, RTI International, Research Triangle Park, NC, USA

[2] Environmental Health Services Branch, Division of Emergency and Environmental Health Services, National Center for Environmental Health, Centers for Disease Control and Prevention, Atlanta, GA, USA

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.

A peer-reviewed article

*Author for correspondence: 770.488.4332; Fax: 770.488.7310
E-mail: lrg0@cdc.gov

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

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]	Practice	Number of groups[a]
Handwashing	**7**	**Determining food doneness**	**6**
Wash hands after visiting restroom	7	Use thermometer	6
Wash hands before preparing food	7	Use length of time cooking	6
Wash hands before preparing raw meat/poultry	7	Use appearance of food	3
Wash hands when changing tasks	7	Use feel of food	3
Wash hands periodically	7	Use thermometer with certain foods	2
Wash hands before putting on gloves/when changing gloves	4	Use thermometer when inexperienced/working with new food	2
Wash hands after handling money	4	**Holding**	**5**
Wash hands after sneezing/coughing	4	Use steam tables	4
Wash hands after eating/drinking	3	Use walk-in coolers	4
Wash hands after taking a break	3	Use sandwich/preparation tables	3
Wash hands after touching face, hair, or clothes	3	Use salad bars	2
Use sanitizer	5	Check temperatures of held foods	3
Cross contamination prevention	**7**	Record temperatures in temperature logs	3
Clean and sanitize work surfaces, utensils, equipment	7	Managers check/record temperatures	2
Sanitize (but not clean and rinse) work surfaces, utensils, equipment	3	Set shelf life for held food	3
Use gloves or utensils to prevent bare hand contact	6	Throw away foods held at improper time/temperature	3
Keep raw meat/poultry separate from other foods with separate storage areas	6	Stir held foods	2
Keep raw meat/poultry separate from other foods during preparation with separate work areas/surfaces	5	Cover held foods	2
Wash hands after preparing raw meat/poultry	5	**Cooling**	**5**
Use stainless steel equipment	2	Place cooling food in walk-in coolers	5
Work only with raw meat/poultry until task is complete	2	Place cooling food in shallow or small pans	4
Flip cutting boards after using one side	1	Use ice baths	4
Glove use	**7**	Use cooling wands/paddles	2
Wear gloves when in the kitchen or preparing food	6	Use blast chiller	1
Wear gloves when preparing raw meat/poultry	6	Check temperatures of cooling food	5
Wear gloves when hands have cuts or scratches	2	Do not check temperatures of cooling food	5
Wear gloves when preparing food don't want to touch directly	2	Record temperatures in temperature logs	2
Wash hands with every glove change	5	Follow improper cooling practices	4
Change gloves when changing tasks or products	5	**Reheating**	**3**
Change gloves after preparing raw meat/poultry	3	Reheat food prior to placing in holding	2
Change gloves when damaged or dirty	2	Do not reheat prior to placing in holding	2
Change gloves periodically	2	Discard foods rather than reheat/Reheat only once	2
Do not wear gloves	5	Check the temperatures of reheated foods	3
Do not wear gloves when cutting food	2	Record temperatures in temperature logs	1
Use gloves improperly	2	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	Factors impacting:	Number of groups[1] Workers	Managers	Total
Handwashing	**7**	**4**	**11**	**Glove use (Continued)**	**7**	**4**	**11**
Sink accessibility	5	4	9	Adequate resources (e.g., gloves)	1	1	2
Time pressure/high volume of business/staffing	4	4	8	Time pressure/high volume of business/staffing	1	1	2
Management emphasis	4	4	8	Worker motivation/experience/age	1	0	1
Negative consequences	5	2	7	Coworker emphasis	1	0	1
Sanitizer use	3	3	6	**Use of thermometer for food doneness**	**7**	**4**	**11**
Glove use	2	3	5	Time pressure/high volume of business/staffing	4	3	7
Restaurant procedures	3	2	5	Type of meat	3	3	6
Worker motivation/experience/age	2	2	4	Restaurant procedures	3	2	5
Expectations of reciprocal treatment	3	1	4	Worker motivation/experience/age	3	1	4
Personal preferences	3	0	3	Health regulations and inspections	0	3	3
Food safety education and training	1	2	3	Thermometer sanitation	2	1	3
Coworker emphasis	2	1	3	Thermometer type	0	2	2
Concern with sanitary appearance	1	1	2	**Holding**	**5**	**4**	**9**
Effect on hands	0	2	2	Equipment/thermometers	3	4	7
Adequate resources (e.g., soap)	1	0	1	Management emphasis	3	2	5
Cross contamination prevention	**7**	**4**	**11**	Food safety education and training	2	2	4
Multiple, color-coded cutting boards	5	3	8	Time pressure/high volume of business/staffing	2	2	4
Glove and utensil use	6	2	8	Restaurant procedures	0	3	3
Sanitizer use	4	2	6	Negative consequences	0	2	2
Separation of work areas/tasks	3	3	6	Worker motivation/experience/age	1	0	1
Management emphasis	3	2	5	Space	0	1	1
Food safety education and training	2	2	4	Hours of operation	0	1	1
Time pressure/high volume of business/staffing	1	3	4	Quality of food	0	1	1
Pre-cooked or prepared meat	3	1	3	**Cooling**	**5**	**3**	**8**
Negative consequences	2	1	3	Time at which cooling occurs	2	2	4
Coworker emphasis	1	0	1	Worker motivation/experience/age	2	0	2
Language differences	0	1	1	Equipment/thermometers	2	0	2
Glove use	**7**	**4**	**11**	Management emphasis	0	2	2
Manager emphasis/requirement	5	2	7	Space	0	2	2
Negative consequences	4	2	6	Time pressure/high volume of business/staffing	1	0	1
Comfort and fit of gloves	4	2	6	**Reheating**	**3**	**3**	**6**
Type of work	2	3	5	Food safety education and training	2	1	3
Personal preferences	4	1	5	Thermometers	2	0	2
Allergies to glove materials	2	3	5	Time pressure/high volume of business/staffing	0	1	1
Concern about sanitary appearance	3	0	2				

[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 resources (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 focused 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.

ACKNOWLEDGMENTS

The authors wish to thank Sheryl Cates and Katherine Kosa (Health, Social and Economics Research, RTI International) for their assistance with study design, participant recruitment, and data collection, and the EHS-Net Working Group (National Center for Environmental Health, CDC) for their guidance concerning study topics and questions.

REFERENCES

1. Bryan, F. 1988. Risks of practices, procedures, and processes that lead to outbreaks of foodborne diseases. J. Food Prot. 51:498–508.
2. Clayton, D., and C. Griffith. 2002. Commercial food handlers' knowledge, attitudes and implementation of food hygiene practices. J. Food Prot. 65 (Sup. A):109. Available at http://www.foodprotection.org/meetingsEducation/IAFP%202002/IAFP%202002%20Posters%20Abstracts.pdf. Last accessed November 1, 2005.
3. Clayton, D., C. Griffith, P. Price, and A. Peters. 2002. Food handlers' beliefs and self-reported practices. Int. J. Env. Health Res. 12:25–39.
4. Clayton, D., and C. Griffith. 2004. Observation of food safety practices in catering using notational analysis. British Food J. 106:211–227.
5. Cotterchio, M., J. Gunn, T. Coffill, P. Tormey, and M. Barry. 1998. Effect of a manager training program on sanitary conditions in restaurants. Public Health Rep. 113:353–358.
6. Ehiri, J., and G. Morris. 1994. Food safety control strategies: A critical review of traditional approaches. Int. J. Env. Health Res. 4:254–263.
7. Ehiri, J., and G. Morris. 1996. Hygiene training and education of food handlers: Does it work? Ecol. Food Nutr. 35:243–251.
8. Food and Drug Administration (FDA). 2001. FDA's recommended national retail food regulatory program standards. Available at http://www.cfsan.fda.gov/~dms/ret-intr.html. Last accessed November 1, 2005.
9. Food and Drug Administration (FDA). 2001. Food code. Available at http://www.cfsan.fda.gov/~dms/fc01-toc.html. Last accessed November 1, 2005.
10. Foster, G., and F. Kaferstein. 1985. Food safety and the behavioral sciences. Soc.Sci. Med. 21:1273–1277.
11. Friedman, C., R. Hoekstra, M. Samuel, R. Marcus, J. Bender, B. Shiferaw, S. Reddy, S. Ahuja, D. Helfrick, F. Hardnett, M. Carter, B. Anderson, and R. Tauxe, for the Emerging Infections Program FoodNet Working Group. 2004. Risk factors for sporadic *Campylobacter* infection in the United States: A case-control study in FoodNet sites. Clin. Infect. Dis. 38:S285–S296.
12. Guzewich, J., and M. Ross. 1999. Evaluation of risks related to microbiological contamination of ready-to-eat food by food preparation workers and the effectiveness of interventions to minimize those risks. http://www.cfsan.fda.gov/~ear/rterisk.html. Last accessed November 1, 2005.
13. Harris, D. 1983. Group interviews via teleconferencing. J. Data Coll. 23:39–41.
14. Howes, M., S. McEwen, M. Griffiths, and L. Harris. 1996. Food handler certification by home study: Measuring changes in knowledge and behavior. Dairy Food Env. Sanit. 16:737–744.
15. Jones, T., B. Imhoff, M. Samuel, P. Mshar, K. McCombs, M. Hawkins, V. Deneen, M. Cambridge, and S. Olsen, for the Emerging Infections Program FoodNet Working Group. 2004. Limitations to successful investigation and reporting of foodborne outbreaks: An analysis of foodborne disease outbreaks in FoodNet catchment areas, 1998–99. Clin. Infect. Dis. 38:S297–S302.
16. Kassenborg, H., C. Hedberg, M. Hoekstra, M. Evans, A. Chin, R. Marcus, D. Vugia, K. Smith, S. Ahuja, L. Slutsker, and P. Griffin, for the Emerging Infections Program FoodNet Working Group. 2004. Farm visits and undercooked hamburgers as major risk factors for sporadic *Escherichia coli* O157:H7 infection: Data from a case-control study in

5 FoodNet sites. Clin. Infect. Dis. 38: S271–S278.
17. Kassenborg, H., K. Smith, D. Vugia, T. Rabatsky-Ehr, M. Bates, M. Carter, N. Dumas, M. Cassidy, N. Marano, R. Tauxe, and F. Angulo, for the Emerging Infections Program FoodNet Working Group. 2004. Fluoroquinolone-resistant *Campylobacter* infections: Eating poultry outside of the home and foreign travel are risk factors. Clin. Infect. Dis. 38:S279–S284.
18. Kendall, P., L. Melcher, and L. Paul. 2000. Factors affecting safe food handling practices in restaurants. Unpublished study conducted by the Department of Food Science and Human Nutrition, Colorado State University Cooperative Extension. Fort Collins, CO.
19. Kimura, A., V. Reddy, R. Marcus, P. Cieslak, J. Mohle-Boetani, H. Kassenborg, S. Segler, F. Hardnett, T. Barrett, D. Swerdlow, for the Emerging Infections Program FoodNet Working Group. 2004. Chicken consumption is a newly identified risk factor for sporadic *Salmonella* Enterica serotype Enteritidis infections in the United States: A case-control study in FoodNet sites. Clin. Infect. Dis. 38:S244–S252.
20. Manning, C., and S. Snider. 1993. Temporary public eating places: Food safety knowledge, attitudes, and practices. J. Environ. Health 56: 24–28.
21. Mathias, R., R. Sizto, A. Hazlewood, and W. Cocksedge. 1995. The effects of inspection frequency and food handler education on restaurant inspection violations. Can. J. Public Health 86:46–50.
22. Montville, R., Y. Chen, and D. Schaffner. 2001. Glove barriers to bacterial cross-contamination between hands to food. J. Food Prot. 64:845–849.
23. Olsen, S., L. MacKinon, J. Goulding, N. Bean, and L. Slutsker. 2000. Surveillance for foodborne disease outbreaks—United States, 1993-1997. MMWR. 49:1–51.
24. Oteri, T., and E. Ekanem. 1989. Food hygiene behavior among hospital food handlers. Public Health 103: 153–159.
25. Redmond, E., and C. Griffith. 2003. Consumer food handling in the home: A review of food safety studies. J. Food Prot. 66:130–161.
26. Silverman, G. 2003. Introduction to Telephone Focus Groups. Report prepared for Market Navigation, Inc. Available at http://www.mnav.com/phonefoc.htm. Last accessed November 1, 2005.
27. Sobel, J., A. Hirshfeld, K. McTigue, C. Burnett, S. Altekruse, F. Brenner, G. Malcolm, S. Mottice, C. Nichols, and D. Swerdlow. 2000. The pandemic of *Salmonella* Enteritidis phage type 4 reaches Utah: a complex investigation confirms the need for continuing rigorous control measures. Epidemiol. Infect. 125:1–8.

Journal of Food Protection, Vol. 71, No. 8, 2008, Pages 1641–1650

Hand Washing Frequencies and Procedures Used in Retail Food Services

CATHERINE STROHBEHN,* JEANNIE SNEED,† PAOLA PAEZ, AND JANELL MEYER

Hotel, Restaurant and Institution Management Program, 31 MacKay Hall, Iowa State University, Ames, Iowa 50011-1121, USA

MS 07-557: Received 19 October 2007/Accepted 28 February 2008

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)*.

* Author for correspondence. Tel: 515-294-3527; Fax: 515-294-6364; E-mail: cstrohbe@iastate.edu.

† Present address: College of Arts and Sciences, Oklahoma State University, Stillwater, OK 74078, USA.

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

$$\text{Hand washing benchmark per hour per employee} = \text{Total number of times observed employees should have washed their hands} \div \text{Total number of observed employee work hours}$$

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)*

	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]			
Task[a]	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)*

	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]			
Task[a]	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.

ACKNOWLEDGMENTS

This research project was funded by the U.S. Department of Agriculture (USDA) Cooperative States Research, Education, and Extension Service project 2005-51110-03282. The contents are solely the responsibility of the authors and do not necessarily represent the views of USDA. The authors thank the retail food service establishments who participated in the project.

REFERENCES

1. Allwood, P. B., T. Jenkins, C. Paulus, L. Johnson, and C. W. Hedberg. 2004. Hand washing compliance among retail food establishment workers in Minnesota. *J. Food Prot.* 62:2825–2828.
2. Arendt, S. W., and J. Sneed. 2007. Employee motivators for following food safety practices: model development. *Food Prot. Trends,* in press.
3. Bean, N. H., P. Griffin, J. Goulding, and C. Ivey. 1990. Foodborne disease outbreaks, 5-year summary, 1983–1987. *J. Food Prot.* 53: 711–728.
4. Boyce, J. M., S. Kelliher, and N. Vallande. 2000. Skin irritation and dryness associated with two hand-hygiene regimens: soap-and-water handwashing versus hand antisepsis with an alcoholic hand gel. *Infect. Control Hosp. Epidemiol.* 21:442–448.
5. Bryan, F. 1988. Risks of practices, procedures, and processes that lead to outbreaks of foodborne diseases. *J. Food Prot.* 51:663–672.
6. Centers for Disease Control. 1990. Viral agents of gastroenteritis: public health importance and outbreak management. *Morb. Mortal. Wkly. Rec. Rep.* (online) 39(RR-5):1–24. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/00001625.htm. Accessed 2 January 2006.
7. Centers for Disease Control and Prevention. 1996. Surveillance for foodborne-disease outbreaks in the United States, 1988–1992. *Morb. Mortal. Wkly. Surv. Summary* 45(SS-5):1–73. Available at: http://www.cdc.gov/mmwr/PDF/ss/ss4505.pdf. Accessed 16 March 2005.
8. Centers for Disease Control and Prevention. 2001. Norwalk-like viruses: public health consequences and outbreak management. *Morb. Mortal. Wkly. Rep.* 50(RR-09):1–18. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5009a1.htm. Accessed 16 December 2005.
9. Gilmore, S. A., N. E. Brown, and J. T. Dana. 1998. A food quality model for school foodservices. *J. Child Nutr. Mgt.* 22:32–39.
10. Green, L., C. Selman, A. Banerjee, R. Marcus, C. Medus, F. Angulo, V. Radke, S. Buchanan, and EHS-Net Working Group. 2005. Foodservice workers' self-reported food preparation practices: an EHS-Net study. *Int. J. Hyg. Environ. Health* 208:27–35.
11. Green, L., C. Selman, V. Radke, D. Ripley, J. Mack, D. Reimann, T. Stigger, M. Motsinger, and L. Bushnel. 2006. Food worker hand washing practices: an observation study. *J. Food Prot.* 62:2417–2423.
12. Guzewich, J., and M. P. Ross. 1999. Evaluation of the risk related to microbiological contamination of ready-to-eat food by food preparation workers and the effectiveness of interventions to minimize those risks. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition. Available at: http://www.cfsan.fda.gov/~ear/rterisk.html. Accessed 16 December 2006.
13. Henroid, D., and J. Sneed. 2004. Readiness to implement hazard analysis critical control point (HACCP) systems in Iowa schools. *J. Am. Diet. Assoc.* 104:180–186.
14. Mead, P. S., L. Slutsker, V. Dietz, L. F. McCaig, J. S. Bresee, C. Shapiro, P. M. Griffin, and R. V. Tauxe. 1999. Food-related illness and death in the United States. *Emerg. Infect. Dis.* 5:607–625.
15. O'Boyle, C., S. J. Henly, and E. Larson. 2001. Understanding adherence to hand hygiene recommendations: theory of planned behavior. *Am. J. Infect. Control* 29:352–360.
16. Paez, P., C. Strohbehn, and J. Sneed. 2007 Handwashing frequencies and methods used in deli-type foodservice operations. *Food Prot. Trends* 29:903–908.
17. Pragle, A. S., A. K. Harding, and J. C. Mack. 2007. Food workers'

perspectives on handwashing behaviors and barriers in the restaurant environment. *J. Environ. Health* 69:27–33.

18. Sneed, J., C. Strohbehn, and S. A. Gilmore. 2007. Impact of mentoring on food safety practices and HACCP implementation in Iowa assisted-living facilities. *Top. Clin. Nutr.* 22:162–174.
19. U.S. Food and Drug Administration. 2000. Report of the FDA Retail Food Program database of foodborne illness risk factors. Available at: http://www.cfsan.fda.gov/~acrobat/retrsk.pdf. Accessed 16 December 2005.
20. U.S. Food and Drug Administration. 2003. Hand hygiene in retail and foodservice establishments. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition. Available at: http://www.cfsan.fda.gov/~comm/handhyg.html. Accessed 15 December 2005.
21. U.S. Food and Drug Administration. 2004. FDA report on the occurrence of foodborne illness risk factors in selected institutional foodservice, restaurant, and retail food store facility types. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition. Available at: http://www.cfsan.fda.gov/~dms/retrsk2.html. Accessed 15 December 2006.
22. U.S. Food and Drug Administration. 2005. Food code. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Available at: http://www.cfsan.fda.gov/~dms/fc05-toc.html. Accessed 15 December 2006.

Environmental Management Department
Val F. Siebal, Director

Divisions
Environmental Health
Environmental Compliance

County of Sacramento

FOR OFFICIAL USE ONLY	
Date Submitted:	
Date Approved:	
Approved by:	

ALTERNATIVE OPERATING PROCEDURES
To Use Bare Hand Contact with Ready-to-Eat Food

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:** ______________________

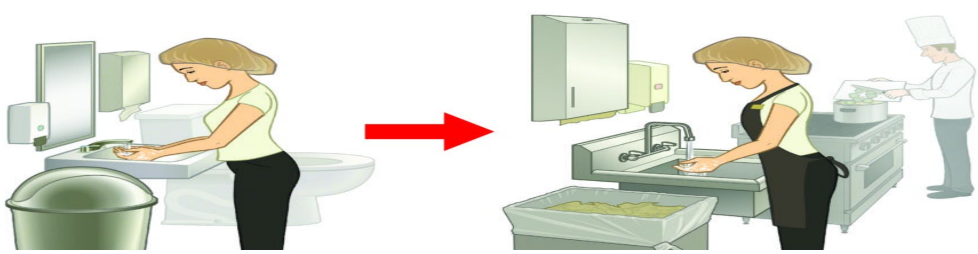
Email address: ______________________

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**.**

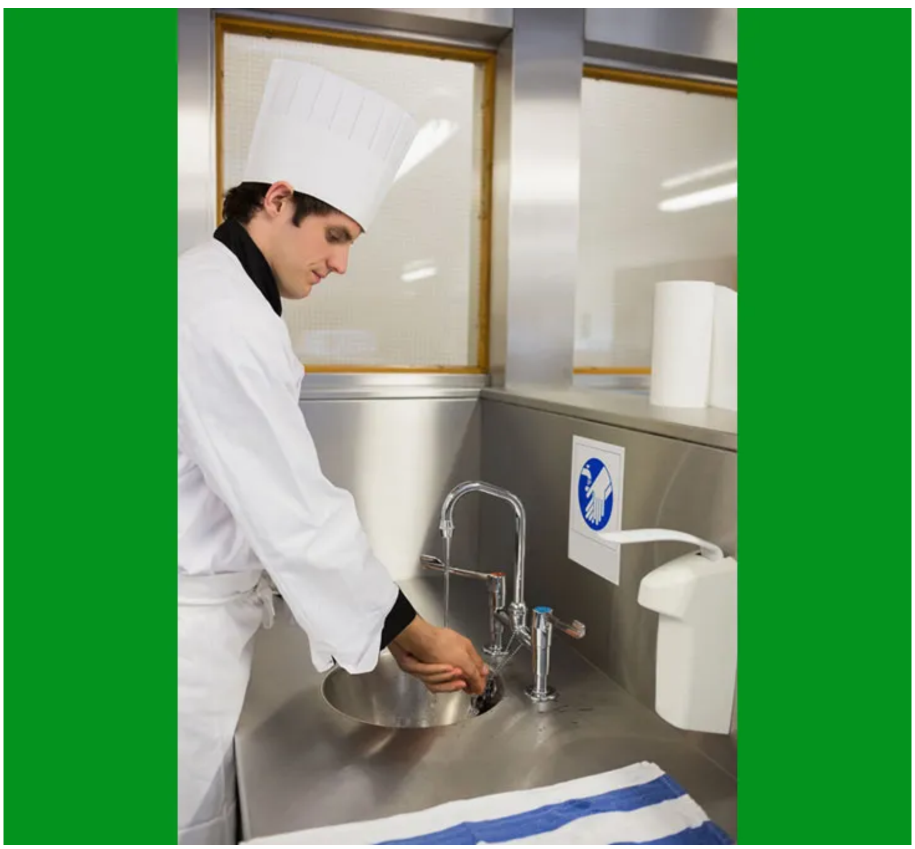
HANDWASHING REMINDERS

- 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

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

Speak Your Mind

Name *

Email *

Website

☐ Notify me of follow-up comments by email.

☐ Notify me of new posts by email.

POST COMMENT

This site uses Akismet to reduce spam. Learn how your comment data is processed.

CLIENTS

SEARCH

Search this website …

CATEGORIES

Select Category

ARCHIVES

Select Month

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.

MOST POPULAR

Food Safety Starts with Smart Restaurant Kitchen Design (208008 Views)

Stay on Top of Food Safety with Health Inspection Checklists (205002 Views)

COVID-19 Restaurant Resources (170781 Views)

Delivery 101: Inspection Tips for Food Safety (157257 Views)

CONNECT WITH US

RESPRO FSP, LLC

Privacy Policy - Terms of Use
P.O. Box 1078
Centerville, Utah 84014
info@ResproFSP.com

TOP

»

«

StateFoodSafety Resources

Up-To-Date News About Food Safety

All Resources (/Resources/index/category/Resources)
Food Safety Articles (/Resources/index/category/Articles)
Training Tips (/Resources/index/category/Training-Tips)
Cartoons (/Resources/index/category/Cartoons)
Posters (/Resources/index/category/Posters)
Client Resources (/Resources/index/category/Client-Resources)
Forms (/Resources/index/category/Forms)
Food Safety Talkabout Videos (/Resources/index/category/Food-Safety-Talkabout-Video)
Other Media (/Resources/index/category/Other-Media)

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.

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
Texas Food Handlers—Train by September 1, 2016

Newer >>
Training Tip: Maintaining a Cleaning Schedule

Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

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 <u>COMPLETED</u> 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

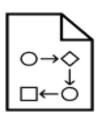
Background

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.

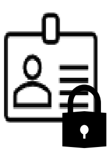
For more information about how food purchase history information is used to investigate outbreaks please visit https://www.afdo.org/resources/purchase-history/.

Best Practices

Work closely with public health officials to assist with the investigation. It is important to establish relationships prior to an investigation.



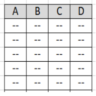
Develop a written process for how information will be shared during illness/outbreak investigations in coordination with your company's legal counsel and your state's public health and regulatory authorities. A plan that is developed in advance and communicated to staff will make the investigation go more smoothly.



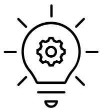
Protect personally identifiable information (PII). Consumer information that directly identifies an individual beyond what has been provided by the public health or regulatory agency should be redacted. Purchases beyond food/grocery items (e.g., pharmacy, liquor, tobacco) may not be needed during a foodborne 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
Feeney	Catherine	Chair	Regulator - State	Rhode Island Department of Health	Providence	RI	14012227717	catherine.feeney@health.ri.gov
Brown	Bob	Member	Industry - Retail Food	Whole Foods Market	Austin	TX	5129447405	robert.brown@wholefoods.com
Botsford	Jennifer	Member	Regulator - State	ADHS	Phoenix	AZ	602-364-3142	jennifer.botsford@azdhs.gov
Johnson	Ann	Member	Regulator - State	FL Department of Agriculture and Consumer Services	Tallahassee	FL	850-728-5894	anna.johnson@FDACS.gov
Jordan	Josh	Member	Regulator - Local	Forsyth County Department of Public Health			336-703-3140	jordanjl@forsyth.cc
Kanwat	Chandra Prakash	Member	Regulator - State	SC Department of Health and Environmental Control	Columbia	SC	803-896-2249	kanwatcp@dhec.sc.gov
McClellan	Hunter	Member	Regulator - State	Nebraska Department of Agriculture	Lincoln	NE	4024716813	hunter.mcclellan@nebraska.gov
Barajas	Alexis	Member	Regulator - Local	SNHD	Las Vegas	NV	702-759-1631	barajas@snhd.org
Salinas	Sabrina	Member	Regulator - Local	Harris County Public Health- Environmental Public Health	Houston	TX	832-840-5683	sabrina.salinas@phs.hctx.net
DiMaggio	Michele	Member	Regulator - Local	Contra Costa County, Environmental Health Services	Concord	CA	925-608-5435	michele.dimaggio@cchealth.org
Morrill	Brandon	Member	Regulator - Local	Washtenaw County Health Department	Ann Arbor	MI	616-516-0644	morrillb@washtenaw.org
Johnson	Jennifer	Member	Industry - Food Service	Yum!	Plano	TX	407-739-8555	jennifer.johnson@yum.com
Bureau	Cathy	Member	Industry - Retail Food	H-E-B/Central Market	Dallas	TX	6513037193	bureau.cathy@heb.com
Fierro	Christine	Member	Industry - Retail Food	Publix Super Markets Inc.	lakeland	FL	863-688-1188	christine.fierro@publix.com
Jennings	Allison	Member	Industry - Retail Food	Albertsons Co.	Boise	ID	12067714021	allison.jennings@albertsons.com
O'Donnell	Kathleen	Member	Industry - Retail Food	Wegmans Food Markets, Inc.	Rochester	NY	585-734-3909	kathleen.odonnell@wegmans.com
Stefanski	Kristina	Member	Industry - Retail Food	Retail Business Services	Quincy	MA	7813850561	kstefans@retailbusinessservices.com
Wilcoxson	Melissa (Lissy)	Member	Industry - Retail Food	Kroger	Cincinnati	OH	513-265-5661	lissy.wilcoxson@kroger.com
Romo	Nela	Member	Industry -Food Service	El Pollo Loco	West Covina	CA	949-689-3101	NROMO@ELPOLLOLOCO.COM
Garren	Donna	Member	Industry - Processing	American Frozen Foods	Arlington	VA	7036630252	dgarren@affi.com
Howell	Allison	Member	Student	The Ohio State University	Columbus	OH		howell.497@osu.edu
Baum	Mitzi	Member	Consumer (organizations)	Stop Foodborne Illness	Chicago	IL	3129258701	mbaum@stopfoodborneillness.org
Richardson	Bridget	Member	Industry - Retail Food	Blue Apron	New York	NY		bridget.richardson@blueapron.com

Alternates

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
McCormick	Zachary	Consultant	Regulatory - Federal				404-718-4389	qkc8@cdc.gov
Kramer	Adam	Consultant Alternate	Regulatory - Federal	CDC			404-498-1228	ank5@cdc.gov
Williams	Laurie	Consultant	Regulatory - Federal	FDA			240-402-2938	Laurie.Williams@fda.hhs.gov
Nerney	Tom	Consultant Alternate	Regulatory - Federal	FDA			781-587-7431	Thomas.Nerney@fda.hhs.gov
Freiman	Jennifer	Consultant	Regulatory - Federal	USDA FSIS				jennifer.freiman@usda.gov
Detwiler	Darin	Alternate	Academia	Northeastern University	Boston	RI		d.detwiler@northeastern.edu
Bryant	Veronica	Alternate	Regulator - State	NCDHHS	Raleigh	NC	919-218-6943	veronica.bryant@dhhs.nc.gov
Hutson	Jennifer	Alternate	Regulator - State	WV DHHR Bureau for Public Health	Charleston	WV	(304)558-2981	jennifer.eb.hutson@wv.gov
Smith	Colleen	Alternate	Regulator - State	NH DHHS	Concord	NH	16032714858	colleen.smith@dhhs.nh.gov
Splawn	Travis	Alternate	Regulator - State	Oklahoma State Department of Inspections and Appeals	Oklahoma City	OK	4055355813	traviss@health.ok.gov
Gillam	Tim	Alternate	Industry - Food Service	Subway Restaurants	Milfrord	CT	(570) 688-3310	gillam_t@subway.com
Baldwin	James	Alternate	Industry - Retail Food	The Golub Corporation - Price Chopper/Market32	Schenectady	NY	5183791516	jimbaldwin@pricechopper.com
Leach	Katie	Alternate	Industry - Retail Food	Retail Business Services supporting the Stop and Shop Stores	Westfield, Ma	MA	413-563-1208	Katie.leach@retailbusinessservices.com
Puente	Eric	Alternate	Industry - Retail Food	Whole Foods Market	Austin	TX	2103918462	eric.puente@wholefoods.com
Schwartz	James	Alternate	Industry - Retail Food	Alberstons Companies	Concord	CA	9254371741	james.schwartz@safeway.com
Seminara	Mario	Alternate	Industry - Support	Food Safety Works LLC	Lakewood	CO	(720) 681-1615	mseminarajr@gmail.com
Kincheloe	James	Alternate	Consumer (organizations)	Center for Science in the Public Interest	Washington	DC	(707) 490-7087	jkincheloe@cspinet.org
Espinoza	Albert	Alternate	Industry - Retail Food	H-E-B	San Antonio	TX	2108845783	espinoza.albert@heb.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.

SHOPPER HISTORY:

Best Practices for Use during Foodborne Illness Investigations

October 2020

SHOP
Shopper History Outbreak Partnership

Table of Contents

1. Purpose and Scope 3
2. Background 3
    a. Document Authors 3
    b. What is Shopper History? 3
    c. When is Shopper History Used in Outbreak Investigations? 4
3. Responsibility 5
    a. Acquiring Information from Case-patients during Interviews 5
    b. Requesting Information from the Retailer 5
    c. Reviewing/Analyzing the Data 6
4. Acquiring Information from Case-Patients during Interviews 6
5. Requesting Information from the Retailer 7
    a. Considerations Specific to Each Type of Shopper History 7
    b. Gathering Information about the Retailer 8
    c. Gathering Information about your Case-Patient 8
    d. Sending a Request to the Retailer 8
    e. Additional Information That May Be Helpful 10
    f. Troubleshooting 10
    g. Limits and Caveats of Shopper/Loyalty Card Data 10
6. Reviewing/Analyzing the Data 11
    a. Verifying the Products 11
    b. Verifying the Consumer 11
    c. Analyzing the Data 11
7. Data Maintenance/Confidentiality Considerations 12
    a. Requesting Data from a Retailer 12
    b. Requesting Data from the Case-Patient or Case-Patient Household 12
    c. Data Maintenance and Storage 12
    d. Sharing Data with Other Partners 12
8. Communications During and After the Outbreak 13
    a. Provide Feedback to Retailers 13
    b. Build Relationships with Retailers 13
9. Glossary 14
10. Resources 14
11. Appendices 15
    a. Appendix 1- Key Points for Obtaining Credit/Debit Transaction Records 15
    b. Appendix 2- Example Request Form for Government Agency Request for Customer Information (Kroger) 17
    c. Appendix 3- Template Letters—Shopper History Request Examples (Tennessee, New York, Minnesota) 18
    d. Appendix 4- Template Call Script Requesting Shopper History from Retailers 22
    e. Appendix 5- Template Letter – Case-patient Requesting Retailer Release Shopper History to Government Agency 23
    f. Appendix 6- Examples of Shopper History Received from Retailers 24
    g. Appendix 7- Example Written Summaries of Shopper History Findings for Sharing with Investigation Partners 26

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?

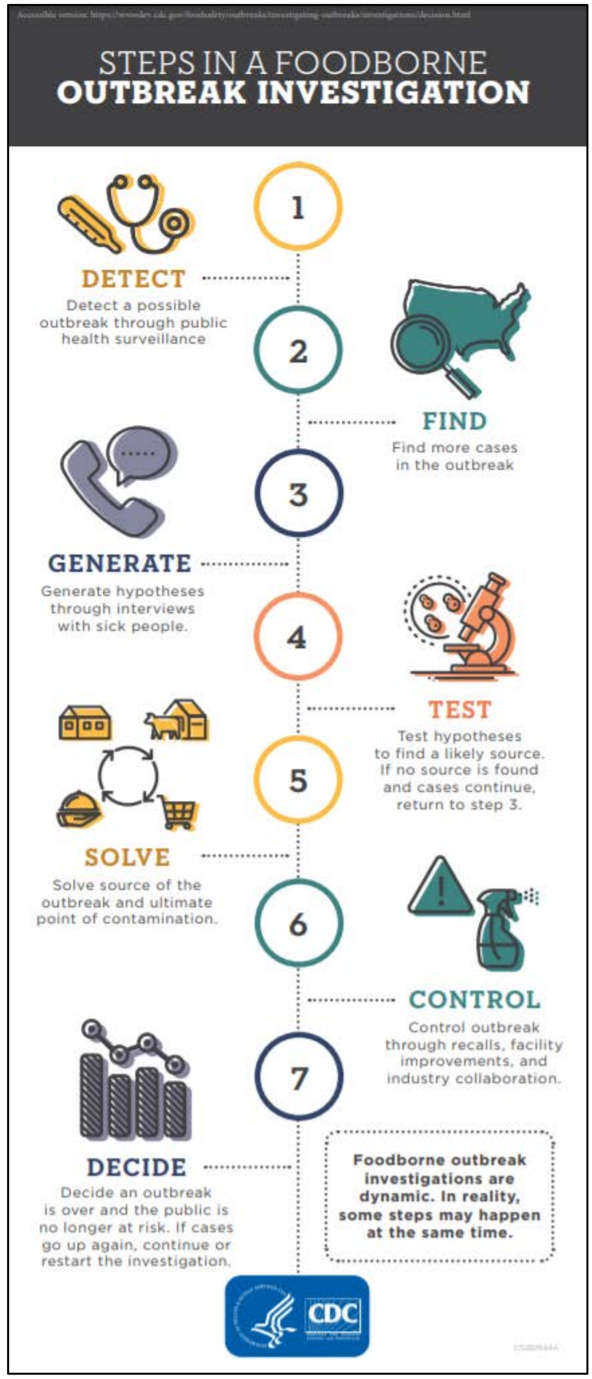
Shopper history refers to any type of record that provides information about a specific shopper's food purchases. Many different terms and sources of information can be used as shopper history. This should include, but is not limited to:

[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.
  - o 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.

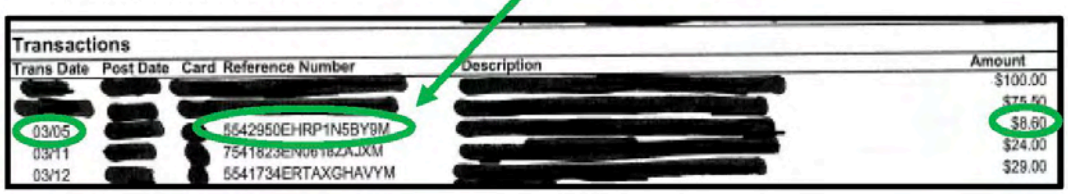
1. Receipt reprints – gathered by case

- 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:



Transactions

Trans Date	Post Date	Card	Reference Number	Description	Amount
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	$100.00
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
03/05	[redacted]	[redacted]	6542950EHRP1N5BY9M	[redacted]	$8.60
03/11	[redacted]	[redacted]	7541823EN06182AJXM	[redacted]	$24.00
03/12	[redacted]	[redacted]	6541734ERTAXGHAVYM	[redacted]	$29.00

- 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 [XXXXXXXXXXX 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)

DEPARTMENT OF HEALTH

P r o t e c t i n g , M a i n t a i n i n g a n d I m p r o v i n g t h e H e a l t h o f A l l M i n n e s o t a n s

[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

An equal opportunity employer

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 J	$5.99	$5.99	Cucina di Carla Six Cheese Ravioli with Marinara Sauce
COLES CHEESESTICKS 11.50 OZ	1.000	1 J	$4.89	$4.89	Coles Cheese Sticks, with A Twist
2@4				($2.89)	*discount*
COLES NACHO CHEESE PRETZEL STICK	1.000	1 J	$4.89	$4.89	Coles Pretzel Sticks, Filled with Pub Cheese
2@4				($2.89)	*discount*
ECK SKLS TKY S SAU	1.000	1 J	$4.39	$4.39	Eckrich Skinless Turkey Smoked Sausage
2@5				($1.89)	*discount*
OUI FRCH PEACH YOG	1.000	1 J	$1.59	$1.59	Yoplait Oui Yogurt, French Style, Peach
KRAFT COOL WHIP ORIGINAL WHIPPED	1.000	1 J	$1.99	$1.99	Cool Whip Whipped Topping, Original
UDRLY SMTH HND CRM	1.000	1 J	$2.99	$2.99	Udderly Smooth Hand Cream Original Formula
EE PANKO	1.000	1 J	$2.29	$2.29	Essential Everyday Bread Crumbs, Crispy, Panko, Plain
RAINBOW ROSE BUNCH 1CT	1.000	1 J	$9.99	$9.99	Rainbow Rose Bunch Dozen
PHILADELPHIA ORIGINAL CREAM CHEE	1.000	1 J	$2.49	$2.49	PHILADELPHIA ORIGINAL CREAM CHEE
PIL SM CINN ROLL	1.000	1 J	$1.79	$1.79	Pillsbury Cinnamon Rolls, with Icing
FR BK BAN NUT LOAF	1.000	1 J	$5.99	$5.99	Fresh Baked Nut Loaf
SPARKLE PRINTS 1 ROLL	1.000	1 J	$1.49	$1.49	Sparkle Paper Towels, Full Sheet, Print, 1 Regular Roll
LEWIS NUTTY OAT	1.000	1 J	$1.89	$1.89	LEWIS NUTTY OAT
BELLA SUN LUCI SUN DRIED TOMATOE	1.000	1 J	$3.99	$3.99	Bella Sun Luci Tomatoes, Sun Dried, Halves
QUAKER CHEWY YOGURT COVERED GRAN	1.000	1 J	$2.99	$2.99	Quaker Chewy Yogurt Granola Bars, Strawberry
BC SCAL/POTATOES	1.000	1 J	$1.99	$1.99	Betty Crocker Scalloped Potatoes
[redacted]	4.000	1 J	$1.00	$4.00	[redacted]
YELLOW ONIONS 3.0 LB	1.000	1 J	$2.99	$2.99	YELLOW ONIONS 3.0 LB
ESSENTIAL EVERYDAY MINI PRETZELS	1.000	1 J	$1.79	$1.79	ESSENTIAL EVERYDAY MINI PRETZELS
HUNT'S MANWICH SLOPPY JOE SAUCE	1.000	1 J	$1.25	$1.25	HUNT'S MANWICH SLOPPY JOE SAUCE
PEPPERS GREEN BELL	1.000	1 J	$1.69	$1.69	PEPPERS GREEN BELL
JELL-O GELATIN DESSERT STRAWBERR	1.000	1 J	$1.29	$1.29	JELL-O GELATIN DESSERT STRAWBERRY
JELL-O GELATIN DESSERT STRAWBERR	1.000	1 J	$1.29	$1.29	JELL-O GELATIN DESSERT STRAWBERRY
EEDY OREGANO LEAVES	1.000	1 J	$1.79	$1.79	Essential everyday OREGANO LEAVES
GRAPES RED SDLSS	2.690	1 J	$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 #: XXXXXXXXXX				$.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,

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

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

References:

1. Brown LG, Ripley D, Blade H, Reimann D, Everstine K, Nicholas D, Egan J, Koktavy N, Quilliam DN. Restaurant food cooling practices. J Food Protect 2012;75(12):2172-2178.
2. Brown LG, Le B, Wong M, Reimann D, Nicholas D, Faw B, Davis E, Selman C. 2014. Restaurant manager and worker food safety certification and knowledge. Food Path Dis 2014;11(11):835-843.
3. Dewey-Mattia D, Manikonda K, Hall AJ, Wise ME, Crowe SJ. Surveillance for foodborne disease outbreaks—United States, 2009-2015. Morb Mortal Wkly Rep 2018;67(10):1-11.
4. Doyle, E. Survival and growth of *Clostridium perfringens* during the cooling step of thermal processing of meat products: A review of the scientific literature. Available at: https://fri.wisc.edu/files/Briefs_File/cperfsurvivgrow.pdf. 2002.
5. Gould HL, Rosenblum I, Nicholas D, Phan Q, Jones TF. Contributing factors in restaurant-associated foodborne disease outbreaks, FoodNet sites, 2006 and 2007. J Food Protect 2013;76(11):1824-1828.
6. Green L, and Selman C. Factors impacting food workers' and managers' safe food preparation practices: a qualitative study. Food Protection Trends 2005;25(12), 981–990.
7. Hedeen N, and Smith K. Restaurant practices for cooling food in Minnesota: an intervention study. Foodborne Pathogens and Disease 2020;17(12), 758-763.
8. Hedeen N, Schaffner D, and Brown LG. Tools and techniques to promote proper food cooling in restaurants. J Env. Health 2022;84(7):8-11.
9. Igo M, Hedeen N, and Schaffner DW. Validation of a simple two-point method to assess restaurant compliance with food code cooling rates. J Food Protect 2020;84(1):6-13.
10. Lipcsei LE, Brown LG, Coleman EW, Kramer A, Masters M, Wittry BC, Reed K, Radke VJ. Foodborne illness outbreaks at retail establishments—National environmental assessment reporting system, 16 state and local health departments, 2014-2016. Morb Mortal Wkly Rep 2019;68(1):1-14.
11. U.S. Food and Drug Administration. FDA report on the occurrence of foodborne illness risk factors in fast food and full-service restaurants, 2013-2014. Available at: https://www.fda.gov/media/117509/download. 2018.
12. Schaffner DW, Brown L, Ripley D, Reimann D, Koktavy N, Blade H, and Nicholas D. Quantitative data analysis to determine best food cooling practices in U.S. restaurants. J Food Protect 2015;78(4):778-783.
13. Washington State Department of Health. Retail Food Code Chapter 246-215 WAC , 03515. Temperature and time control--Cooling (FDA Food Code 3-501.14). Available at: https://doh.wa.gov/sites/default/files/legacy/Documents/4400/FoodCodeRuleRevision-WAC246215-EffectiveMarch12022.pdf?uid=6386926f12346. 2022
14. Wittry BC, Holst M, Anderberg J, and Hedeen N. Operational antecedents associated with *Clostridum perfringens* outbreaks in retail food establishments, United States, 2015-2018. Foodborne Pathogens and Disease 2022;19(3):209-216.

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.

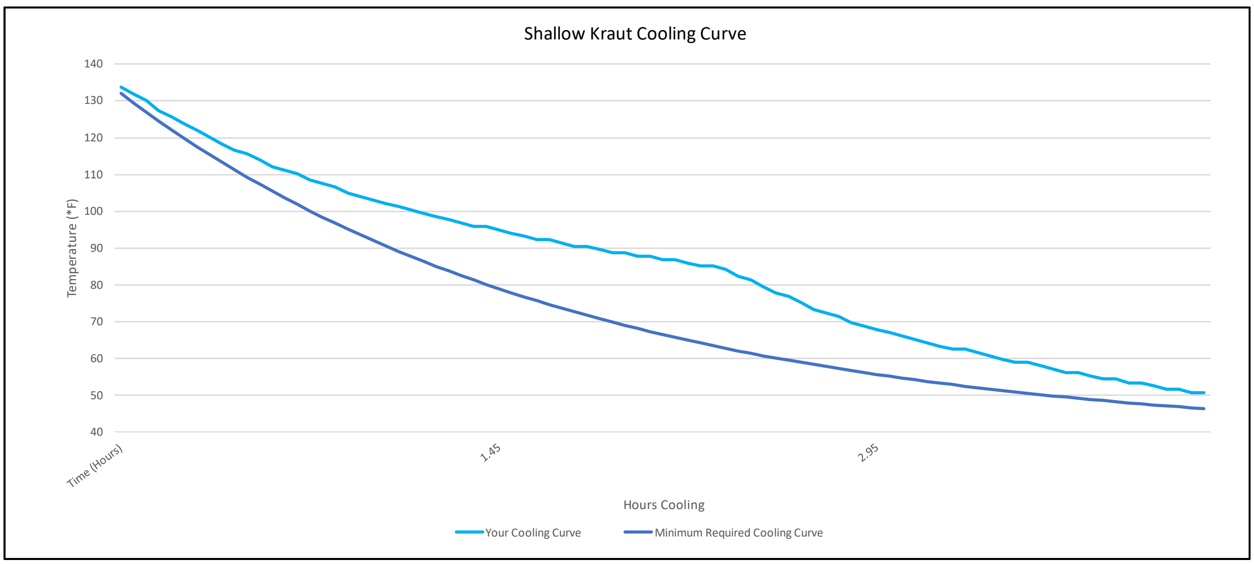
There are two instances where 2-inch cooling would appear be “risky” but are explained by mitigating circumstances. These two instances are for Sausage Gravy and Shallow Kraut. The cooling curve for Shallow Kraut is biphasic, which indicates that the ambient temperature changed during the cooling process. 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

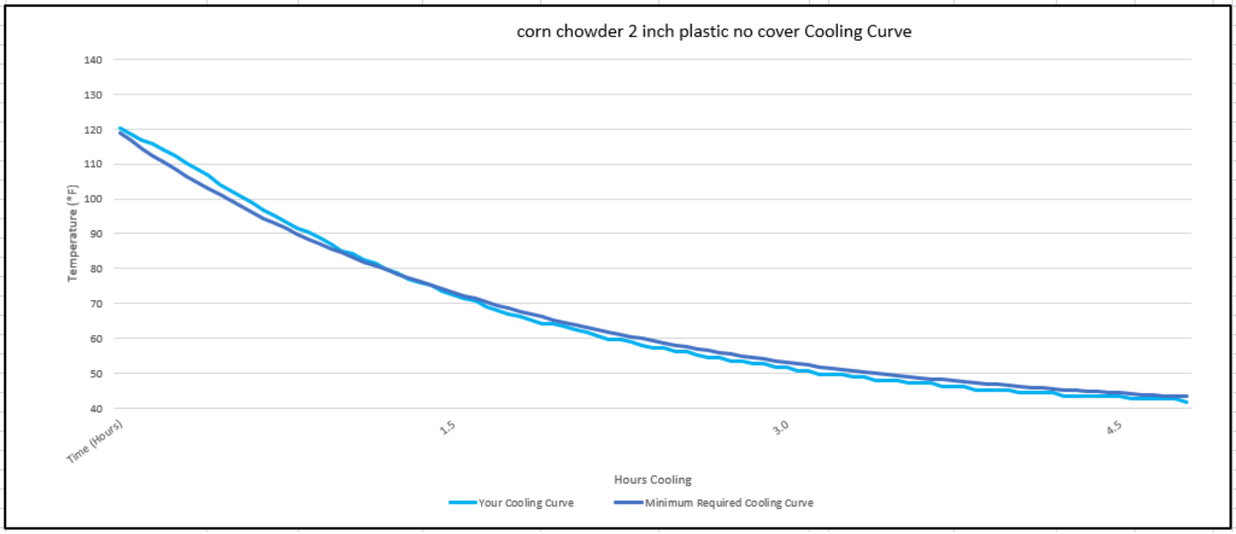
* The determination of cooling curves that “almost” meet the food code is somewhat subjective but these are curves where (a) the first phase of cooling happens more rapidly than the food code allows while the second part happens more slowly, (b) where the first part of the curve matches the food code 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.**

Journal of Food Protection, Vol. 75, No. 12, 2012, Pages 2172–2178
doi:10.4315/0362-028X.JFP-12-256

Restaurant Food Cooling Practices†

LAURA GREEN BROWN,[1]* DANNY RIPLEY,[2] HENRY BLADE,[3] DAVE REIMANN,[4] KAREN EVERSTINE,[5] DAVE NICHOLAS,[6] JESSICA EGAN,[6] NICOLE KOKTAVY,[5] DANIELA N. QUILLIAM,[3] AND THE EHS-NET WORKING GROUP[1]

[1]*National Center for Environmental Health, Centers for Disease Control and Prevention, MS F60, 4770 Buford Highway, Atlanta, Georgia 30341;* [2]*Metro Nashville–Davidson County Public Health Department, 311 23rd Avenue, North Nashville, Tennessee 37203;* [3]*Rhode Island Department of Health, 3 Capitol Hill, Cannon Building, Room 203, Providence, Rhode Island 02908;* [4]*Minnesota Department of Health, 12 Civic Center Plaza, Suite 2105, Mankato, Minnesota 56001;* [5]*Minnesota Department of Health, 625 Robert Street North, Saint Paul, Minnesota 55164; and* [6]*New York State Department of Health, Bureau of Community Environmental Health & Food Protection, 547 River Street, Flannigan Square, Room 515, Troy, New York 12180, USA*

MS 12-256: Received 5 June 2012/Accepted 17 August 2012

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.

* Author for correspondence. Tel: 770-488-4332; Fax: 770-488-7310; E-mail: lrgreen@cdc.gov.

† This publication is based on data collected and provided by the Centers for Disease Control and Prevention's Environmental Health Specialists Network (EHS-Net). The findings and conclusions in this report are those of the author(s) and do not necessarily represent the views of the Centers for Disease Control and Prevention/the Agency for Toxic Substances and Disease Registry.

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.

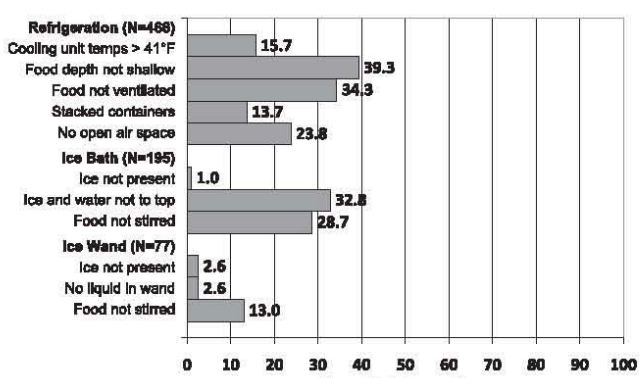


FIGURE 1. *Frequencies of improper food cooling practices observed in refrigeration, ice bath, and ice wand steps in 410 restaurants.*

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.

ACKNOWLEDGMENTS

This study was conducted by states receiving CDC grant awards funded under CDC-RFA-EH10-001. We thank Glenda Lewis, Kevin Smith, and Laurie Williams with the FDA; Scott Seys and Patsy White with the USDA; and Robert Tauxe and Brenda Le with the CDC for helpful comments on the manuscript. We also thank the restaurant managers and owners who participated in this study.

REFERENCES

1. Centers for Disease Control and Prevention. 2012. Foodborne Outbreak Reporting System. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta.
2. Clayton, D., C. Griffith, P. Price, and A. Peters. 2002. Food handlers' beliefs and self-reported practices. *Int. J. Environ. Health Res.* 12: 25–39.
3. Green, L., and C. Selman. 2005. Factors impacting food worker's and managers' safe food preparation practices: a qualitative study. *Food Prot. Trends* 25:981–990.
4. U.S. Food and Drug Administration. Chap. 3—Food; Part 3-5—Limitation of growth of organisms of public health concern. *In*: Food Code 2009. Available at: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/ucm186451.htm#part3-5. Accessed 24 April 2012.
5. U.S. Food and Drug Administration. Food Code, 2009: Annex 4—management of food safety practices—achieving active managerial control of foodborne illness risk factors. Available at: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/ucm188363.htm. Accessed 24 April 2012.
6. U.S. Food and Drug Administration. 2009. FDA report on the occurrence of foodborne illness risk factors in selected institutional foodservice, restaurant, and retail food store facility types. Available at: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm224338.htm. Accessed 24 April 2012.

Journal of Food Protection, Vol. 78, No. 4, 2015, Pages 778–783
doi:10.4315/0362-028X.JFP-14-252

Quantitative Data Analysis To Determine Best Food Cooling Practices in U.S. Restaurants†

DONALD W. SCHAFFNER,[1]* LAURA GREEN BROWN,[2] DANNY RIPLEY,[3] DAVE REIMANN,[4] NICOLE KOKTAVY,[5] HENRY BLADE,[6] AND DAVID NICHOLAS[7]

[1]*Food Science Department, Rutgers University, 65 Dudley Road, New Brunswick, New Jersey 08901;* [2]*National Center for Environmental Health, Centers for Disease Control and Prevention, MS F60, 4770 Buford Highway, Chamblee, Georgia 30341;* [3]*Metro Nashville/Davidson County Public Health Department, 311 23rd Avenue North, Nashville, Tennessee 37203;* [4]*Minnesota Department of Health, 12 Civic Center Plaza, Suite 2105, Mankato, Minnesota 56001;* [5]*Minnesota Department of Health, 625 Robert Street North, Saint Paul, Minnesota 55164;* [6]*Rhode Island Department of Health, 3 Capitol Hill, Cannon Building, Room 203, Providence, Rhode Island 02908; and* [7]*New York State Department of Health, Bureau of Community Environmental Health and Food Protection, Corning Tower, Empire State Plaza, Albany, New York 12237, USA*

MS 14-252: Received 30 May 2014/Accepted 1 September 2014

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)*.

* Author for correspondence. Tel: 732-982-7475; Fax: 732-932-6776; E-mail: schaffner@aesop.rutgers.edu.

† This publication is based on data collected and provided by the Centers for Disease Control and Prevention's (CDC) Environmental Health Specialists Network (EHS-Net). The findings and conclusions in this report are those of the author(s) and do not necessarily represent the views of the CDC/the Agency for Toxic Substances and Disease Registry.

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

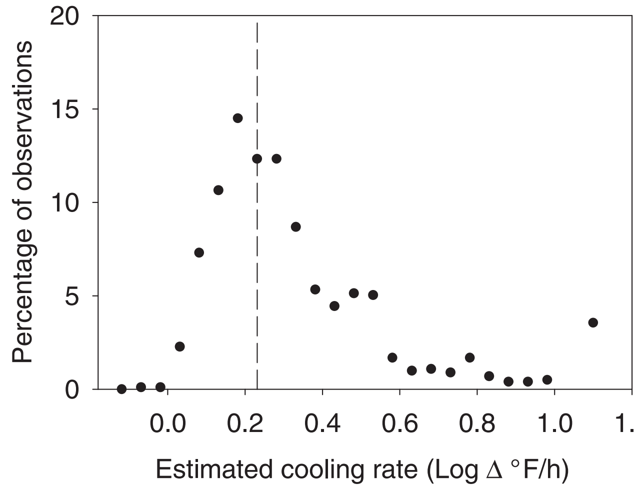


FIGURE 1. *Frequency distribution of estimated cooling rates of 1,014 observations of cooling food. Food Code cooling rate is 0.23 (cooling to 41°F [5°C] within 6 h), indicated by the dotted vertical line.*

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.

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

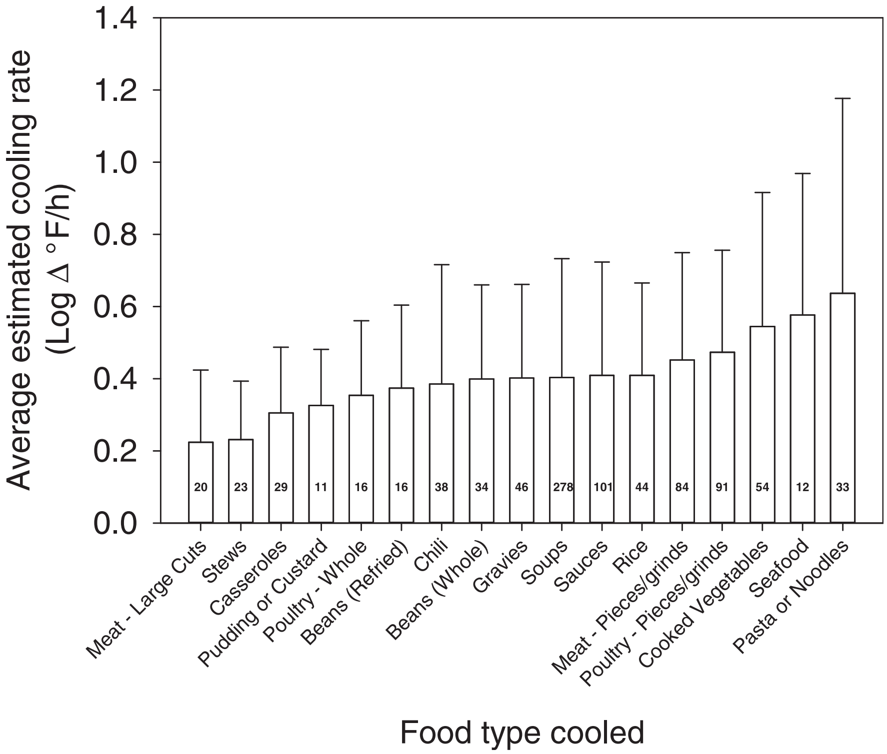


FIGURE 2. *Relationship between food type and the average estimated cooling rate. Food Code cooling rate is 0.23 (cooling to 41°F [5°C] within 6 h). Error bars represent the standard deviation of the cooling rate, and numbers superimposed on the bars represent the number of times each cooling rate was 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

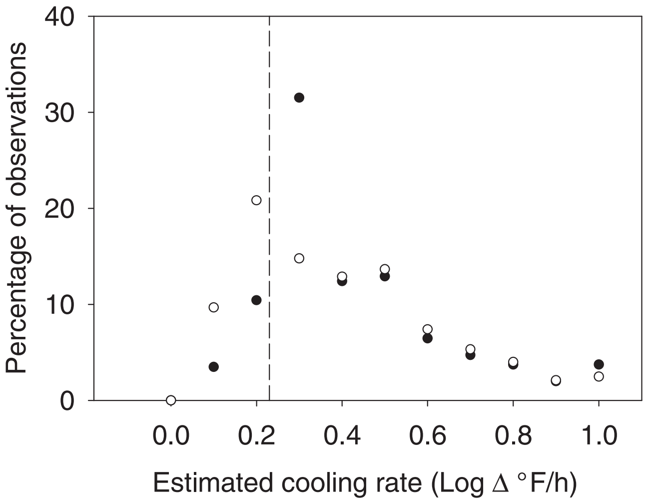


FIGURE 3. *Effect of active temperature monitoring by food workers and estimated cooling rate. Closed circles indicate cooling rates for monitored food; open circles indicate cooling rates for unmonitored food. Food Code cooling rate is 0.23 (cooling to 41°F [5°C] within 6 h), indicated by the dotted vertical line.*

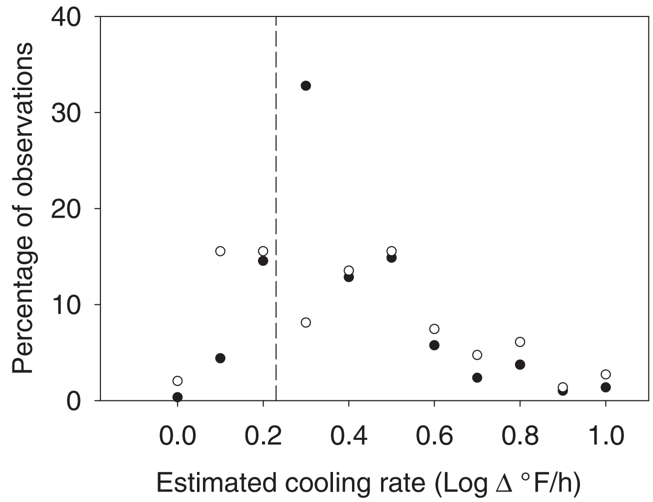


FIGURE 5. *Effect of ventilation on estimated cooling rate. Closed circles indicate ventilated food cooling rates; open circles indicate unventilated food cooling rates. Food Code cooling rate is 0.23 (cooling to 41°F [5°C] within 6 h), indicated by the dotted vertical line.*

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.

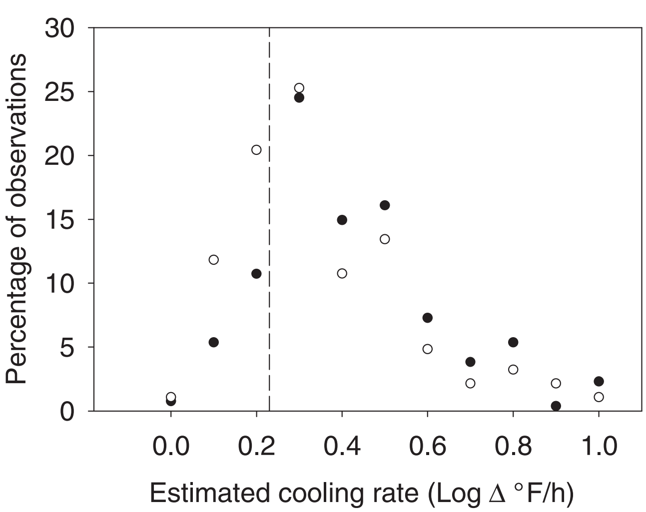


FIGURE 4. *Effect of food depth on estimated cooling rate. Cooling rates for food in shallow pans (≤3 in. [7.6 cm] deep) indicated by closed circles; cooling rates for food in deep pans (>3 in. [7.6 cm] deep) indicated by open circles. Food Code cooling rate is 0.23 (cooling to 41°F [5°C] within 6 h), 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.

REFERENCES

1. Brown, L. G., D. Ripley, H. Blade, D. Reimann, K. Everstine, D. Nicholas, J. Egan, N. Koktavy, and D. N. Quilliam. 2012. Restaurant food cooling practices. *J. Food Prot.* 75:2172–2178.
2. Cevallos-Cevallos, J. M., E. D. Akins, L. M. Friedrich, M. D. Danyluk, and A. H. Simonne. 2012. Growth of *Clostridium perfringens* during cooling of refried beans. *J. Food Prot.* 75:1783–1790.
3. de Jong, A. E. I., R. R. Beumer, and M. H. Zwietering. 2005. Modeling growth of *Clostridium perfringens* in pea soup during cooling. *Risk Anal.* 25:61–73.
4. de Jong, A. E. I., F. M. Rombouts, and R. R. Beumer. 2004. Effect of cooling on *Clostridium perfringens* in pea soup. *J. Food Prot.* 67: 352–356.
5. Gould, L. H., I. Rosenblum, D. Nicholas, Q. Phan, and T. F. Jones. 2013. Contributing factors in restaurant-associated foodborne disease outbreaks, FoodNet sites, 2006 and 2007. *J. Food Prot.* 76:1824–1828.
6. Le Marc, Y., J. Plowman, C. F. Aldus, M. Munoz-Cuevas, J. Baranyi, and M. W. Peck. 2008. Modelling the growth of *Clostridium perfringens* during the cooling of bulk meat. *Int. J. Food Microbiol.* 128:41–50.
7. Lynch, M., J. Painter, R. Woodruff, and C. Braden. 2006. Surveillance for foodborne-disease outbreaks—United States, 1998–2002. *Morb. Mortal. Wkly. Rep.* 55:1–48.
8. Selman, C., and J. Guzewich. 2013. Environmental assessment in outbreak investigations, p. 98–106. *In* Y. Motarjemi, G. Moy, and E. Todd (ed.), Encyclopedia of food safety, vol. 4. Academic Press, Waltham, MA.
9. Smith-Simpson, S., and D. W. Schaffner. 2005. Development of a model to predict growth of *Clostridium perfringens* in cooked beef during cooling. *J. Food Prot.* 68:336–341.
10. Snyder, O. P. 1999. The basics of cooling food. Available at: http://www.hi-tm.com/Documents/Basic-cool.html. Accessed 20 February 2014.
11. Taormina, P. J., and W. J. Dorsa. 2004. Growth potential of *Clostridium perfringens* during cooling of cooked meats. *J. Food Prot.* 67:1537–1547.
12. U.S. Department of Agriculture, Food Safety and Inspection Service. 1999. Appendix B, Compliance guidelines for cooling heat-treated meat and poultry products (stabilization). Available at: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F/95-033F_Appendix%20B.htm. Accessed 20 February 2014.
13. U.S. Food and Drug Administration. 2009. Chap. 2—Management and personnel, part 2-1—Supervision. *In* FDA Food Code 2009. Available at: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm181242.htm. Accessed 20 February 2014.
14. U.S. Food and Drug Administration. 2009. Chap. 3—Food, part 3-5—Limitation of growth of organisms of public health concern. *In* FDA Food Code 2009. Available at: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm186451.htm#part3-5. Accessed 20 February 2014.
15. U.S. Food and Drug Administration. 2009. FDA report on the occurrence of foodborne illness risk factors in selected institutional foodservice, restaurant, and retail food store facility types. Available at: http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM224682.pdf. Accessed 20 February 2014.

FOODBORNE PATHOGENS AND DISEASE
Volume XX, Number XX, 2020

DOI: 10.1089/fpd.2020.2801

Restaurant Practices for Cooling Food in Minnesota: An Intervention Study

Nicole Hedeen[1] and Kirk Smith[2]

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

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

[1]Environmental Health Division and [2]Infectious Disease Epidemiology, Prevention and Control Division, Minnesota Department of Health, St. Paul, Minnesota, USA.

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.

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.

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.

Acknowledgments

The authors would like to extend special thanks to the sanitarians who allowed them to collect data within their inspecting jurisdictions and to Leeann Austin (MDH), Deanna Scher (MDH), Kim Carlton (MDH), Dr. Laura Brown (CDC), Dr. E. Rickamer Hoover (Laulima Government Solutions, LLC), and Greg Stevens (MDH).

Disclosure Statement

No competing financial interests exist.

Funding Information

This study was supported by CDC awards funded under the Environmental Health Specialists Network Cooperative Agreement (grant no. U01-EH001295-02).

Supplementary Material

Supplementary Figure S1
Supplementary Figure S2
Supplementary Figure S3
Supplementary Figure S4

References

Bjorndal L. Carryover effects: What are they, why are they problematic, and what can you do about them? 2018. Available at: https://www.students4bestevidence.net/carryover-effects-what-are-they-why-are-they-problematic-and-what-can-you-do-about-them/, accessed August 26, 2019.

Brown LG, Le B, Wong M, Reimann D, Nicholas D, Faw B, Davis E, Selman C. 2014. Restaurant manager and worker food safety certification and knowledge. Food Path Dis 2014; 11:835–843.

Brown LG, Ripley D, Blade H, Reimann D, Everstine K, Nicholas D, Egan J, Koktavy N, Quilliam DN. Restaurant food cooling practices. J Food Protect 2012;75:2172–2178.

Centers for Disease Control and Prevention. *Clostridium perfringens*. 2018. Available at: https://www.cdc.gov/foodsafety/diseases/clostridium-perfringens.html, accessed August 26, 2019.

Dewey-Mattia D, Manikonda K, Hall AJ, Wise ME, Crowe SJ. Surveillance for foodborne disease outbreaks—United States, 2009–2015. Morb Mortal Wkly Rep 2018;67:1–11.

Doyle, E. Survival and growth of *Clostridium perfringens* during the cooling step of thermal processing of meat products: A review of the scientific literature. 2002. Available at: https://fri.wisc.edu/files/Briefs_File/cperfsurvivgrow.pdf, accessed August 26, 2019.

Gould HL, Rosenblum I, Nicholas D, Phan Q, Jones TF. Contributing factors in restaurant-associated foodborne disease outbreaks, FoodNet sites, 2006 and 2007. J Food Protect 2013;76:1824–1828.

Lipcsei LE, Brown LG, Coleman EW, Kramer A, Masters M, Wittry BC, Reed K, Radke VJ. Foodborne illness outbreaks at retail establishments—National environmental assessment reporting system, 16 state and local health departments, 2014–2016. Morb Mortal Wkly Rep 2019;68:1–14.

Minnesota Department of Health and Department of Agriculture. Minnesota Food Code: Cooling (MN 4626.0385). 1998. Available at: https://www.revisor.mn.gov/rules/4626/date/1998, accessed December 15, 2019.

Schaffner DW, Brown L, Ripley D, Reimann D, Koktavy N, Blade H, and Nicholas D. Quantitative data analysis to determine best food cooling practices in U.S. restaurants. J Food Protect 2015;78:778–783.

University of Minnesota Extension. What is the risk? Cooling hot food. 2018. Available at: https://extension.umn.edu/food-service-industry/what-risk-cooling-hot-food, accessed August 26, 2019.

U.S. Food and Drug Administration. FDA report on the occurrence of foodborne illness risk factors in fast food and full-service restaurants, 2013–2014. 2018. Available at: https://www.fda.gov/media/117509/download, accessed May 13, 2019.

U.S. Food and Drug Administration. FDA Food Code 2017: Annex 3—Public health reasons/administrative guidelines. 2017. Available at: https://www.fda.gov/media/110822/download, accessed May 13, 2019.

U.S. Food and Drug Administration. FDA Food Code 2017: Chapter 3, food. 2017. Available at: https://www.fda.gov/media/110822/download, accessed May 13, 2019.

U.S. Food and Drug Administration. Danger Zone. 2017. Available at: https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/danger-zone-40-f-140-f/CT_Index, accessed May 13, 2019.

Address correspondence to:
Nicole Hedeen, MS
Environmental Health Division
Minnesota Department of Health
625 Robert Street North
St. Paul, MN 55164
USA

E-mail: nicole.hedeen@state.mn.us

Journal of Food Protection, Vol. 84, No. 1, 2021, Pages 6–13
https://doi.org/10.4315/JFP-20-257

Research Paper

Validation of a Simple Two-Point Method To Assess Restaurant Compliance with Food Code Cooling Rates

MATTHEW J. IGO,[1] NICOLE HEDEEN,[2] AND DONALD W. SCHAFFNER[1]*

[1]Department of Food Science, Rutgers University, 65 Dudley Road, New Brunswick, New Jersey 08901 (ORCID: https://orcid.org/0000-0001-9200-0400 [D.W.S.]); and [2]Minnesota Department of Health, 625 North Robert Street, P.O. Box 64975, St. Paul, Minnesota 55164, USA

MS 20-257: Received 1 July 2020/Accepted 1 August 2020/Published Online 7 August 2020

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 ≥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 ≥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

* Author for correspondence. Tel: 848-932-5411; Fax: 732-932-6776; E-mail: don.schaffner@rutgers.edu.

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 $[\text{Log}(T_1 - T_{df}) - \text{Log}(T_2 - T_{df})]/t$, 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)					Simulation predicted cooling rate relative to 0.23 (1/h)[a]		
	Summary statistics			Upper and lower percentiles				
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).

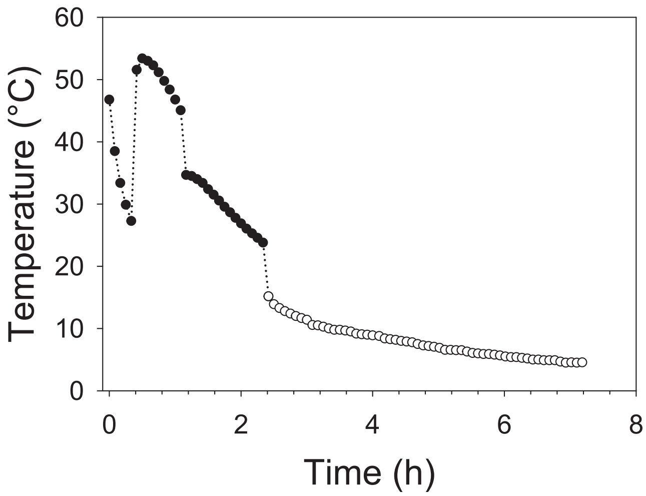


FIGURE 1. *Atypical cooling profile for Alfredo sauce. Solid circles, times and temperatures associated with product temperatures between 60.0 and 21.1°C (140 and 70°F). Open circles, times and temperatures associated with product temperatures between 21.0 and 4.4°C (70 and 41°F).*

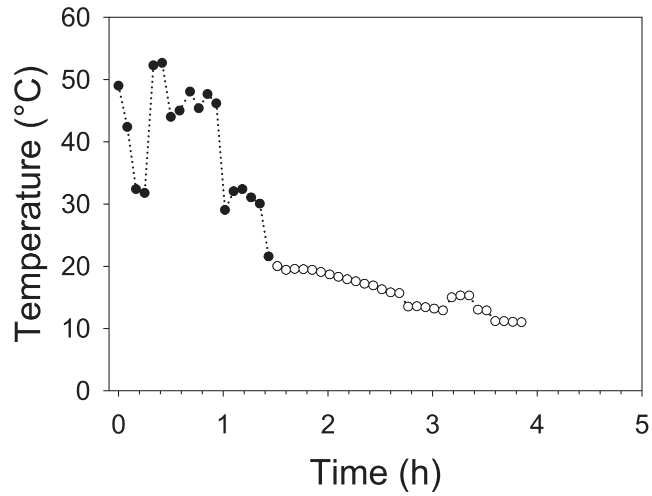


FIGURE 2. *Atypical cooling profile for chicken wild rice soup. Solid circles, times and temperatures associated with product temperatures between 60.0 and 21.1°C (140 and 70°F). Open circles, times and temperatures associated with product temperatures between 21.0 and 4.4°C (70 and 41°F).*

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

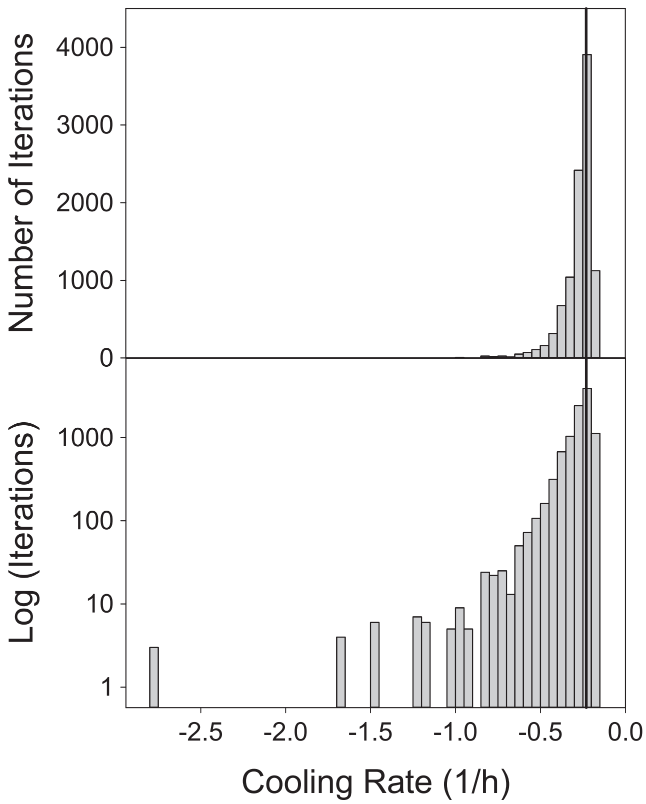


FIGURE 3. *Distribution of simulated cooling rates from the Alfredo sauce simulation. Top panel, distributions of iterations; bottom panel, log (iterations). Vertical black line, –0.23 (1/h), is equivalent to the FDA Model Food Code cooling rate. Cooling rates to the right of the black line are slower than permitted, whereas cooling rates to the left are faster than permitted.*

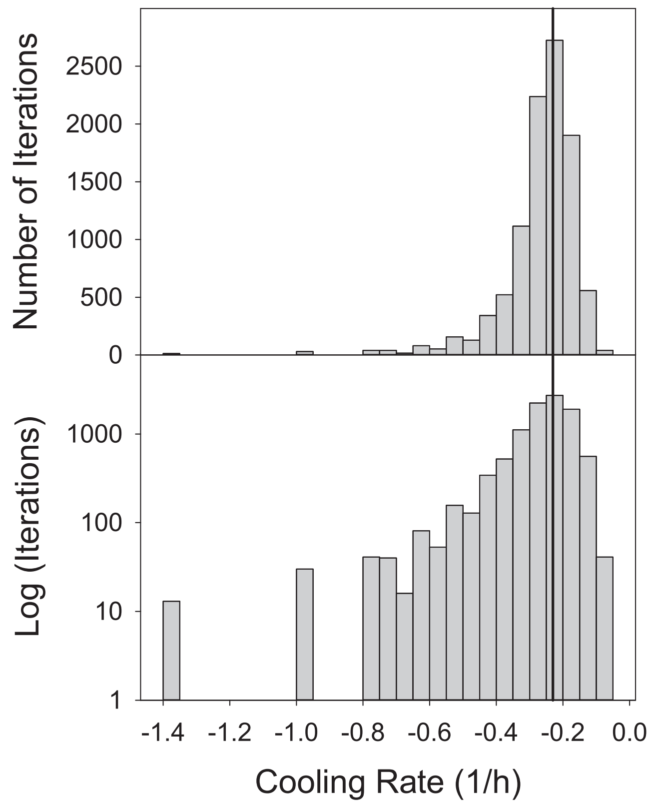


FIGURE 4. *Distribution of simulated cooling rates from the chicken wild rice soup simulation. Top panel, distributions of iterations; bottom panel, log (iterations). Vertical black line, –0.23 (1/h), is equivalent to the FDA Model Food Code cooling rate. Cooling rates to the right of the black line 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 ≥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.

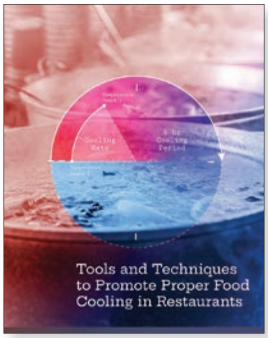
C. perfringens is the pathogen that is most closely associated with foodborne illnesses related to the cooling of foods *(1, 21)*. *C. perfringens* spores can survive the cooking process, and during inadequate cooling, the spores can begin to germinate and grow to levels that could cause illness *(18)*. *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.

REFERENCES

1. Amezquita, A., C. Weller, L. Wang, H. Thippareddi, and D. Burson. 2005. Development of an integrated model for heat transfer and dynamic growth of *Clostridium perfringens* during the cooling of cooked boneless ham. *Int. J. Food Microbiol*. 101:123–144.
2. Beardall, L., P. Paez, R. K. Phebus, T. Watkins, and S. E. Gragg. 2019. Control of *Bacillus cereus* populations in brown rice by use of common foodservice cooling methods. *Food Prot. Trends* 39:145–153.
3. Bennett, S. D., K. A. Walsh, and L. H. Gould. 2013. Foodborne disease outbreaks caused by *Bacillus cereus, Clostridium perfringens,* and *Staphylococcus aureus*—United States, 1998–2008. *Clin. Infect. Dis*. 57:425–433.
4. Brown, L. G., D. Ripley, H. Blade, D. Reimann, K. Everstine, D. Nicholas, J. Egan, N. Koktavy, D. N. Quilliam, and EHS-NET Working Group. 2012. Restaurant food cooling practices. *J. Food Prot*. 75:2172–2178.
5. Bryan, F. L. 1988. Risks of practices, procedures and processes that lead to outbreaks of foodborne diseases. *J. Food Prot*. 51:663–673.
6. Brynestad, S., and P. E. Granum. 2002. *Clostridium perfringens* and foodborne infections. *Int. J. Food Microbiol*. 74:195–202.
7. Cevallos-Cevallos, J. M., E. D. Akins, L. M. Friedrich, M. D. Danyluk, and A. H. Simonne. 2012. Growth of *Clostridium perfringens* during cooling of refried beans. *J. Food Prot*. 75:1783–1790.
8. Cronin, U. P., and M. G. Wilkinson. 2009. The growth, physiology and toxigenic potential of *Bacillus cereus* in cooked rice during storage temperature abuse. *Food Control* 20:822–828.
9. De Jong, A. E., R. R. Beumer, and M. H. Zwietering. 2005. Modeling growth of *Clostridium perfringens* in pea soup during cooling. *Risk Anal*. 25:61–73.
10. De Jong, A. E., F. Rombouts, and R. Beumer. 2004. Behavior of *Clostridium perfringens* at low temperatures. *Int. J. Food Microbiol*. 97:71–80.
11. Dewey-Mattia, D., K. Manikonda, A. J. Hall, M. E. Wise, and S. J. Crowe. 2018. Surveillance for foodborne disease outbreaks—United States, 2009–2015. *MMWR Surveill. Summ*. 67:1.
12. Dominianni, C., K. Lane, M. Ahmed, S. Johnson, W. McKelvey, and K. Ito. 2018. Hot weather impacts on New York City restaurant food safety violations and operations. *J. Food Prot*. 81:1048–1054.
13. Dréan, P., C. M. McAuley, S. C. Moore, N. Fegan, and E. M. Fox. 2015. Characterization of the spore-forming *Bacillus cereus* sensu lato group and *Clostridium perfringens* bacteria isolated from the Australian dairy farm environment. *BMC Microbiol*. 15:38.
14. Gould, L. H., I. Rosenblum, D. Nicholas, Q. Phan, and T. F. Jones. 2013. Contributing factors in restaurant-associated foodborne disease outbreaks, FoodNet sites, 2006 and 2007. *J. Food Prot*. 76:1824–1828.
15. Grass, J. E., L. H. Gould, and B. E. Mahon. 2013. Epidemiology of foodborne disease outbreaks caused by *Clostridium perfringens,* United States, 1998–2010. *Foodborne Pathog. Dis*. 10:131–136.
16. Green, L. R., and C. Selman. 2005. Factors impacting food workers' and managers' safe food preparation practices: a qualitative study. *Food Prot. Trends* 25:981–990.
17. Hedeen, N., and K. Smith. Restaurant practices for cooling food in Minnesota: an intervention study. *Foodborne Pathog. Dis.,* in press. https://doi.org/10.1089/fpd.2020.2801
18. Huang, L., C. Li, and C.-A. Hwang. 2018. Growth/no growth boundary of *Clostridium perfringens* from spores in cooked meat: a logistic analysis. *Int. J. Food Microbiol*. 266:257–266.
19. Juneja, V. K., C. E. Golden, A. Mishra, M. A. Harrison, T. Mohr, and M. Silverman. 2019. Predictive model for growth of *Bacillus cereus* during cooling of cooked rice. *Int. J. Food Microbiol*. 290:49–58.
20. Juneja, V. K., T. B. Mohr, M. Silverman, and O. P. Snyder, Jr. 2018. Influence of cooling rate on growth of *Bacillus cereus* from spore inocula in cooked rice, beans, pasta, and combination products containing meat or poultry. *J. Food Prot*. 81:430–436.
21. Li, M., L. Huang, Y. Zhu, and Q. Wei. 2019. Growth of *Clostridium perfringens* in roasted chicken and braised beef during cooling—one-step dynamic analysis and modeling. *Food Control*. https://doi.org/10.1016/j.foodcont.2019.106739
22. Luo, K., J. Wang, S.-Y. Kim, S.-H. Kim, and D.-H. Oh. 2017. Experimental studies and modeling the behavior of anaerobic growth of *Clostridium perfringens* in cooked rice under non-isothermal conditions. *Food Control* 71:137–142.
23. Minnesota Department of Health and Department of Agriculture. 1998. Minnesota Food Code: Cooling (MN 4626.0385). Minnesota Department of Health and Department of Agriculture, St. Paul.
24. Rachtanapun, C., J. Tantala, P. Klinmalai, and S. Ratanasumawong. 2015. Effect of chitosan on *Bacillus cereus* inhibition and quality of cooked rice during storage. *Int. J. Food Sci. Technol*. 50:2419–2426.
25. Scallan, E., R. M. Hoekstra, F. J. Angulo, R. V. Tauxe, M.-A. Widdowson, S. L. Roy, J. L. Jones, and P. M. Griffin. 2011. Foodborne illness acquired in the United States—major pathogens. *Emerg. Infect. Dis*. 17:7–15.
26. Schaffner, D. W., L. G. Brown, D. Ripley, D. Reimann, N. Koktavy, H. Blade, and D. Nicholas. 2015. Quantitative data analysis to determine best food cooling practices in U.S. restaurants. *J. Food Prot*. 78:778–783.
27. Smith-Simpson, S., and D. W. Schaffner. 2005. Development of a model to predict growth of *Clostridium perfringens* in cooked beef during cooling. *J. Food Prot*. 68:336–341.
28. Todd, E. C., J. D. Greig, C. A. Bartleson, and B. S. Michaels. 2007. Outbreaks where food workers have been implicated in the spread of foodborne disease. Part 3. Factors contributing to outbreaks and description of outbreak categories. *J. Food Prot*. 70:2199–2217.
29. U.S. Food and Drug Administration. 2009. FDA report on the occurrence of foodborne illness risk factors in selected institutional foodservice, restaurant, and retail food store facility types 2009. Available at: https://wayback.archive-it.org/7993/20170406023004/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm224321.htm. Accessed 20 April 2020.
30. U.S. Food and Drug Administration. 2017. Food, chap. 3. *In* FDA Food Code 2017. U.S. Food and Drug Administration, Washington, DC.
31. Wen, Q., and B. A. McClane. 2004. Detection of enterotoxigenic *Clostridium perfringens* type A isolates in American retail foods. *Appl. Environ. Microbiol*. 70:2685–2691.

GUEST COMMENTARY



Tools and Techniques to Promote Proper Food Cooling in Restaurants

Nicole D. Hedeen, MS, RS
Environmental Health Division, Minnesota Department of Health

Donald Schaffner, PhD
Food Science Department, Rutgers University

Laura Green Brown, PhD
National Center for Environmental Health, Centers for Disease Control and Prevention

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 $[\text{Log}(T_1 - T_{df}) - \text{Log}(T_2 - T_{df})]/\delta t$) 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.

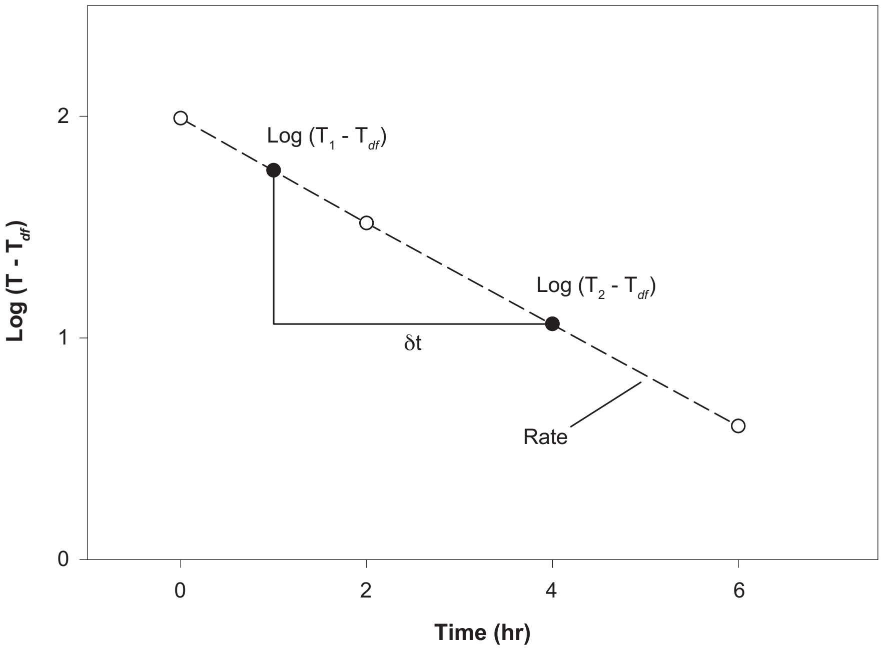
The Food and Drug Administration (FDA) model *Food Code* (Section 3-501.14) provides guidelines for retail and foodservice establishments to cool foods classified as needing time and temperature control for safety. These guidelines state that foods must be cooled from 135 °F (57 °C) to 70 °F (21 °C) 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 °F to 70 °F 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.

Corresponding Author: Nicole D. Hedeen, Senior Epidemiologist, Environmental Health Division, Minnesota Department of Health, 625 Robert Street North, Saint Paul, MN 55164. Email: nicole.hedeen@state.mn.us.

References

Brown, L.G., Ripley, D., Blade, H., Reimann, D., Everstine, K., Nicholas, D., Egan, J., Koktavy, N., Quilliam, D.N., & EHS-Net Working Group. (2012). Restaurant food cooling practices. *Journal of Food Protection*, *75*(12), 2172–2178. https://doi.org/10.4315/0362-028X.JFP-12-256

Food and Drug Administration. (2018). *FDA report on the occurrence of foodborne illness risk factors in fast food and full-service restaurants, 2013–2014*. https://www.fda.gov/media/117509/download

Gould, L.H., Rosenblum, I., Nicholas, D., Phan, Q., & Jones, T.F. (2013). Contributing factors in restaurant-associated foodborne disease outbreaks, FoodNet sites, 2006 and 2007. *Journal of Food Protection*, *76*(11), 1824–1828. https://doi.org/10.4315/0362-028X.JFP-13-037

Green, L., & Selman, C. (2005). Factors impacting food workers' and managers' safe food preparation practices: A qualitative study. *Food Protection Trends*, *25*(12), 981–990.

Hedeen, N., & Smith, K. (2020). Restaurant practices for cooling food in Minnesota: An intervention study. *Foodborne Pathogens and Disease*, *17*(12), 758–763. https://doi.org/10.1089/fpd.2020.2801

Igo, M.J., Hedeen, N., & Schaffner, D.W. (2021). Validation of a simple two-point method to assess restaurant compliance with *Food*

References

Code cooling rates. *Journal of Food Protection*, *84*(1), 6–13. https://doi.org/10.4315/JFP-20-257

Lipcsei, L.E., Brown, L.G., Coleman, E.W., Kramer, A., Masters, M., Wittry, B.C., Reed, K., & Radke, V.J. (2019). Foodborne illness outbreaks at retail establishments—National Environmental Assessment Reporting System, 16 state and local health departments, 2014–2016. *Morbidity and Mortality Weekly Report*, *68*(1), 1–20. http://doi.org/10.15585/mmwr.ss6801a1

Schaffner, D.W., Brown, L.G., Ripley, D., Reimann, D., Koktavy, N., Blade, H., & Nicholas, D. (2015). Quantitative data analysis to determine best food cooling practices in U.S. restaurants. *Journal of Food Protection*, *78*(4), 778–783. http://doi.org/10.4315/0362-028X.JFP-14-252

U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2017). *Food code: 2017 recommendations of the United States Public Health Service, Food and Drug Administration*. https://www.fda.gov/media/110822/download

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.

FOODBORNE PATHOGENS AND DISEASE
Volume XX, Number XX, 2022

DOI: 10.1089/fpd.2021.0068

Operational Antecedents Associated with *Clostridium perfringens* Outbreaks in Retail Food Establishments, United States, 2015–2018

Beth C. Wittry,[1,i] Meghan M. Holst,[1] Janet Anderberg,[2] and Nicole Hedeen[3]

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

[1]Centers for Disease Control and Prevention, National Center for Environmental Health, Atlanta, Georgia, USA.
[2]Food Safety Program, Washington State Department of Health, Olympia, Washington, USA.
[3]Environmental Health Division, Minnesota Department of Health, St. Paul, Minnesota, USA.
[i]ORCID ID (https://orcid.org/0000-0002-3891-4348).

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.

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.

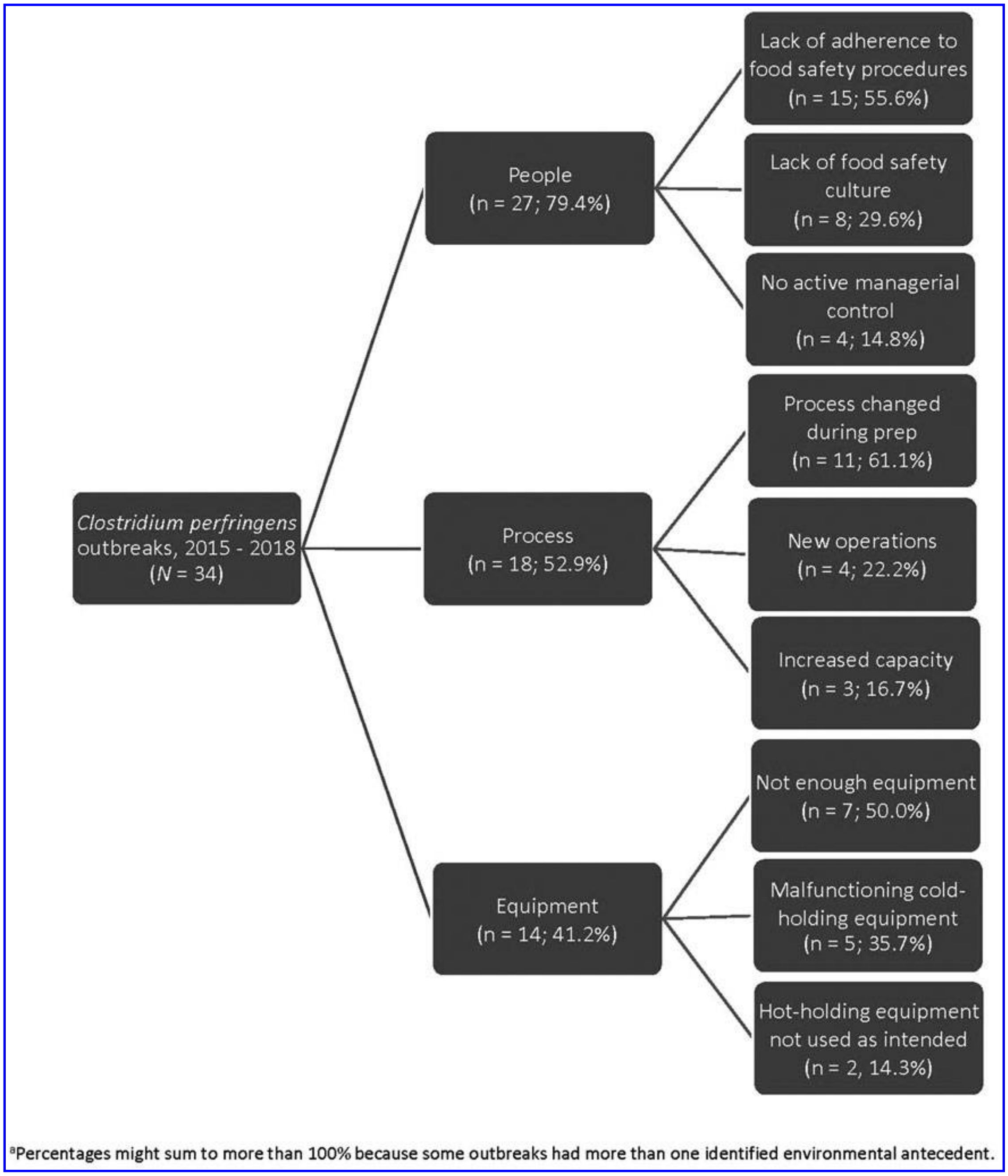


FIG. 1. Operational antecedents in *Clostridium perfringens* outbreaks, National Environmental Assessment Reporting System, 2015–2018 ($N = 34$).

(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?

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.

Acknowledgments

This publication is based, in part, on data collected and provided by the Centers for Disease Control and Prevention's (CDC) Environmental Health Specialists Network (EHS-Net), which is supported by a CDC grant award funded under RFA-EH-15-001. We thank the NEARS site staff who collected and entered their outbreak data. The findings and conclusions in this report are those of the authors and do not necessarily represent the views of CDC or the Agency for Toxic Substances and Disease Registry.

Disclosure Statement

No competing financial interests exist.

Funding Information

This project was also supported, in part, by an appointment to the Research Participation Program at CDC administered by the Oak Ridge Institute for Science and Education through an interagency agreement between the U.S. Department of Energy and CDC.

References

Brown LG, Hoover ER, Ripley D, Matis B, Nicholas D, Hedeen N, Faw B. Retail Deli Slicer cleaning frequency—Six selected sites, United States, 2012. Morb Mortal Wkly Rep 2016;65:306–310.

Brown LG, Hoover ER, Selman CA, Coleman EW, Schurz-Rogers H. Outbreak characteristics associated with identification of contributing factors to foodborne illness outbreaks. Epidemiol Infect 2017;145:2254–2262.

Brown LG, Le B, Wong MR, Reimann DW, Nicholas D, Faw B, Davis E, Selman CA. Restaurant manager and worker food safety certification and knowledge. Foodborne Pathog Dis 2014;11:835–843.

Brown LG, Ripley D, Blade H, Reimann D, Everstine K, Nicholas D, Egan J, Koktavy N, Quilliam DN. Restaurant food cooling practices. J Food Prot 2012;75:2172–2178.

[CDC] Centers for Disease Control and Prevention. Environmental assessment definitions. 2015, Available at: https://www.cdc.gov/nceh/ehs/nears/ea-definitions.htm#antecedents, accessed November 17, 2020.

[CDC] Centers for Disease Control and Prevention. Prevent illness from *C. perfringens*. Food Safety 2018, Available at: https://www.cdc.gov/foodsafety/diseases/clostridium-perfringens.html, accessed April 27, 2020.

[CDC] Centers for Disease Control and Prevention. National Environmental Assessment Reporting System (NEARS). Environmental Health Services. 2019, Available at: https://

www.cdc.gov/nceh/ehs/nears/index.htm, accessed April 5, 2021.

Corbin JM, Strauss A. Grounded theory research: Procedures, canons, and evaluative criteria. Qual Sociol 1990;13:3–21.

Green LR, Selman CA. Factors impacting food workers' and managers' safe food preparation practices: A qualitative study. Food Prot Trends 2005;25:981–990.

Hedberg CW, Smith S, Kirkland E, Radke V, Jones T. Systematic environmental evaluations to identify food safety differences between outbreak and non-outbreak restaurants. J Food Prot 2006;69:2697–2702.

Hedeen N, Smith K. Restaurant practices for cooling food in minnesota: An intervention study. Foodborne Pathog Dis 2020;17:758–763.

Hoover ER, Hedeen N, Freeland A, Kambhampati A, Dewey-Mattia D, Scott K, Hall AJ, Brown LG. Restaurant policies and practices related to norovirus outbreak size and duration. J Food Prot 2020;83:1607–1618.

Kalinowski RM, Tompkin RB, Bodnaruk PW, Pruett WP, Jr. Impact of cooking, cooling, and subsequent refrigeration on the growth or survival of *Clostridium perfringens* in cooked meat and poultry products. J Food Prot 2003;66:1227–1232.

Kramer A. Comparison of food establishment characteristics between viral and bacterial-caused foodborne outbreaks reported to the national environmental assessment reporting system. Kentucky International Convention Center 2019 International Association of Food Protection. 2019. Available at: https://www.foodprotection.org/upl/downloads/meeting/archive/5d489fb9158a2191f5c6.pdf, accessed November 10, 2020.

Kufel JSZ, Resnick BA, Fox MA, McGready J, Yager JP, Burke TA. The impact of local environmental health capacity on foodborne illness morbidity in maryland. Am J Public Health 2011;101:1495–1500.

Liggans GL, Boyer MS, Williams LB, Destromp KW, Hoang ST. Food safety management systems, certified food protection managers, and compliance with food safety practices associated with the control of listeria monocytogenes in foods at restaurants. J Food Prot 2019;82:1116–1123.

Lipcsei LE, Brown LG, Coleman EW, Kramer A, Masters M, Wittry BC, Reed K, Radke VJ. Foodborne illness outbreaks at retail establishments—National environmental assessment reporting system, 16 state and local health departments, 2014–2016. MMWR Surveill Summ 2019;68:1–20.

Oravetz M. Cooling protocol compliance of restaurants in Carson City and Douglas County NV. 2019, accessed November 10, 2020. Available at: https://www.ifpti.org/cohort-7/jwzz3nl9adr3eyct8v33lsdgqq51v0.

Powell DA, Jacob CJ, Chapman BJ. Enhancing food safety culture to reduce rates of foodborne illness. Food Control 2011;22:817–822.

Sahin H. The level of burnout of kitchen personnel in accommodation facilities. Int J Bus Soc Sci 2012;3:116–120.

Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, Jones JL, Griffin PM. Foodborne illness acquired in the United States—Major pathogens. Emerg Infect Dis 2011;17:7–15.

Selman CA, Guzewich JJ. Public health measures: Environmental assessment in outbreak investigations. In: Motarjemi Y, ed. *Encyclopedia of Food Safety*. Waltham, MA: Academic Press, 2014, pp. 98–106.

Smith-Simpson S, Schaffner DW. Development of a model to predict growth of *Clostridium perfringens* in cooked beef during cooling. J Food Prot 2005;68:336–341.

Sumner S, Brown LG, Frick R, Stone C, Carpenter LR, Bushnell L, Nicholas D, Mack J, Blade H, Tobin-D'Angelo M, Everstine K. Factors associated with food workers working while experiencing vomiting or diarrhea. J Food Prot 2011; 74:215–220.

Taormina PJ, Dorsa WJ. Growth potential of *Clostridium perfringens* during cooling of cooked meats. J Food Prot 2004; 67:1537–1547.

United States Food and Drug Administration (FDA). HACCP Principles and Application Guidelines. 2017a. Available at: https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/haccp-principles-application-guidelines, accessed November 10, 2020.

United States Food and Drug Administration (FDA). The Food Code 2017. 2017b. Available at: https://www.fda.gov/media/110822/download, accessed June 5, 2020.

United States Food and Drug Administration (FDA) National Retail Food Team. FDA report on the occurance of foodborne illness risk factors in fast food and full-service restaurants 2013–2014. 2018. Available at: https://www.fda.gov/media/117509/download, accessed July 19, 2020.

World Health Organization. Foodborne disease outbreaks: Guidelines for investigation and control. 2008. Available at: https://www.who.int/foodsafety/publications/foodborne_disease/outbreak_guidelines.pdf, accessed July 7, 2020.

Address correspondence to:
Beth C. Wittry, MPH
Centers for Disease Control and Prevention
National Center for Environmental Health
4770 Buford Highway
Atlanta, GA 30341
USA

E-mail: xks5@cdc.gov

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
Vice President
(206) 423-4816
Home Office
3401 Lind Avenue SW
Renton, WA 98057

applied sciences

MDPI

Article

Effect of Time and Temperature on Physicochemical and Microbiological Properties of Sous Vide Chicken Breast Fillets

Hossein Haghighi [1,*,†], Anna Maria Belmonte [1,†], Francesca Masino [1,2], Giovanna Minelli [1,2], Domenico Pietro Lo Fiego [1,2] and Andrea Pulvirenti [1,2]

1 Department of Life Sciences, University of Modena and Reggio Emilia, 42122 Reggio Emilia, Italy; 71483@studenti.unimore.it (A.M.B.); francesca.masino@unimore.it (F.M.); giovanna.minelli@unimore.it (G.M.); domenicopietro.lofiego@unimore.it (D.P.L.F.); andrea.pulvirenti@unimore.it (A.P.)

2 Interdepartmental Research Centre BIOGEST-SITEIA, University of Modena and Reggio Emilia, 42124 Reggio Emilia, Italy

* Correspondence: hossein.haghighi@unimore.it

† Share first authorship.

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

check for updates

Citation: Haghighi, H.; Belmonte, A.M.; Masino, F.; Minelli, G.; Lo Fiego, D.P.; Pulvirenti, A. Effect of Time and Temperature on Physicochemical and Microbiological Properties of Sous Vide Chicken Breast Fillets. *Appl. Sci.* **2021**, *11*, 3189. https://doi.org/10.3390/app11073189

Academic Editor: Isidoro Garcia-Garcia

Received: 25 February 2021
Accepted: 30 March 2021
Published: 2 April 2021

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].

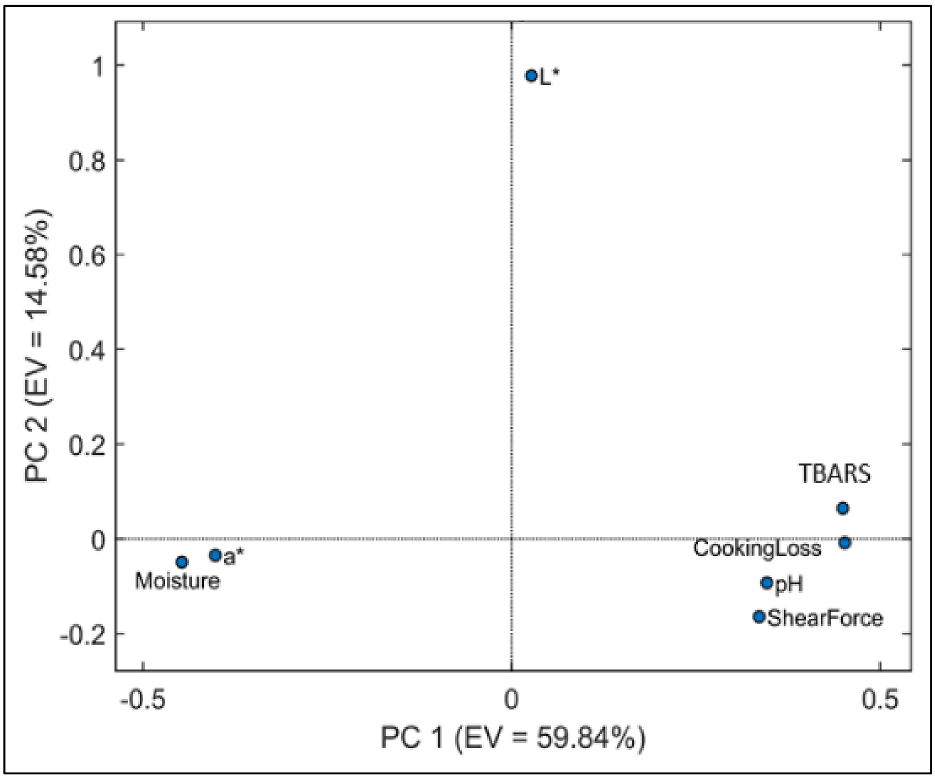


Figure 1. PC1 vs. PC2: Loading plot of physicochemical variables studied in sous vide chicken fillet breasts cooked at different combinations of temperature (60, 70, 80, and 100 °C) and time (60, 90, 120, and 150 min).

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.

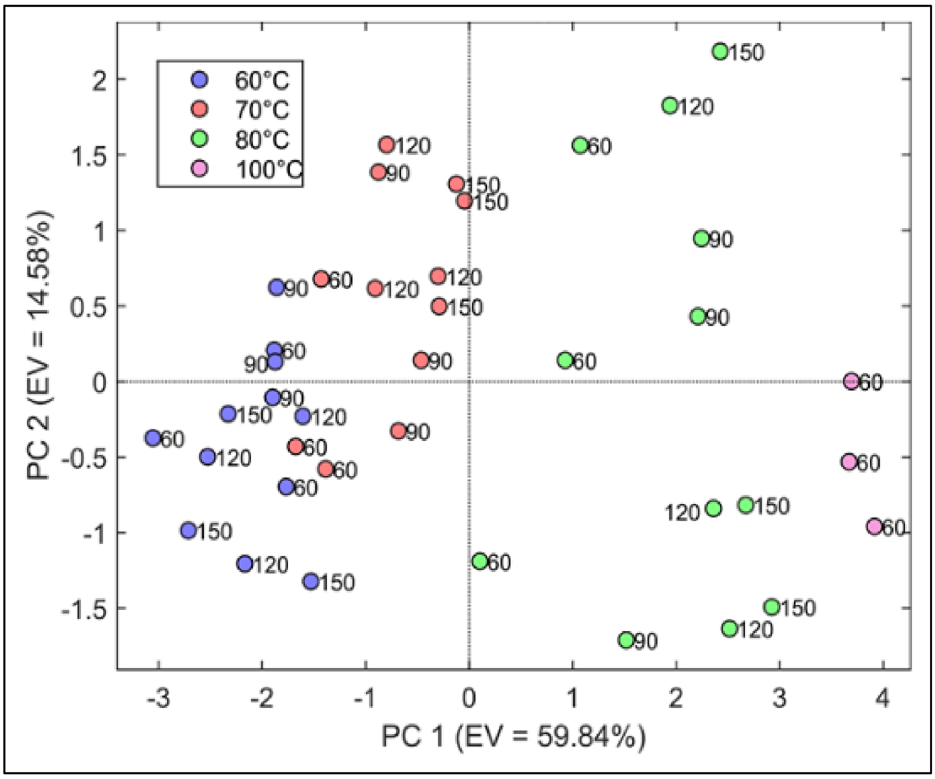


Figure 2. PC1 vs. PC2: Score plot of physicochemical variables studied in sous vide chicken fillet breasts cooked at different combinations of temperature (60, 70, 80, and 100 °C) and time (60, 90, 120, and 150 min). The symbol's color corresponds to cooking temperature (60, 70, 80, and 100 °C) and the 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] reported 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.

Author Contributions: Conceptualization, H.H., and A.M.B.; methodology, H.H., and A.M.B.; software, H.H., A.M.B., and F.M.; validation, H.H., and A.M.B.; formal analysis, H.H., and A.M.B.; investigation, H.H., and A.M.B.; resources, D.P.L.F., and A.P.; data curation, H.H., and A.M.B.; writing—original draft preparation, H.H., and A.M.B.; writing—review and editing, H.H; and A.M.B.; visualization, H.H., and A.M.B.; supervision, D.P.L.F., G.M., and A.P.; project administration, H.H.; funding acquisition, A.P. All authors have read and agreed to the published version of the manuscript.

Funding: This research was funded "FAR" INTERDISCIPLINARI-LS 2018 PROT.161714 Titolo: "DEL TRATTAMENTO TERMICO SOUS-VIDE: QUALITÀ REALE E PERCEPITA.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

Conflicts of Interest: The authors declare no conflict of interest.

References

1. Biesalski, H.-K. Meat as a component of a healthy diet—Are there any risks or benefits if meat is avoided in the diet? *Meat Sci.* **2005**, *70*, 509–524. [CrossRef] [PubMed]
2. Czarnowska-Kujawska, M.; Draszanowska, A.; Gujska, E. Effect of Different Cooking Methods on Folate Content in Chicken Liver. *Foods* **2020**, *9*, 1431. [CrossRef] [PubMed]
3. Davey, C.L.; Gilbert, K.V. Temperature-dependent cooking toughness in beef. *J. Sci. Food Agric.* **1974**, *25*, 931–938. [CrossRef]
4. Gök, V.; Uzun, T.; Tomar, O.; Çağlar, M.Y.; Çağlar, A. The effect of cooking methods on some quality characteristics of gluteus medius. *Food Sci. Technol.* **2019**, *39*, 999–1004. [CrossRef]
5. Nithyalakshmi, V.; Preetha, R. Effect of cooking conditions on physico-chemical and textural properties of emu (Dromaius novaehollandiae) meat. *Int. Food Res. J.* **2015**, *22*, 1924–1930.
6. Tornberg, E. Effects of heat on meat proteins—Implications on structure and quality of meat products. *Meat Sci.* **2005**, *70*, 493–508. [CrossRef]
7. Roldán, M.; Antequera, T.; Martín, A.; Mayoral, A.I.; Ruiz, J. Effect of different temperature–time combinations on physicochemical, microbiological, textural and structural features of sous-vide cooked lamb loins. *Meat Sci.* **2013**, *93*, 572–578. [CrossRef] [PubMed]
8. Dominguez-Hernandez, E.; Salaseviciene, A.; Ertbjerg, P. Low-temperature long-time cooking of meat: Eating quality and underlying mechanisms. *Meat Sci.* **2018**, *143*, 104–113. [CrossRef]
9. Baldwin, D.E. Sous vide cooking: A review. *Int. J. Gastron. Food Sci.* **2012**, *1*, 15–30. [CrossRef]
10. Zavadlav, S.; Blažić, M.; Van De Velde, F.; Vignatti, C.; Fenoglio, C.; Piagentini, A.M.; Pirovani, M.E.; Perotti, C.M.; Kovačević, D.B.; Putnik, P. *Sous-Vide* as a Technique for Preparing Healthy and High-Quality Vegetable and Seafood Products. *Foods* **2020**, *9*, 1537. [CrossRef]
11. Albistur, A.R.-; Gámbaro, A. Consumer perception of a non-traditional market on sous-vide dishes. *Int. J. Gastron. Food Sci.* **2018**, *11*, 20–24. [CrossRef]
12. Christensen, L.; Gunvig, A.; Tørngren, M.A.; Aaslyng, M.D.; Knøchel, S.; Christensen, M. Sensory characteristics of meat cooked for prolonged times at low temperature. *Meat Sci.* **2012**, *90*, 485–489. [CrossRef]
13. Cho, D.K.; Lee, B.; Oh, H.; Lee, J.S.; Kim, Y.S.; Choi, Y.M. Effect of Searing Process on Quality Characteristics and Storage Stability of Sous-Vide Cooked Pork Patties. *Foods* **2020**, *9*, 1011. [CrossRef]
14. Rondanelli, M.; Daglia, M.; Meneghini, S.; Di Lorenzo, A.; Peroni, G.; Faliva, M.A.; Perna, S. Nutritional advantages of sous-vide cooking compared to boiling on cereals and legumes: Determination of ashes and metals content in ready-to-eat products. *Food Sci. Nutr.* **2017**, *5*, 827–833. [CrossRef]
15. Schellekens, M. New research issues in sous-vide cooking. *Trends Food Sci. Technol.* **1996**, *7*, 256–262. [CrossRef]
16. Jeong, S.-H.; Kim, E.-C.; Lee, D.-U. The Impact of a Consecutive Process of Pulsed Electric Field, Sous-Vide Cooking, and Reheating on the Properties of Beef Semitendinosus Muscle. *Foods* **2020**, *9*, 1674. [CrossRef]
17. Hong, G.-E.; Kim, J.-H.; Ahn, S.-J.; Lee, C.-H. Changes in Meat Quality Characteristics of the Sous-vide Cooked Chicken Breast during Refrigerated Storage. *Food Sci. Anim. Resour.* **2015**, *35*, 757–764. [CrossRef]
18. Rizzo, V.; Amoroso, L.; Licciardello, F.; Mazzaglia, A.; Muratore, G.; Restuccia, C.; Lombardo, S.; Pandino, G.; Strano, M.G.; Mauromicale, G. The effect of sous vide packaging with rosemary essential oil on storage quality of fresh-cut potato. *LWT* **2018**, *94*, 111–118. [CrossRef]
19. Głuchowski, A.; Czarniecka-Skubina, E.; Wasiak-Zys, G.; Nowak, D.; Skubina, C.-; Zys, W. Effect of Various Cooking Methods on Technological and Sensory Quality of Atlantic Salmon (Salmo salar). *Foods* **2019**, *8*, 323. [CrossRef]
20. Becker, A.; Boulaaba, A.; Pingen, S.; Krischek, C.; Klein, G. Low temperature cooking of pork meat—Physicochemical and sensory aspects. *Meat Sci.* **2016**, *118*, 82–88. [CrossRef]
21. Christensen, L.; Ertbjerg, P.; Aaslyng, M.D.; Christensen, M. Effect of prolonged heat treatment from 48 °C to 63°C on toughness, cooking loss and color of pork. *Meat Sci.* **2011**, *88*, 280–285. [CrossRef]
22. Jeong, K.; Hyeonbin, O.; Shin, S.Y.; Kim, Y.-S. Effects of sous-vide method at different temperatures, times and vacuum degrees on the quality, structural, and microbiological properties of pork ham. *Meat Sci.* **2018**, *143*, 1–7. [CrossRef] [PubMed]
23. del Pulgar, J.S.; Gázquez, A.; Ruiz-Carrascal, J. Physico-chemical, textural and structural characteristics of sous-vide cooked pork cheeks as affected by vacuum, cooking temperature, and cooking time. *Meat Sci.* **2012**, *90*, 828–835. [CrossRef] [PubMed]
24. Botinestean, C.; Keenan, D.F.; Kerry, J.P.; Hamill, R.M. The effect of thermal treatments including sous-vide, blast freezing and their combinations on beef tenderness of M. semitendinosus steaks targeted at elderly consumers. *LWT* **2016**, *74*, 154–159. [CrossRef]
25. Gómez, I.; Ibañez, F.C.; Beriain, M.J. Physicochemical and sensory properties of sous vide meat and meat analog products marinated and cooked at different temperature-time combinations. *Int. J. Food Prop.* **2019**, *22*, 1693–1708. [CrossRef]
26. Bıyıklı, M.; Akoğlu, A.; Kurhan, Ş.; Akoğlu, İ.T. Effect of different Sous Vide cooking temperature-time combinations on the physicochemical, microbiological, and sensory properties of turkey cutlet. *Int. J. Gastron. Food Sci.* **2020**, *20*, 100204. [CrossRef]

27. Akoğlu, I.; Bıyıklı, M.; Akoglu, A.; Kurhan, Ş.; Biyikli, M. Determination of the Quality and Shelf Life of Sous Vide Cooked Turkey Cutlet Stored at 4 and 12 °C. *Braz. J. Poult. Sci.* **2018**, *20*, 1–8. [CrossRef]
28. Naveena, B.M.; Khansole, P.S.; Kumar, M.S.; Krishnaiah, N.; Kulkarni, V.V.; Deepak, S.J. Effect of sous vide processing on physicochemical, ultrastructural, microbial and sensory changes in vacuum packaged chicken sausages. *Food Sci. Technol. Int.* **2016**, *23*, 75–85. [CrossRef]
29. Park, C.; Lee, B.; Oh, E.; Kim, Y.; Choi, Y. Combined effects of sous-vide cooking conditions on meat and sensory quality characteristics of chicken breast meat. *Poult. Sci.* **2020**, *99*, 3286–3291. [CrossRef]
30. Karpińska-Tymoszczyk, M.; Draszanowska, A.; Danowska-Oziewicz, M.; Kurp, L. The effect of low-temperature thermal processing on the quality of chicken breast fillets. *Food Sci. Technol. Int.* **2020**, *26*, 563–573. [CrossRef]
31. Can, Ö.; Harun, F. Shelf Life of Chicken Meat Balls Submitted to Sous Vide Treatment. *Braz. J. Poult. Sci.* **2015**, *17*, 137–144. [CrossRef]
32. AOAC. *AOAC Official Methods of Analysis*, 18th ed.; AOAC International: Rockville, MD, USA, 2005; ISBN 0935584870.
33. Da Silva-Buzanello, R.A.; Schuch, A.F.; Gasparin, A.W.; Torquato, A.S.; Scremin, F.R.; Canan, C.; Soares, A.L. Quality parameters of chicken breast meat affected by carcass scalding conditions. *Asian-Australas. J. Anim. Sci.* **2019**, *32*, 1186–1194. [CrossRef] [PubMed]
34. Haghighi, H.; Gullo, M.; La China, S.; Pfeifer, F.; Siesler, H.W.; Licciardello, F.; Pulvirenti, A. Characterization of bio-nanocomposite films based on gelatin/polyvinyl alcohol blend reinforced with bacterial cellulose nanowhiskers for food packaging applications. *Food Hydrocoll.* **2021**, *113*, 106454. [CrossRef]
35. Honikel, K.O. Reference methods for the assessment of physical characteristics of meat. *Meat Sci.* **1998**, *49*, 447–457. [CrossRef]
36. Siu, G.M.; Draper, H.H. A Survey of the Malonaldehyde Content of Retail Meats and Fish. *J. Food Sci.* **1978**, *43*, 1147–1149. [CrossRef]
37. ISO. *ISO 4833-1 Microbiology of the Food Chain—Horizontal Method for the Enumeration of Microorganisms, Part 1, Count at 30 °C by the Pour Plate Technique*; ISO: Geneva, Switzerland, 2013; p. 9.
38. ISO. *ISO 17410 Microbiology of the Food Chain—Horizontal Method for the Enumeration of Psychrotrophic Microorganisms*; ISO: Geneva, Switzerland, 2019; p. 10.
39. ISO. *ISO 21528-1 Microbiology of the Food Chain—Horizontal Method for the Detection and Enumeration of Enterobacteriaceae—Part 1: Detection of Enterobacteriaceae*; ISO: Geneva, Switzerland, 2017; p. 17.
40. Brambila, G.S.; Chatterjee, D.; Bowker, B.; Zhuang, H. Descriptive texture analyses of cooked patties made of chicken breast with the woody breast condition. *Poult. Sci.* **2017**, *96*, 3489–3494. [CrossRef] [PubMed]
41. Murphy, R.Y.; Marks, B.P. Effect of meat temperature on proteins, texture, and cook loss for ground chicken breast patties. *Poult. Sci.* **2000**, *79*, 99–104. [CrossRef]
42. Murphy, R.Y.; Johnson, E.R.; Duncan, L.K.; Clausen, E.C.; Davis, M.D.; March, J.A. Heat Transfer Properties, Moisture Loss, Product Yield, and Soluble Proteins in Chicken Breast Patties During Air Convection Cooking. *Poult. Sci.* **2001**, *80*, 508–514. [CrossRef]
43. Ismail, I.; Hwang, Y.-H.; Bakhsh, A.; Joo, S.-T. The alternative approach of low temperature-long time cooking on bovine semitendinosus meat quality. *Asian Australas. J. Anim. Sci.* **2019**, *32*, 282–289. [CrossRef] [PubMed]
44. Aaslyng, M.D.; Bejerholm, C.; Ertbjerg, P.; Bertram, H.C.; Andersen, H.J. Cooking loss and juiciness of pork in relation to raw meat quality and cooking procedure. *Food Qual. Prefer.* **2003**, *14*, 277–288. [CrossRef]
45. Roldán, M.; Antequera, T.; Hernández, A.; Ruiz, J.; Ruiz-Carrascal, J. Physicochemical and microbiological changes during the refrigerated storage of lamb loins sous-vide cooked at different combinations of time and temperature. *Food Sci. Technol. Int.* **2014**, *21*, 512–522. [CrossRef]
46. Purslow, P.; Oiseth, S.; Hughes, J.; Warner, R. The structural basis of cooking loss in beef: Variations with temperature and ageing. *Food Res. Int.* **2016**, *89*, 739–748. [CrossRef] [PubMed]
47. Li, C.; Wang, D.; Xu, W.; Gao, F.; Zhou, G. Effect of final cooked temperature on tenderness, protein solubility and microstructure of duck breast muscle. *LWT* **2013**, *51*, 266–274. [CrossRef]
48. Wideman, N.; O'Bryan, C.; Crandall, P. Factors affecting poultry meat colour and consumer preferences—A review. *World's Poult. Sci. J.* **2016**, *72*, 353–366. [CrossRef]
49. Cobos, Á.; Diaz, O. Chemical Composition of Meat and Meat Products. In *Handbook of Food Chemistry*; Cheung, P.C.K., Ed.; Springer: Berlin/Heidelberg, Germany, 2014; pp. 1–32.
50. Khan, A.; Allen, K.; Wang, X. Effect of Type I and Type II Antioxidants on Oxidative Stability, Microbial Growth, pH, and Color in Raw Poultry Meat. *Food Nutr. Sci.* **2015**, *6*, 1541–1551. [CrossRef]
51. García-Segovia, P.; Andrés-Bello, A.; Martínez-Monzó, J. Effect of cooking method on mechanical properties, color and structure of beef muscle (M. pectoralis). *J. Food Eng.* **2007**, *80*, 813–821. [CrossRef]
52. Holownia, K.; Chinnan, M.S.; Reynolds, A.E.; Koehler, P.E. Evaluation of induced color changes in chicken breast meat during simulation of pink color defect. *Poult. Sci.* **2003**, *82*, 1049–1059. [CrossRef] [PubMed]
53. Fabre, R.; Dalzotto, G.; Perlo, F.; Bonato, P.; Teira, G.; Tisocco, O. Cooking method effect on Warner-Bratzler shear force of different beef muscles. *Meat Sci.* **2018**, *138*, 10–14. [CrossRef]
54. Turner, B.E.; Larick, D.K. Palatability of Sous Vide Processed Chicken Breast. *Poult. Sci.* **1996**, *75*, 1056–1063. [CrossRef]

55. Barbanti, D.; Pasquini, M. Influence of cooking conditions on cooking loss and tenderness of raw and marinated chicken breast meat. *LWT* **2005**, *38*, 895–901. [CrossRef]
56. Warner, R.; Ha, M.; Sikes, A.; Vaskoska, R. Cooking and Novel Postmortem Treatments to Improve Meat Texture. In *New Aspects of Meat Quality*; Elsevier BV: Amsterdam, The Netherlands, 2017; pp. 387–423.
57. Laakkonen, E.; Wellington, G.H.; Sherbon, J.N. Low-Temperature, Long-Time Heating of Bovine Muscle 1. Changes in Tenderness, Water-Binding Capacity, pH and Amount of Water-Soluble Components. *J. Food Sci.* **1970**, *35*, 175–177. [CrossRef]
58. Bigi, F.; Haghighi, H.; De Leo, R.; Ulrici, A.; Pulvirenti, A. Multivariate exploratory data analysis by PCA of the combined effect of film-forming composition, drying conditions, and UV-C irradiation on the functional properties of films based on chitosan and pectin. *LWT* **2021**, *137*, 110432. [CrossRef]

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
…"

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)

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.

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

Author:

Elizabeth Main, *University of Pennsylvania*

Advisors:

Claire Robertson-Kraft, *University of Pennsylvania*
Nic Esposito, *City of Philadelphia*
Haley Jordan, *City of Philadelphia*
Helena Rudoff, *City of Philadelphia*

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

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.

Beach Beat: We need food safety boots on the ground and we need them right now

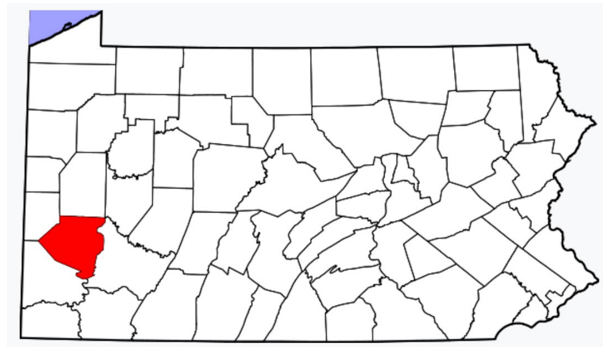
By Coral Beach on March 17, 2022

– 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).

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.

Steven Mandernach

“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

FSN Editors

FSN Writers & Contributors

Stay Connected

Subscribe by email

Events Calendar

Food Recalls

Hummus recalled in Canada over plastic in product

Another patient confirmed in outbreak traced to enoki mushrooms; FDA renews warning

Error causes recalled frozen berries to be put back on sale

FDA says Utopia Foods enoki mushrooms traced to outbreak of Listeria infections

MORE RECALLS

Editorials & Guest Opinions

Publisher’s Platform: Context for criminal prosecutions in food safety cases

By Bill Marler on January 23, 2023

FDA’s Traceability Rule: What are the next steps for the agency and industry

By Guest Opinion on January 19, 2023

2023 is the year for MCOOL

By Guest Opinion on January 17, 2023

MORE OP-EDS

Letters to the Editor

Latest from Twitter

Food Safety Guides

Cooking Temperatures

Cross-Contamination

Foodborne Pathogens

 Find Your Health Department

 Restaurant Inspections

 eFood Alert Blog

Marler Blog

Marler Clark logo

1012 First Avenue
Fifth Floor
Seattle, Washington
98104-1008

- Consumer Education
- Enforcement
- Events
- Food Policy & Law
- Food Recalls
- Food Safety Guides
- Foodborne Illness Investigations
- Foodborne Illness Outbreaks
- For Foodies
- Government Agencies
- Lawsuits & Litigation
- Letters to the Editor
- Local Food
- Media Kit
- Nutrition & Public Health
- Opinion & Contributed Articles
- Science & Research
- Sustainability
- Technology
- Victim Stories
- World

Environmental Health Regulatory Food Safety Program Capacity Assessment

Initial Assessment Results
April 2011

Assessment report compiled by the National Environmental Health Association (NEHA).

720 South Colorado Blvd.
Suite 1000-N
Denver, Colorado 80246-1926
Phone (303) 756-9090
Fax (303) 691-9490
www.neha.org

Acknowledgements

The National Environmental Health Association (NEHA) conducted this project with support from the U.S. Food and Drug Administration/Center for Food Safety and Applied Nutrition/Office of Food Defense, Communication and Emergency Response (FDA/CFSAN/OFDCER) through a contract with the Association of Public Health Laboratories (APHL). The contents are solely the responsibility of the authors and do not necessarily represent the official views of FDA or APHL.

Partners for this project included NEHA, APHL, Association of Food and Drug Officials (AFDO), the National Association of County and City Health Officials (NACCHO), the Association of State and Territorial Health Officials (ASTHO), FDA/CFSAN/OFDCER, the Centers for Disease Control and Prevention/Coordinating Center for Infectious Diseases/National Center for Zoonotic, Vector-borne, and Enteric Diseases (CDC/CCID/NCZVED) Food Safety Office, and members of the Council to Improve Foodborne Outbreak Response (CIFOR) Workgroup on workforce issues.

NEHA acknowledges the NEHA staff and partners who assisted with this project: Larry Marcum, JD, MPA, Research & Development Managing Director, NEHA; Vanessa De Arman, Food Safety Project Specialist, NEHA; Kristen Ruby, Project Specialist, NEHA; Joseph Corby, Executive Director, AFDO; Jennifer Li, MHS, Environmental Health Director, NACCHO; Abraham Kulungara, MPH, Environmental Health Director, ASTHO; John "Jack" Guzewich, RS, MPH, Environmental Health Senior Advisor, FDA/CFSAN/OFDCER; Donald Sharp, MD, DTM&H, Food Safety Office Associate Director, CDC/CCID/NCZVED; and members of the CIFOR Workgroup on workforce issues: Scott E. Holmes, Environmental Public Health Manager, Lincoln-Lancaster County Health Department; Robyn M. Atkinson, PhD, HCLD, Knoxville Regional Laboratory Director, Tennessee Department of Health Laboratory Services, State Laboratory Deputy Director; Joe Russell, RS, MPH, Public Health Officer, Flathead County (MT) Health Department; Marion F. Aller, DVM, DABT, Acting Deputy Commissioner, Florida Department of Agriculture and Consumer Services; and Lauren Rosenberg, MPA, Research Analyst, Council of State and Territorial Epidemiologists.

NEHA also acknowledges all of the state and local government agencies that responded to the assessment because without their feedback and support we would have been unable to report this data and these important workforce trends.

Table of Contents

Table of Contents		Page
1.0	**Introduction** **1.1 Assessment Result Overview**	**6**
2.0	**Please provide the following information: State, Name of jurisdiction or organization, and Job title** **2.1 State** Table 2.1.1 U.S. State Participation **2.2 Jurisdiction/Organization** Table 2.2.1 Assessment Participant Local and State Agency Breakdown by State **2.3 Job Title** Table 2.3.1 Assessment Participant Job Titles	**10**
3.0	**Please indicate the level of government in which you work.** Graph 3.0.1 Percent of Assessment Participants from the Different Levels of Government	**20**
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.** Table 4.0.1 Indicated Degrees of Impact to Administrative Capacity for all Assessment Participants Table 4.0.2 Indicated Degrees of Impact to Administrative Capacity for Local Agency Assessment Participants Table 4.0.3 Indicated Degrees of Impact to Administrative Capacity for State Agency Assessment Participants **4.1 Comparison of Total and Local and State Agency Percentages** Chart 4.1.1 Staff Sizes Chart 4.1.2 Staff Salaries Chart 4.1.3 Overall Budget Chart 4.1.4 Training Budget Chart 4.1.5 Travel Budget Chart 4.1.6 Technology/Equipment Budget Chart 4.1.7 Grant Funding	**21**
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.** Table 5.0.1 Indicated Degrees of Impact to Programmatic Capacity for all Assessment Participants Table 5.0.2 Indicated Degrees of Impact to Programmatic Capacity for Local Agency Assessment Participants Table 5.0.3 Indicated Degrees of Impact to Programmatic Capacity for State Agency Assessment Participants	**34**

Table of Contents (continued)

		Page
5.0 (cont.)	**5.1 Comparison of Total and Local and State Agency Percentages**	**34**
	Chart 5.1.1 Ability to Support Government Mandated Services	
	Chart 5.1.2 Services Offered to Retail Food Facilities	
	Chart 5.1.3 Services Offered to Other Government Programs and Departments	
	Chart 5.1.4 Services Offered to the General Public	
	Chart 5.1.5 Partnerships with Other Groups and Organizations	
	Chart 5.1.6 Quality of Inspections Conducted	
	Chart 5.1.7 Inspection Fees	
	Chart 5.1.8 Ability to Conduct Environmental Assessments/Investigations in Response to Outbreaks	
	Chart 5.1.9 Ability to Respond/Investigate Consumer Foodborne Illness Complaints	
	Chart 5.1.10 Ability to Respond to Food Recalls	
	Chart 5.1.11 Number of Programs Supported by Your Jurisdiction	
	Chart 5.1.12 Outsourcing of Programs	
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.**	**50**
	6.1 Program Effects at the Local Agency Level	
	6.1.1 Decreases	
	6.1.2 Increases	
	6.1.3 Outsourcing	
	6.2 Program Effects at the State Agency Level	
	6.2.1 Decreases	
	6.2.2 Increases	
	6.2.3 Outsourcing	
7.0	**Please indicate any impacts experienced in your regulatory food safety program's inspections over the last two years. Check all that apply.**	**55**
	Chart 7.0.1 Percent of Regulatory Food Safety Program Inspection Impacts Indicated by Total, Local Agency, and State Agency Assessment Participants	
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.**	**56**
	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	
	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	
	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	

Table of Contents (continued)

		Page
8.0 (cont.)	**8.1 Comparison of Total and Local and State Agency Percentages** Chart 8.1.1 Program Funding Chart 8.1.2 Staff Size Chart 8.1.3 Training for Staff Chart 8.1.4 Qualifications and Competency of Staff Chart 8.1.5 Other Food Safety Workload Expectations Chart 8.1.6 Other Workload Expectations	**56**
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** **9.2 State Agency Comments**	**66**
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** **10.2 State Agency Comments**	**69**
11.0	**Appendix** **11.1 Environmental Health Regulatory Food Safety Program Capacity Assessment Zoomerang Survey Tool**	**72**

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)

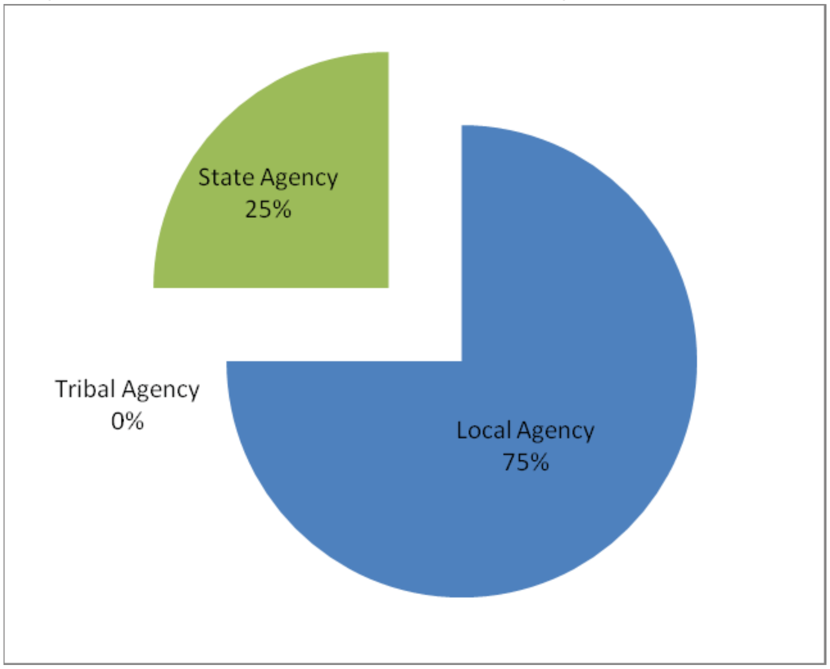
Table 2.3.1 Assessment Participant Job Titles (Continued)

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%

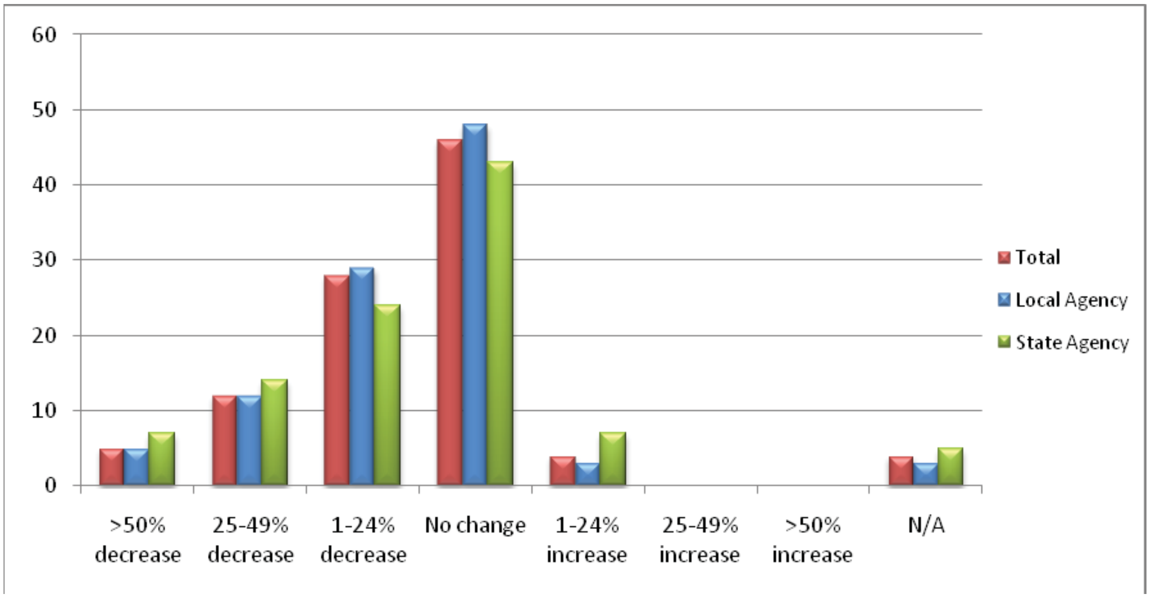
Table 4.0.3 Indicated Degrees of Impact to Administrative Capacities for State Agency Assessment Participants

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

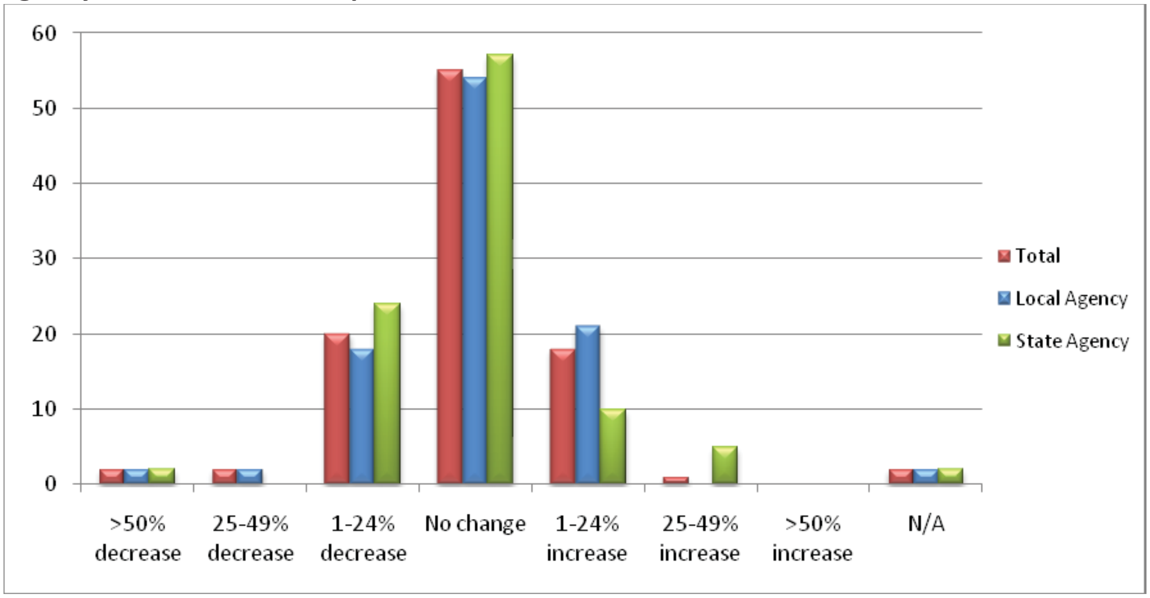
- Loss of assistant director position and delay in filling director position for 8 months

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

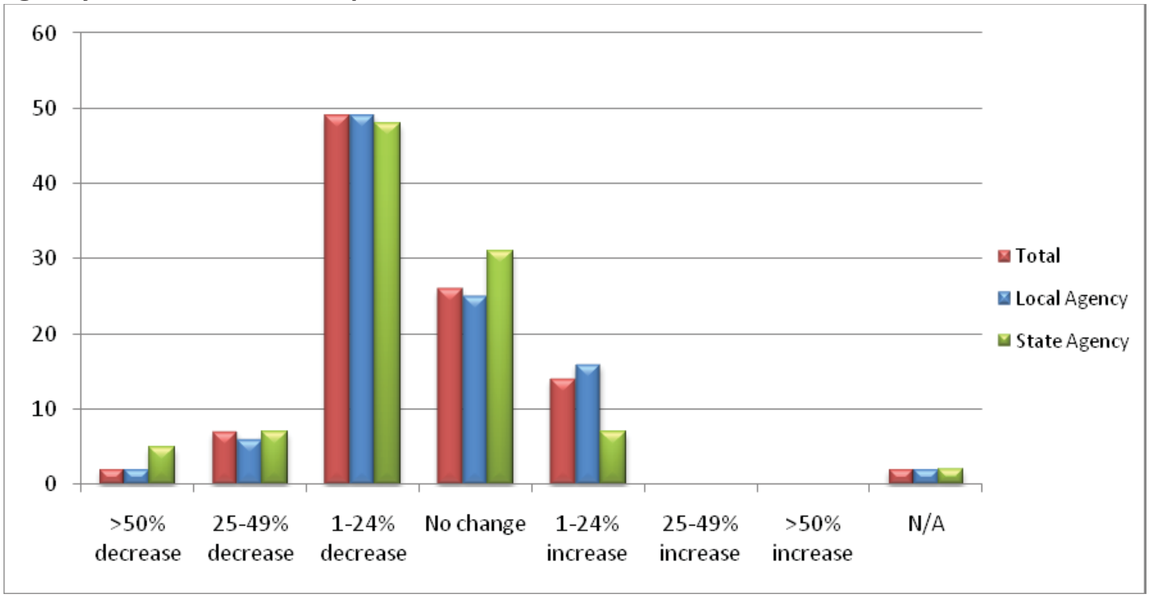
- Base salary means average $15,000 per annual
- Field staff given 2% increase but had to take 2 days furlough.

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

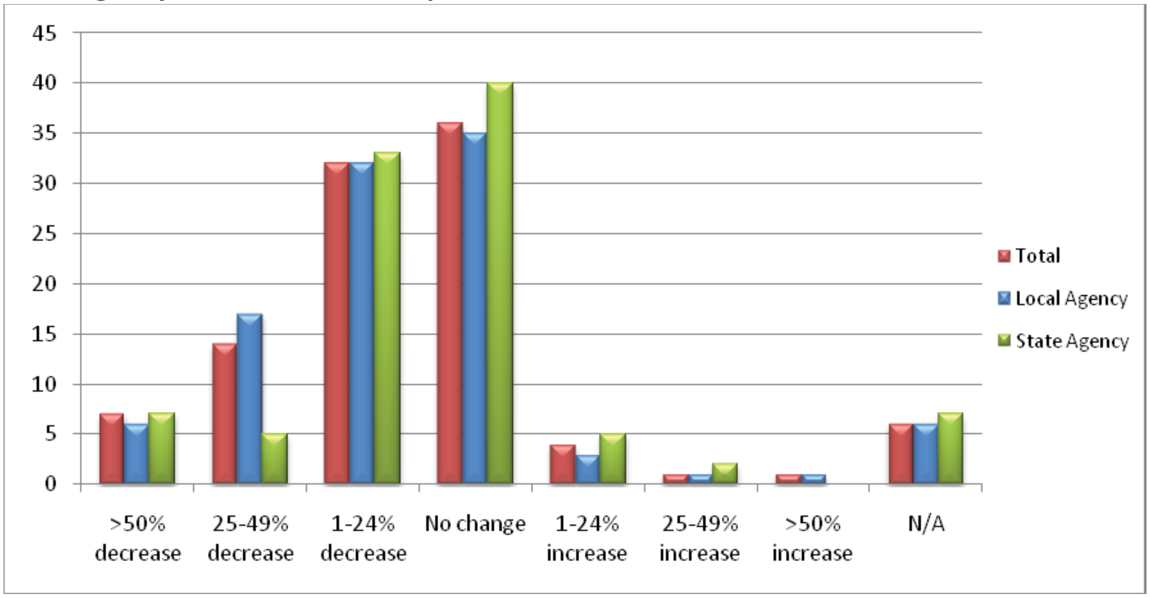
Local Agency

- 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

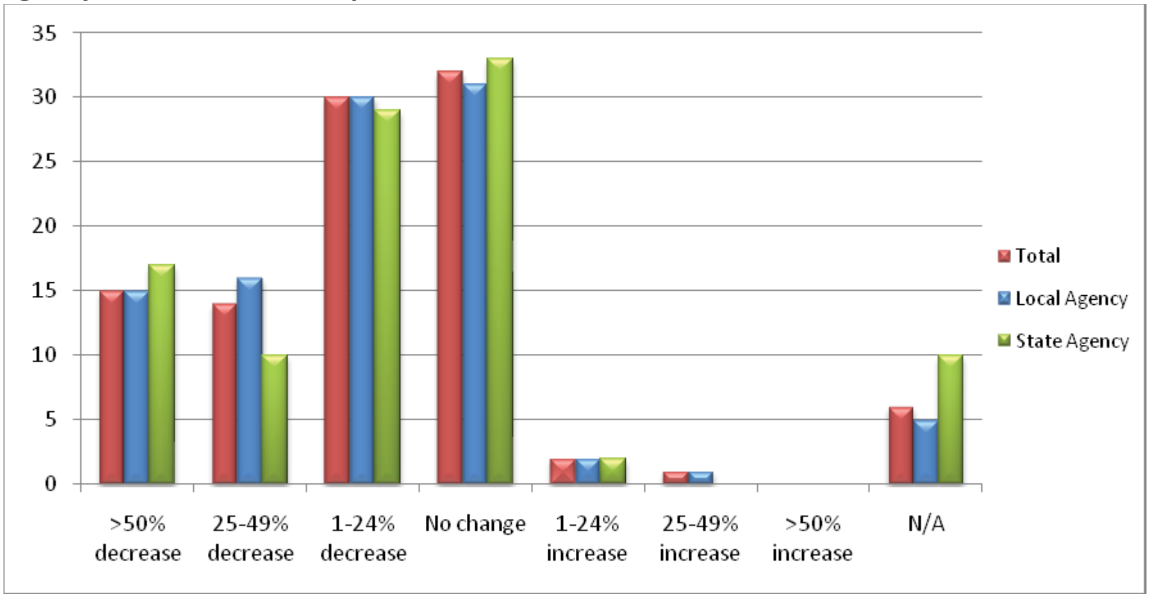
- A fee increase has allowed for increased training to allow for uniformity.

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

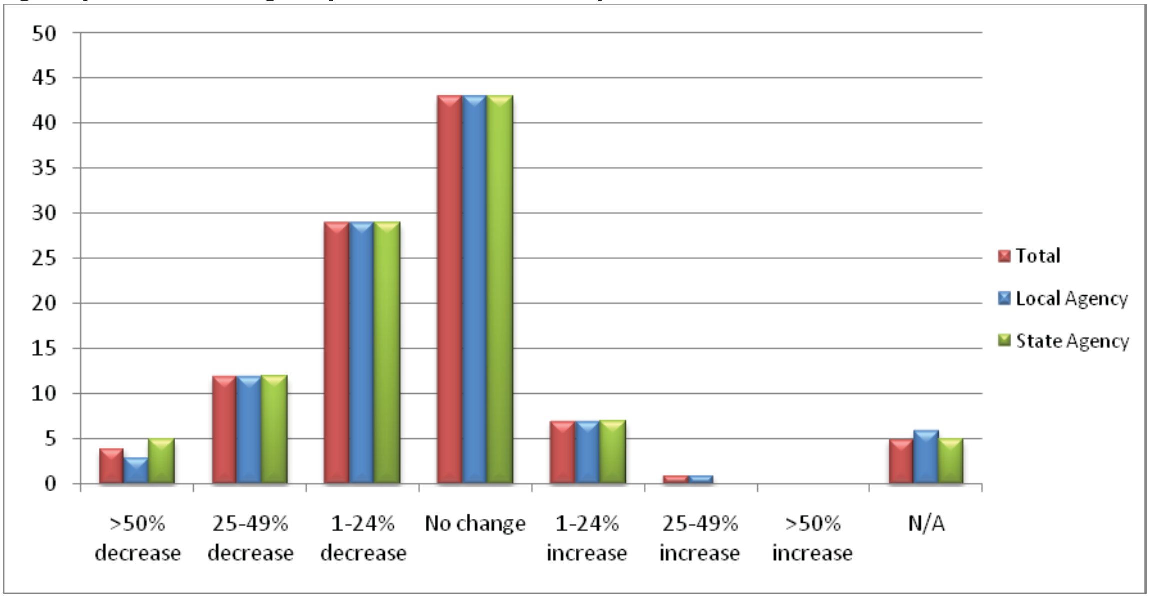
Local Agency

- 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

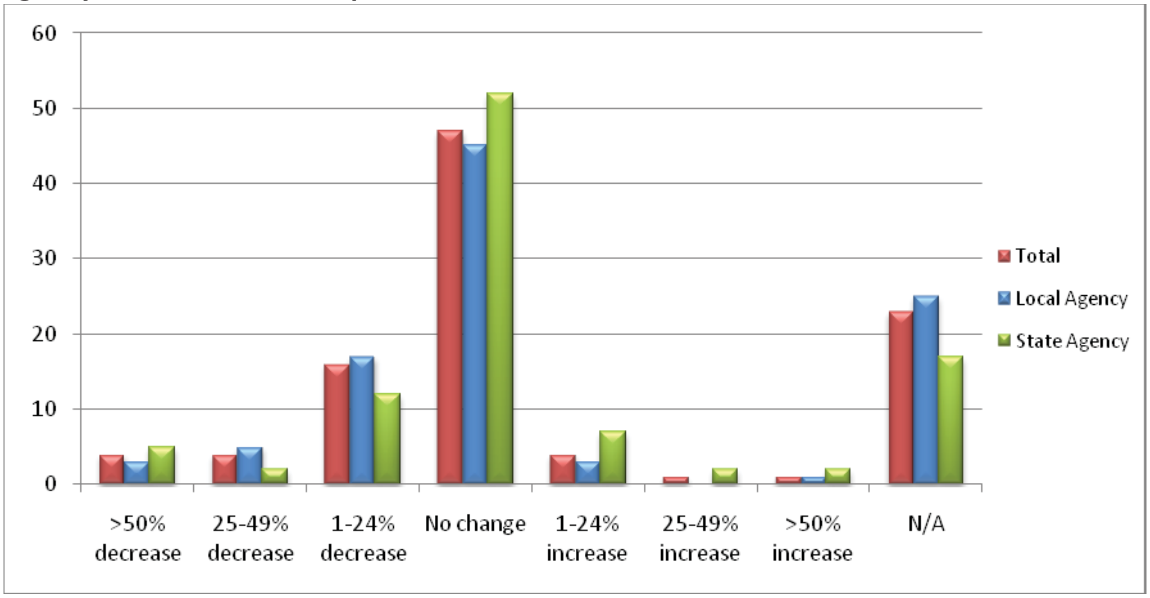
- The same fee increase has impacted our ability to update equipment.
- grant monies from FDA

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%

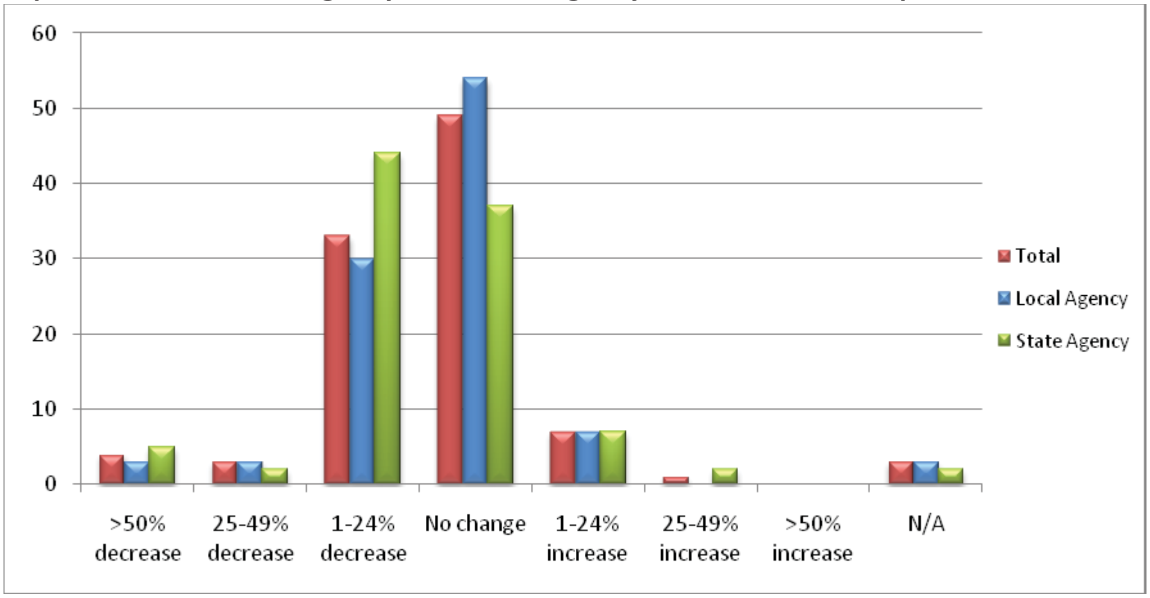
Table 5.0.3 Indicated Degrees of Impact to Programmatic Capacities for State Agency Assessment Participants

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

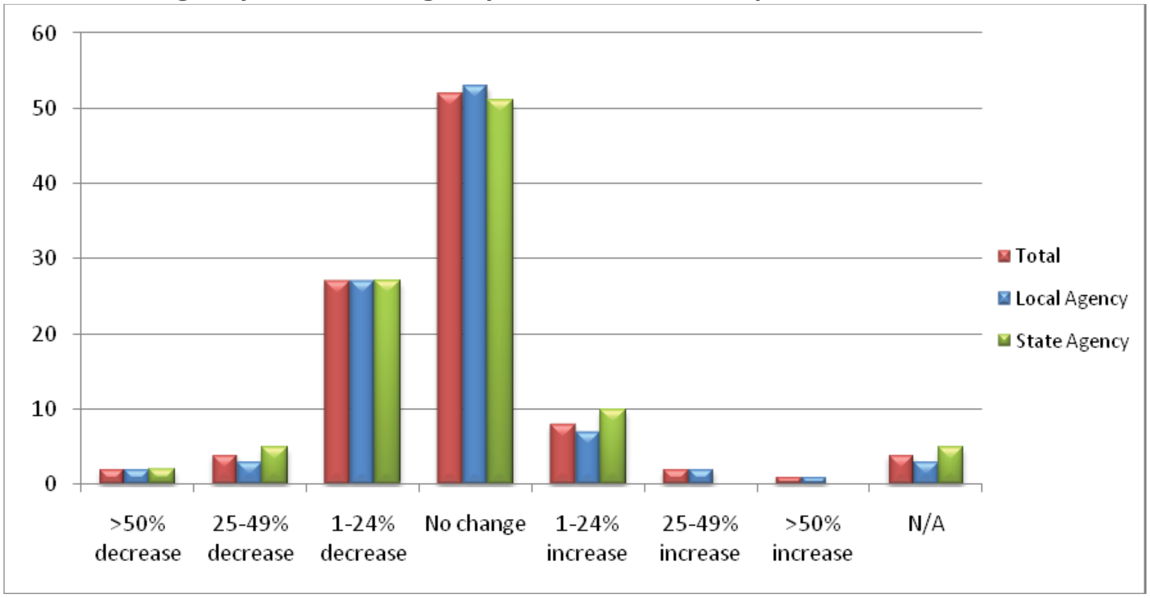
- Continues to be an area of concern.
- Our major program cuts were 5 years ago- program cut by 50%

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

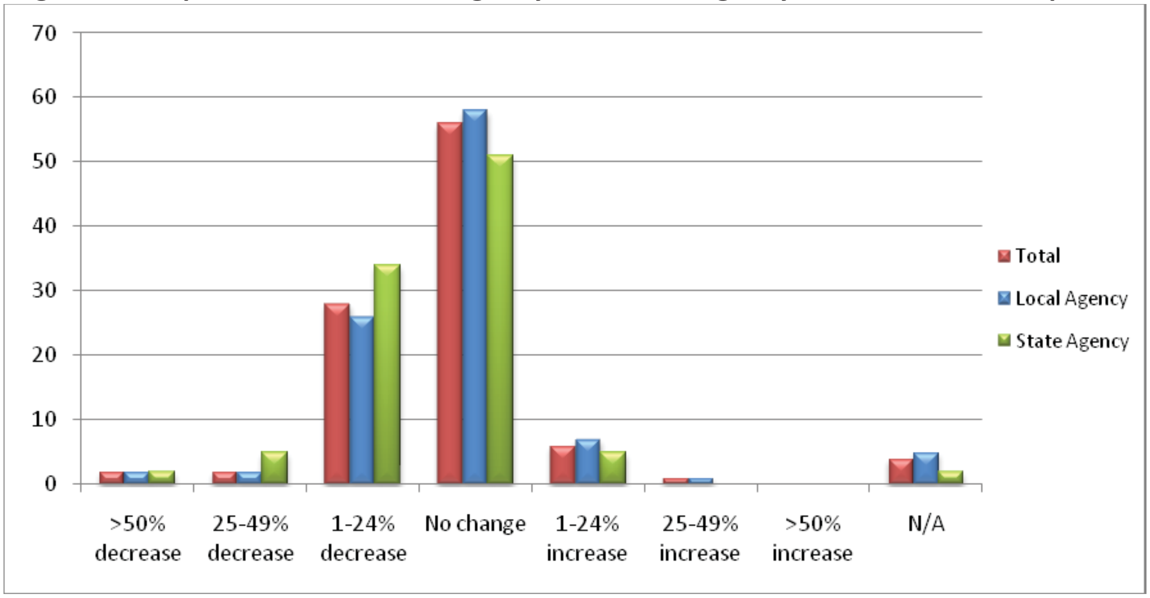
- Increased # of certified manager classes 2x

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

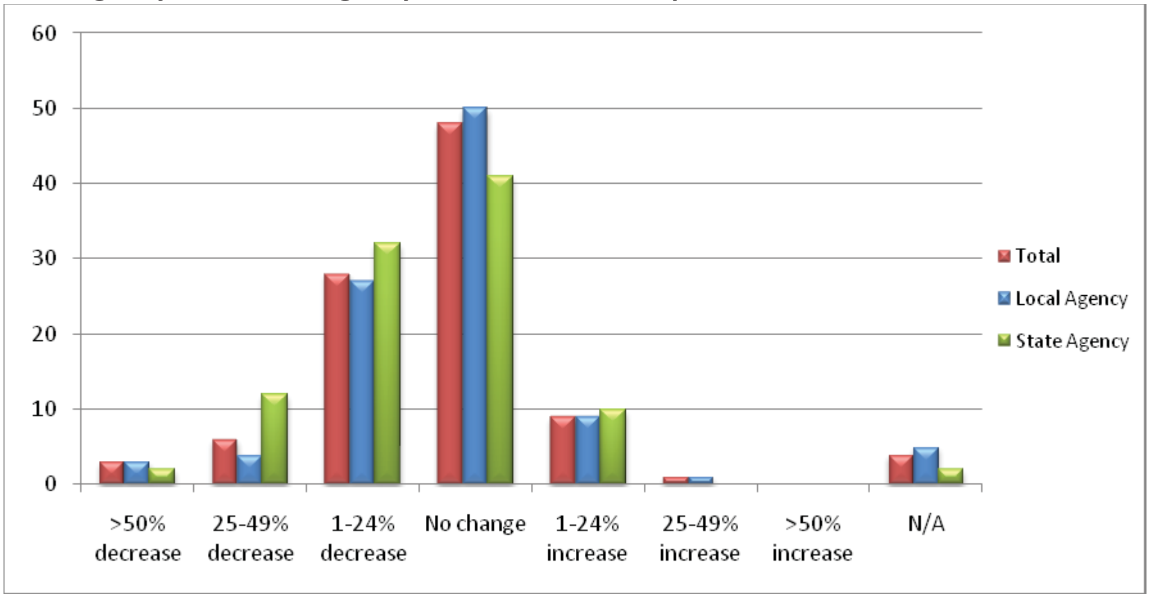
- Promotion and presentation of personal hygiene, NCDs program such as tobacco cessation, proper diet and better choices to improve lifestyle at respective gov'tal department

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

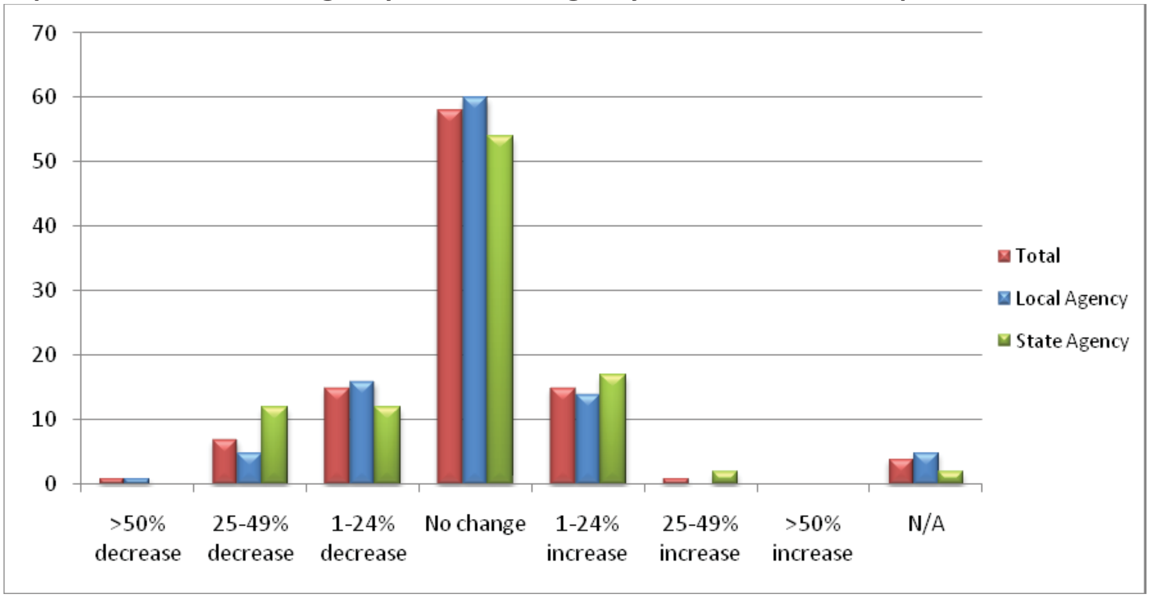
Local Agency

- 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

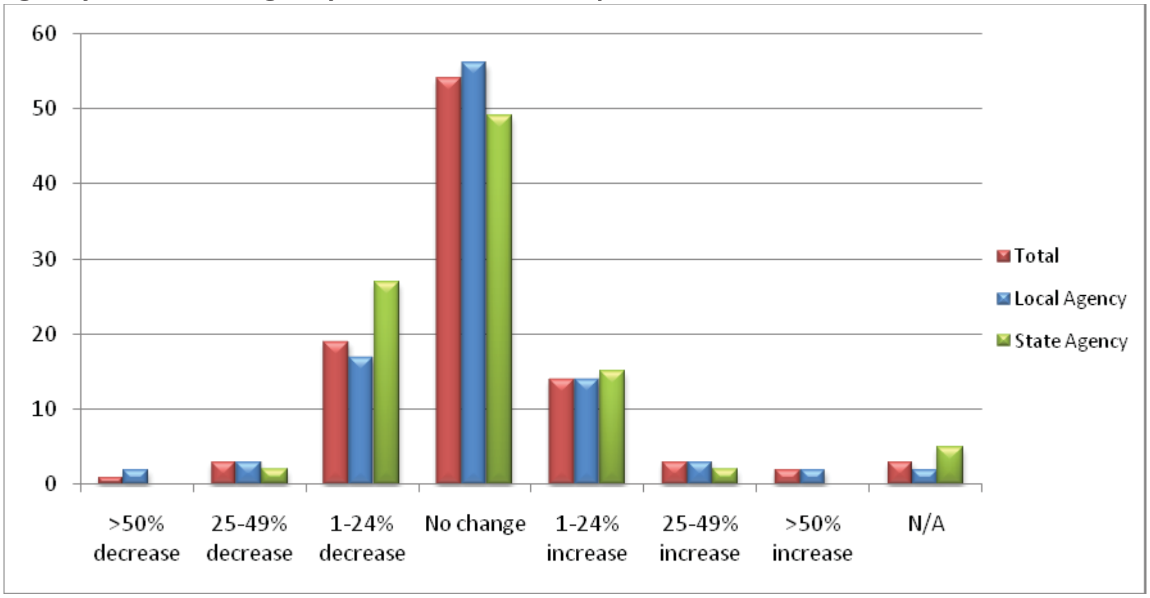
- Environmental Health program is integrated partner in promotion of NCDs programs with community. Partnership, includes Public School system, community coalitions such as Diabetes, Cancer, hotel associations.

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

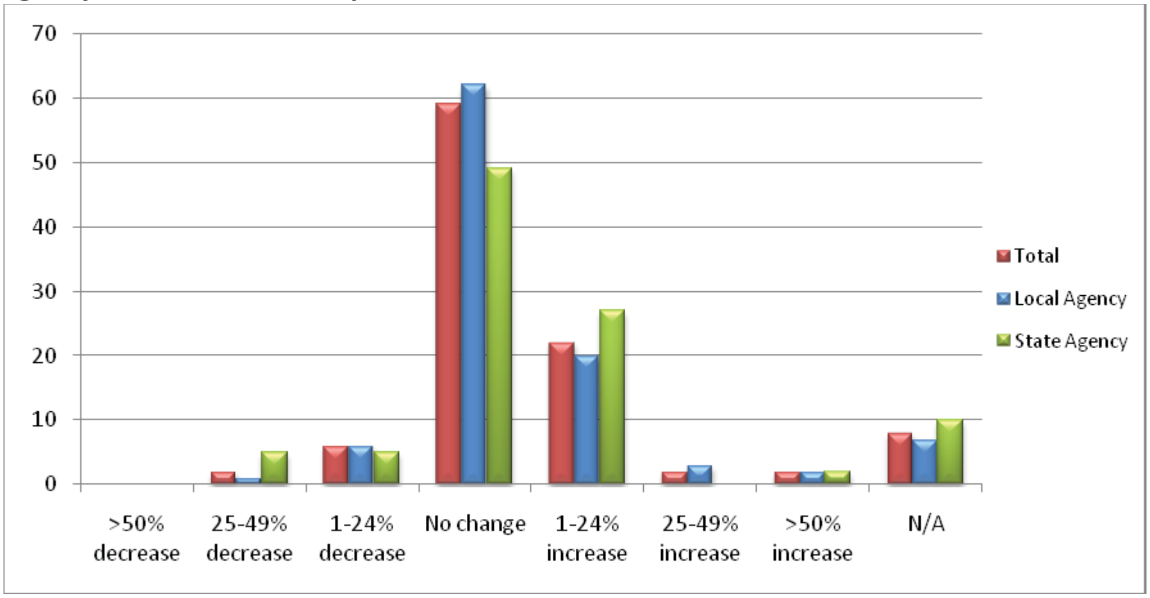
- We have great inspectors

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

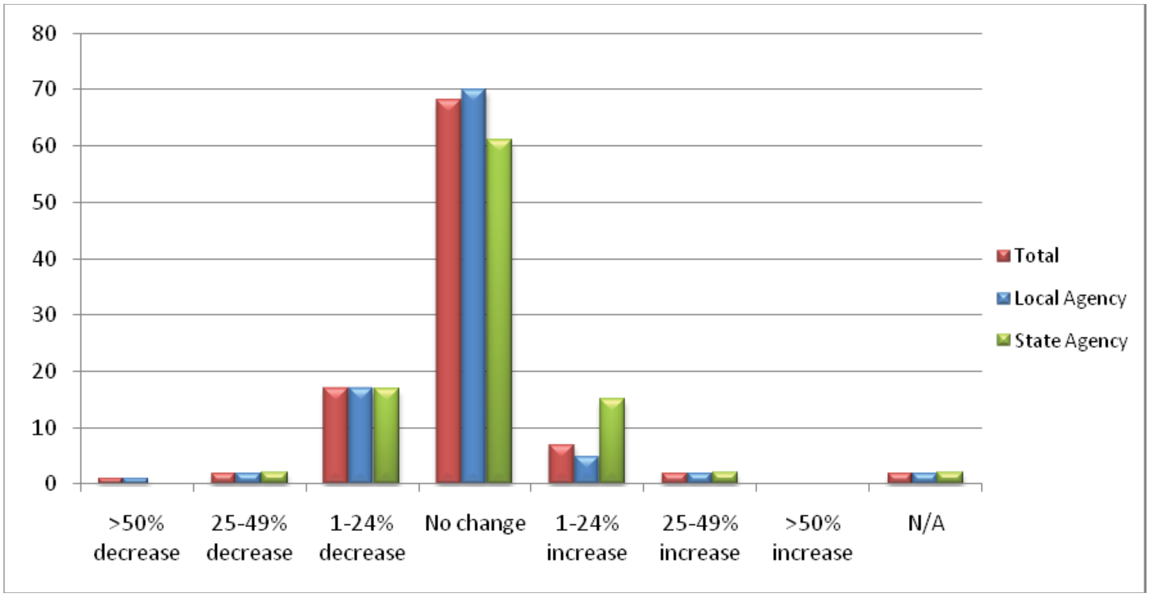
- No change and no hope of getting them changed.
- Proposed bill in 2010-11 to increase fees, governor would not allow.

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

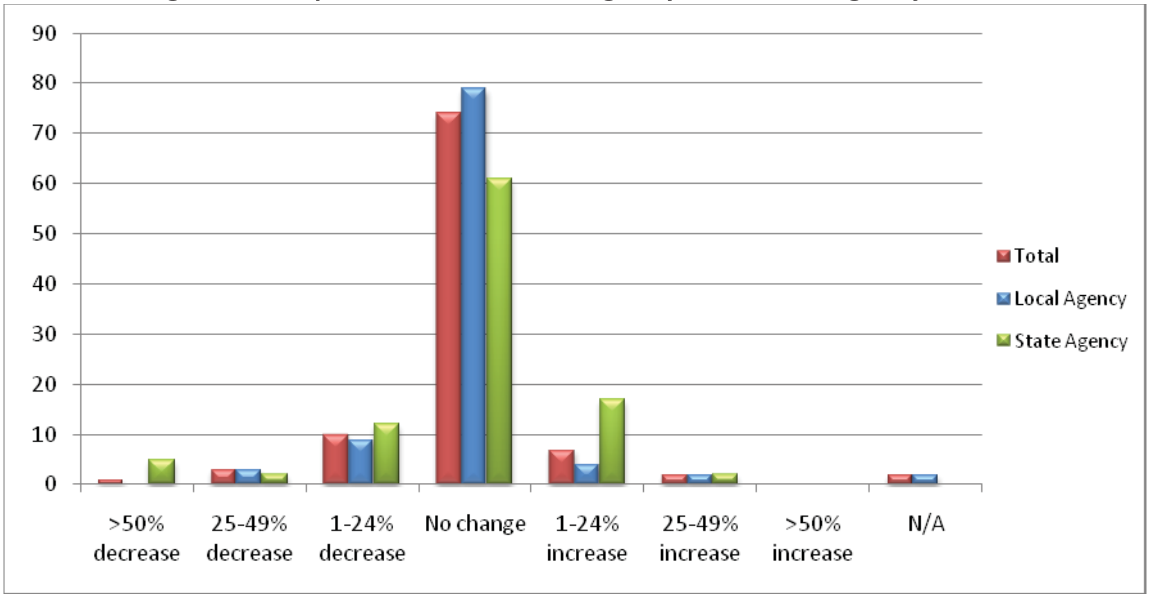
- In the event of an outbreak, our county public health, env. health and the county who handles our food inspections would work together.
- Reviewed CIFOR guidelines, updated all policies, included CIFOR guidance on env assessments, achieved compliance with FDA Standard # 5 on foodborne outbreak response

- 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

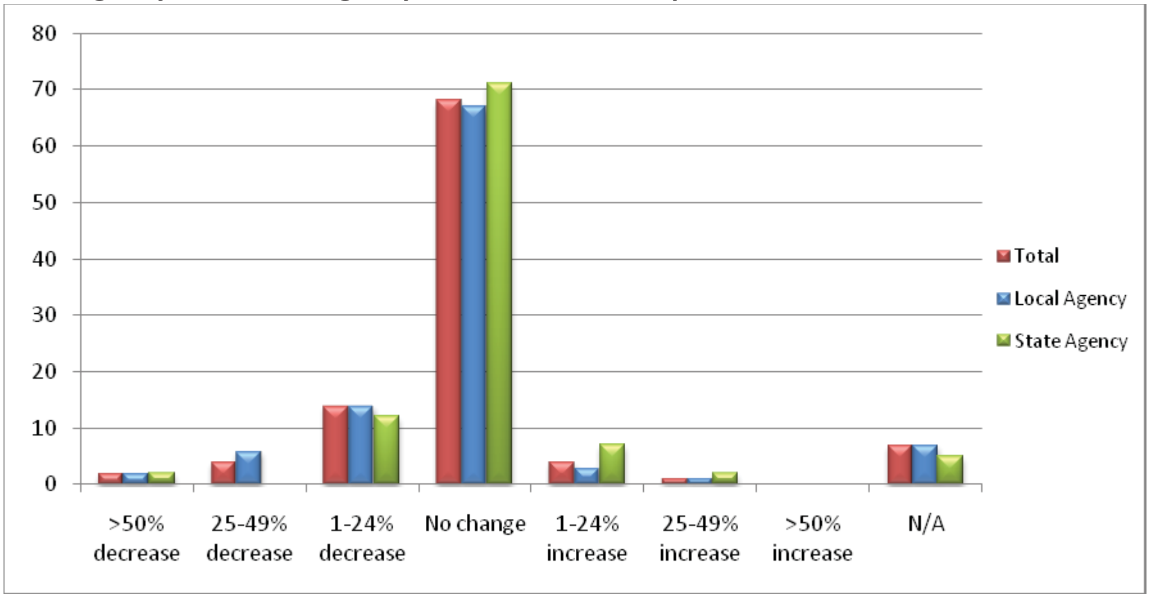
- Public health nurses assist.
- We still begin investigation within 24 hrs of receiving complaint.
- We have not reduced staffing/commitment to this high priority item.
- Public health risk reduction is a priority
- Depending on magnitude of the event.
- no change, we continue to prioritize investigation 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

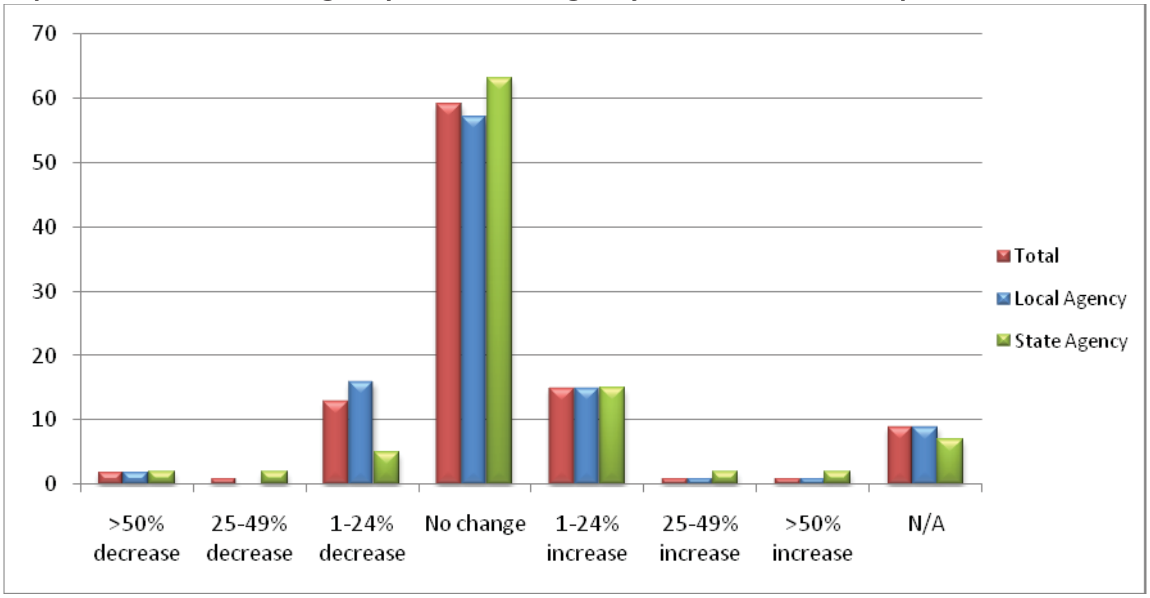
- We have never had this ability and have no mandate by law to do so.

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

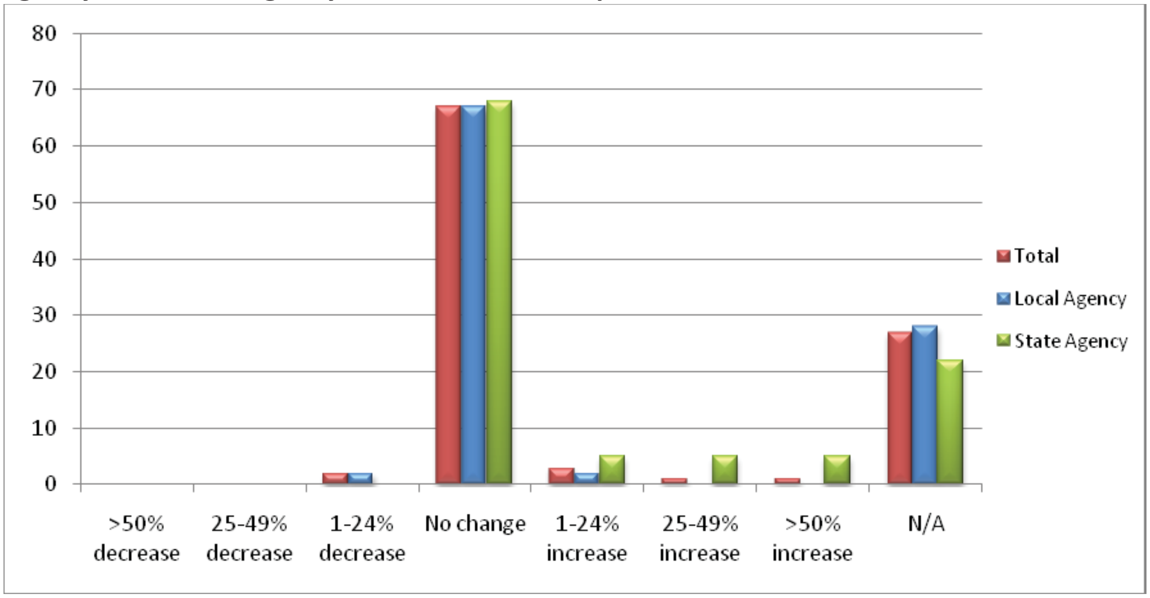
- ‘do more with less', new regs and programs in all areas of EH continue to land in our jurisdiction--not just food

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.

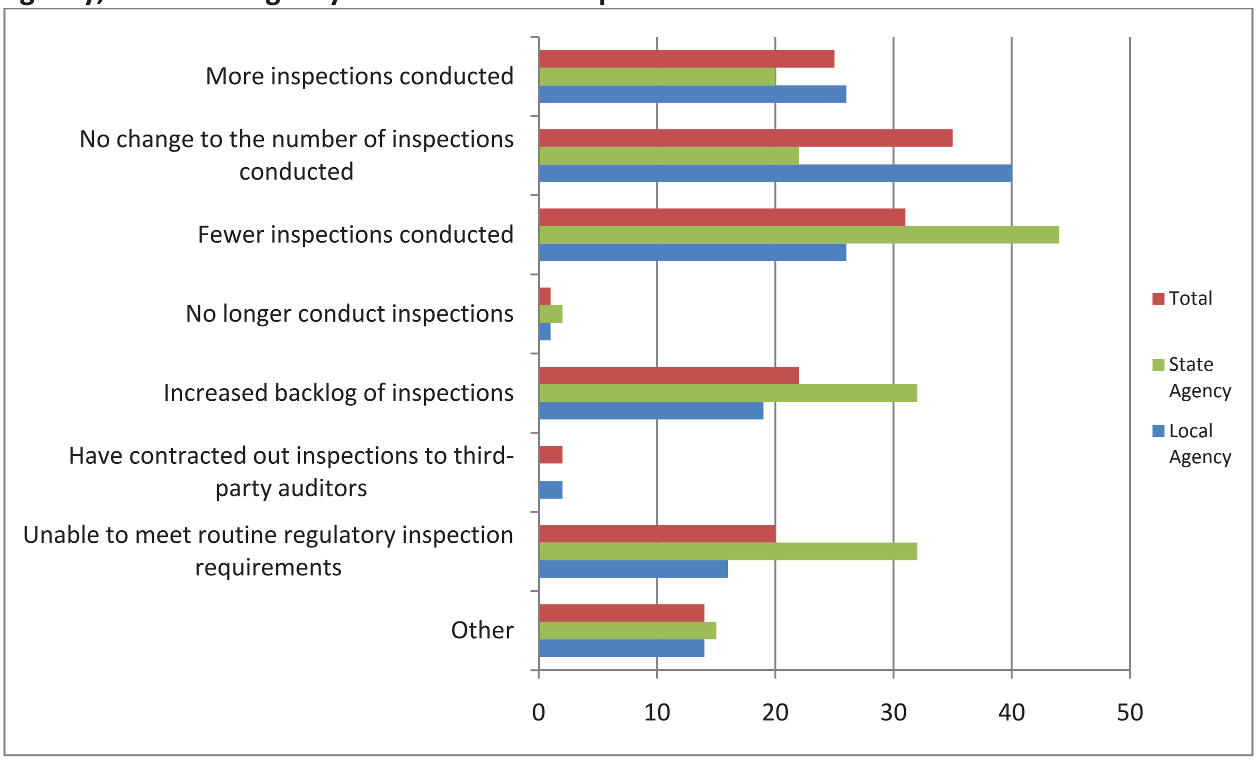
6.2.3 Outsourcing

- 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%

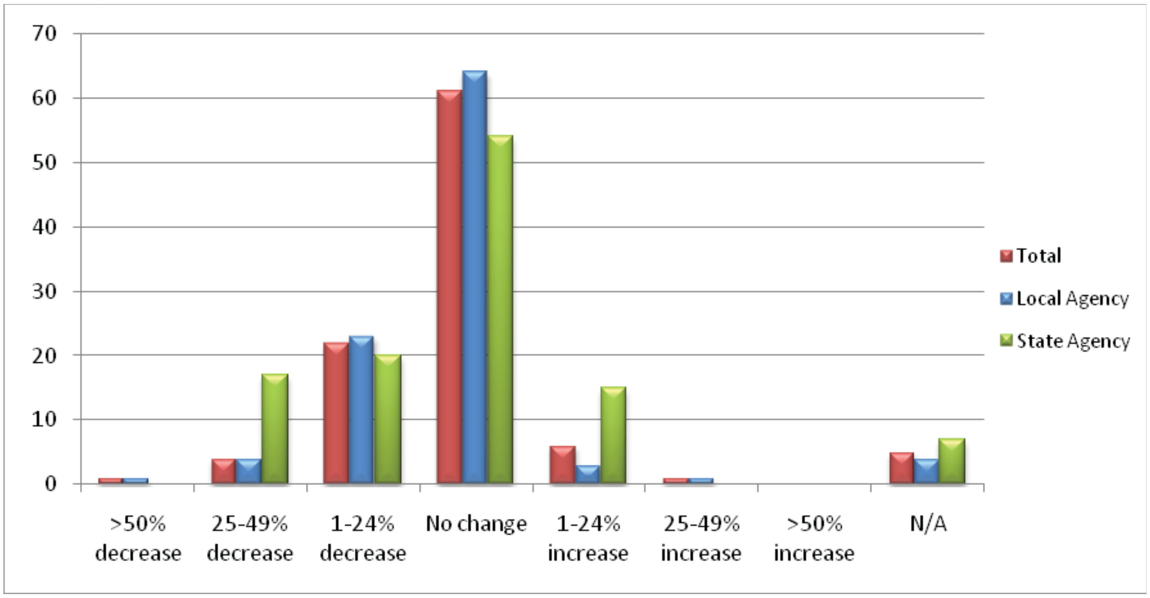
Table 8.0.3 Indicated Degrees of Impact to Regulatory Food Safety Program Capacity to Investigate and Respond to Foodborne Illness Outbreaks for State Agency Assessment Participants

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

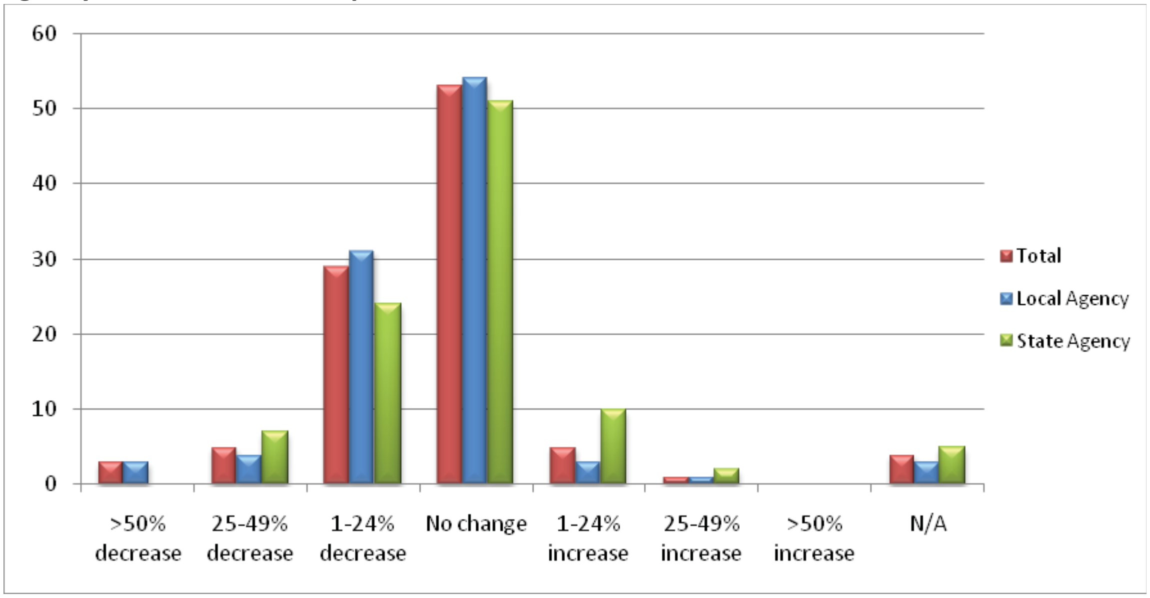
- received an FDA RRT grant. State funding has decreased significantly.

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

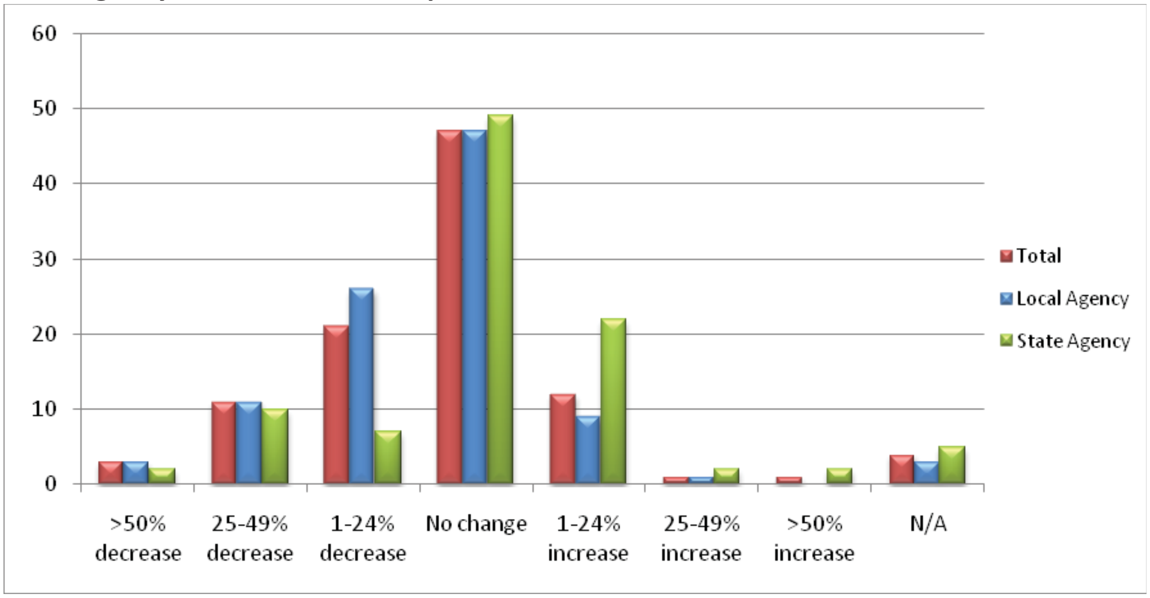
Local Agency

- 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

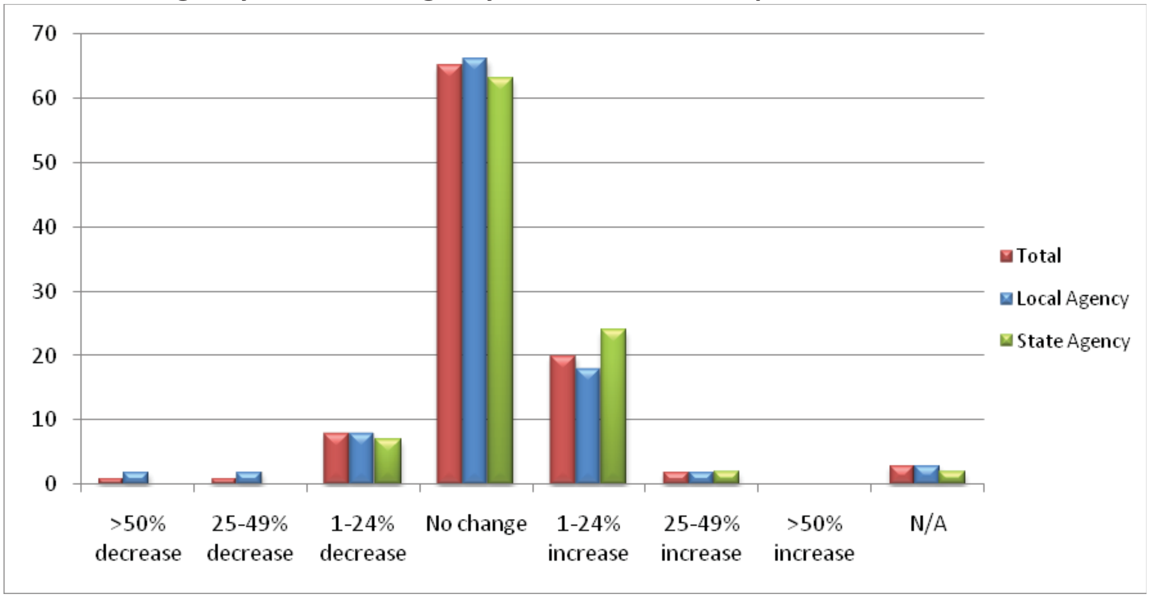
- Due to an increase in licensing fees and an increased focus on training we have been able to increase the training provided to inspectors.

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

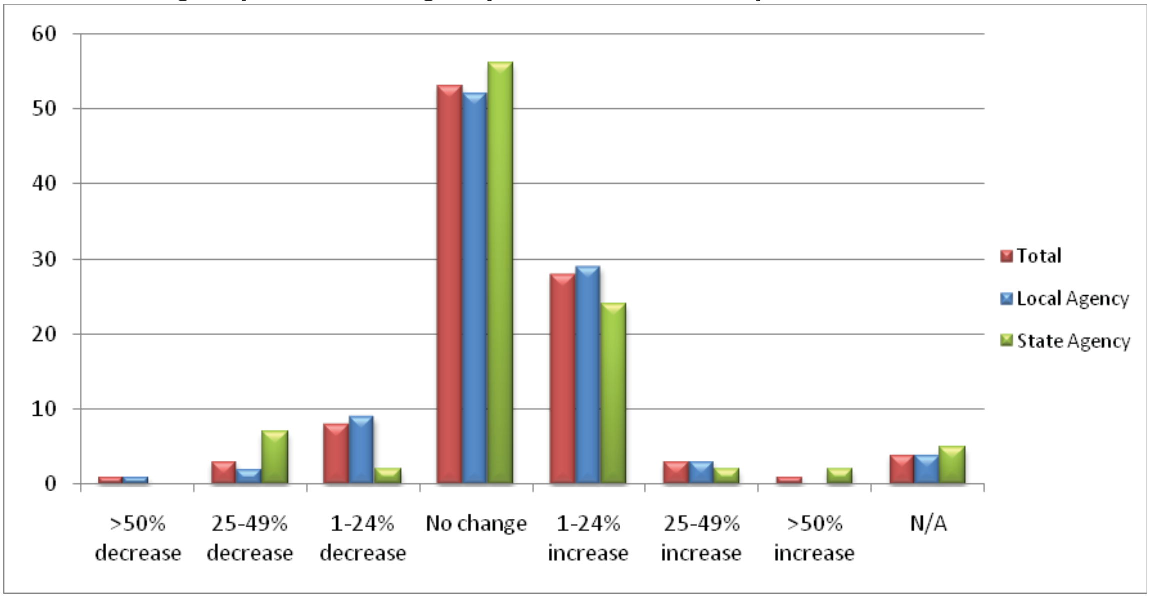
Local Agency

- 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

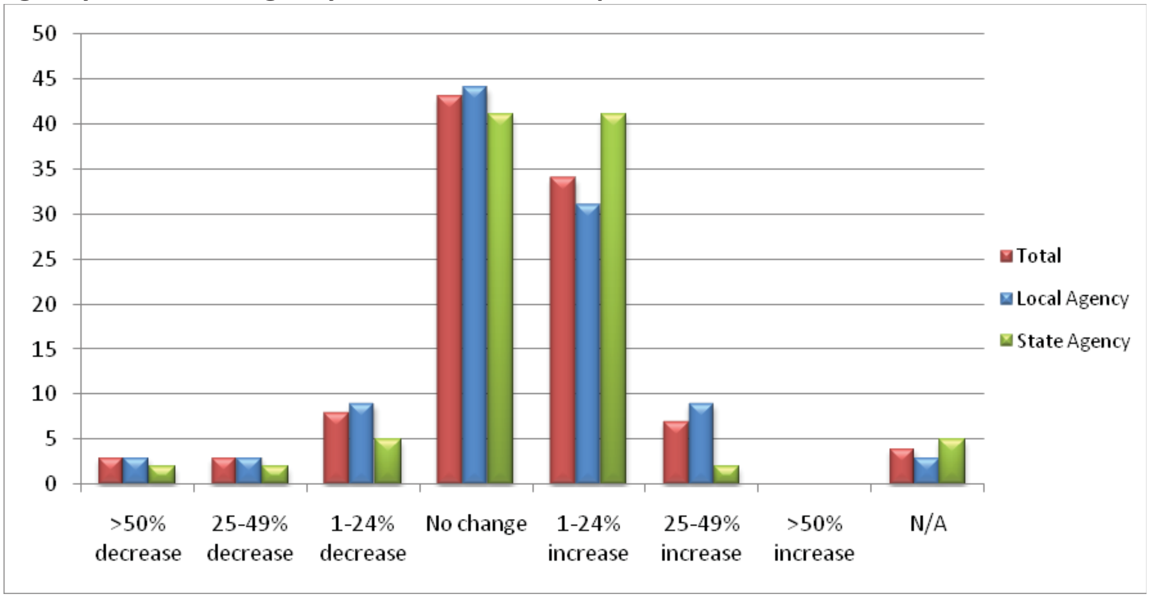
- It has been made clear to the inspectors that numbers of inspections conducted in a day are far more important than conducting a quality inspection. We are expected to conduct 4 inspections a day, regardless of the size or scope of the facility

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 6

Article preview

- Abstract
- Introduction
- Section snippets
- References (33)
- Cited by (9)
- Recommended articles (6)

Food Control

Volume 85, March 2018, Pages 459-465

Differences between official inspections and third party audits of food establishments

Author links open overlay panel M.Turku[a] O.Lepistö[b] J.Lundén[a]PersonEnvelope

https://doi.org/10.1016/j.foodcont.2017.10.031Get rights and content

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.

References (33)

- J. Trienekens *et al.*

  [Quality and safety standards in the food industry, developments and challenges]

International Journal of Production Economics

(2008)

- J. Qijun *et al.*

  Barriers and benefits to the adoption of a third party certified food safety management system in the food processing sector in Shanghai, China

  Food Control

  (2016)

- E.L. Psomas *et al.*

  HACCP effectiveness between ISO 22000 certified and non-certified dairy companies

  Food Control

  (2015)

- L.D. Mensah *et al.*

  Implementation of food safety management systems in the UK

  Food Control

  (2011)

- T. Läikkö-Roto *et al.*

  Consistency in inspection processes of food control officials and efficacy of official controls in restaurants in Finland

  Food Control

  (2015)

- K. Kettunen *et al.*

  Effectiveness of enforcement measures in local food control in Finland

  Food Control

  (2015)

- L. Jacxsens *et al.*

  Measuring microbial food safety output and comparing self-checking systems of food business operators in Belgium

  Food Control

  (2015)

- L. Fulponi

[Private voluntary standards in the food system: The perspective of major food retailers in OECD countries]

Food Policy

(2006)

- C. Escanciano *et al.*

[Reasons and constraints to implementing an ISO 22000 food safety management system: Evidence from Spain]

Food Control

(2014)

- P. Crandall *et al.*

[Companies' opinions and acceptance of global food safety initiative benchmarks after implementation]

Journal of Food Protection

(2012)

- J. Buckley

[Food safety regulation and small processing: A case study of interactions between processors and inspectors]

Food Policy

(2015)

- F. Albersmeier *et al.*

[The reliability of third-party certification in the food chain: From checklists to risk-oriented auditing]

Food Control

(2009)

- Anonymous

Study to evaluate the effectiveness of independently accredited assurance schemes and the role they could play in the delivery of official controls at UK points of entry

- Anonymous

Summary: Risks in the meat supply chain

(2014)
- BRC

Global standard

Food Safety

(2017)
- CFIA

Private certification policy (food safety)

(2016)

Navigate DownView more references

Cited by (9)

- **[Using data mining as a tool for anomaly detection in food safety audit data]**

  2022, Food Control

  Show abstractNavigate Down

  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

  Show abstractNavigate Down

  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

  Show abstractNavigate Down

  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

  Show abstractNavigate Down

  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

  Show abstractNavigate Down

  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

  Show abstractNavigate Down

  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.

[Arrow Up and RightView all citing articles on Scopus]

Recommended articles (6)

- 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

  Show abstractNavigate Down

  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

Show abstractNavigate Down

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

Show abstractNavigate Down

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
  Show abstractNavigate Down

  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
  Show abstractNavigate Down

  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
  Show abstractNavigate Down

  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.

View full text

Comprehensive Reviews in Food Science and Food Safety / Volume 16, Issue 5 / p. 760-775

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

First published: 03 August 2017
https://doi.org/10.1111/1541-4337.12293

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.

42 Admin. & Reg. L. News 22 (2016-2017)
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.

Identity and Numbers of Bacteria Present on Tabletops and in Dishcloths Used to Wipe Down Tabletops in Public Restaurants and Bars

Food Protection Trends, Vol. 26, No. 11, Pages 786–792

6200 Aurora Ave., Suite 200W, Des Moines, IA 50322-2864

Identity and Numbers of Bacteria Present on Tabletops and in Dishcloths Used to Wipe Down Tabletops in Public Restaurants and Bars

M. SUSANA YEPIZ-GOMEZ, KELLY R. BRIGHT,* and CHARLES P. GERBA
The University of Arizona, Dept. of Soil, Water and Environmental Science, Tucson, AZ 85721, USA

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

*Author for correspondence: 520.626.8094; Fax: 520.621.6163
E-mail: bright@u.arizona.edu

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, inadequate 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

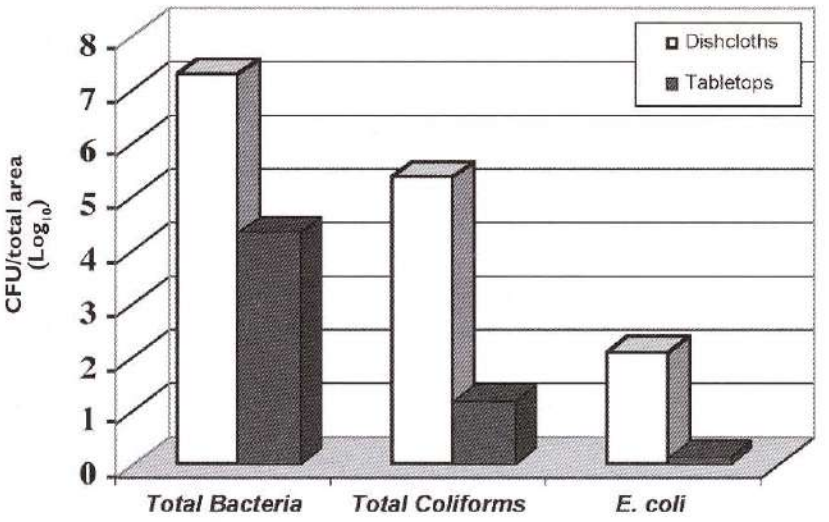


FIGURE 2. Comparison of bacterial levels in dishcloths from restaurants and bars

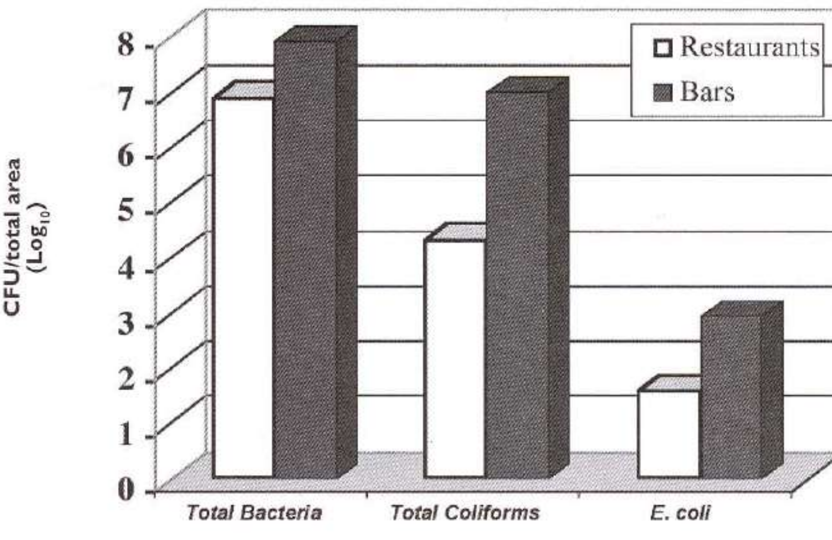
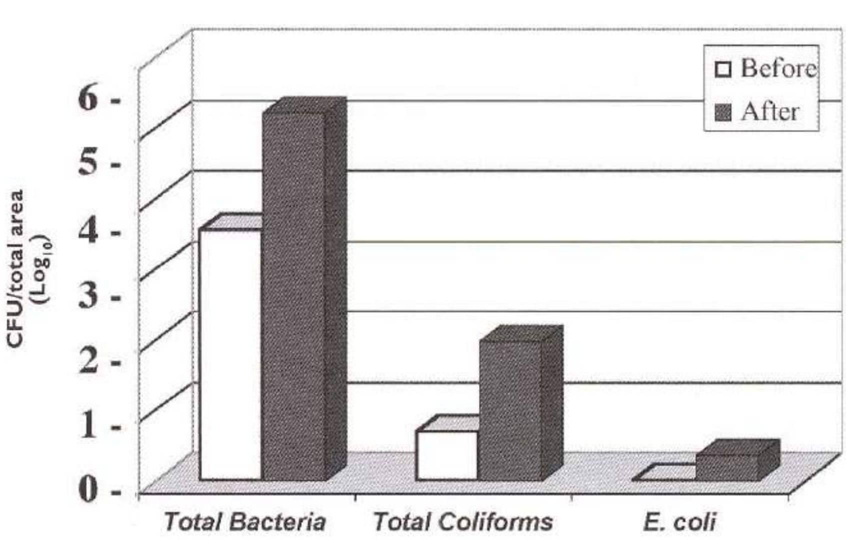


FIGURE 3. Bacteria found on tabletops before and after cleaning in restaurants



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 1. 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 warneri	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]	Household Kitchens 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 maculicola* (16.2%), *Pseudomonas putida* (16.2%), *Pseudomonas fluorescens* (8.1%), *Ralstonia (Pseudomonas) pickettii* (8.1%) and *Enterobacter cloacae* (8.1%).

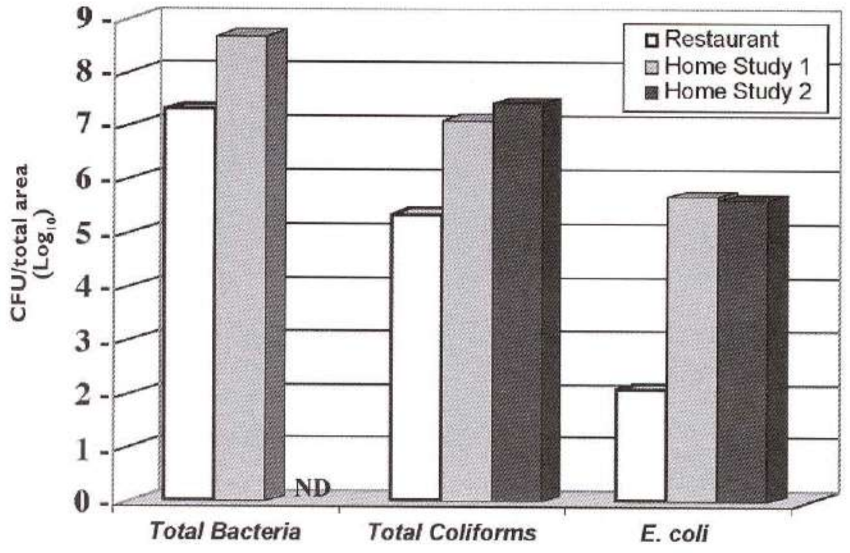
The most common genera isolated (Table 2) were *Pseudomonas* (6 species, 21 isolates, 56.8% frequency), *Klebsiella* (4 species, 10 isolates, 27.0% frequency), *Listeria* (1 species, 9 isolates, 24.3% frequency), *Enterobacter* (5 species, 8 isolates, 21.6% frequency) and *Staphylococcus* (4 species, 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.

ACKNOWLEDGMENTS

The authors thank the Departamento de Investigación y Posgrado en Alimentos at the Universidad de Sonora in Hermosillo, Senora, Mexico for their scholarship support of M. Susana Yepiz-Gomez.

REFERENCES

1. Anonymous. 2005. Federal Food Code. U.S. Department of Health and Human Services, Food and Drug Administration, College Park, MD.
2. Bean, N. H., J. S. Goulding, C. Lao, and F. J. Angulo. 1996. Surveillance for foodborne-disease outbreaks – United States, 1988 – 1992. MMWR 45(SS5):1–66.
3. Chaidez, C., and C. P. Gerba. 2000. Bacteriological analysis of cellulose sponges and loofahs in domestic kitchens from a developing country. Dairy Food Environ. Sanit. 20: 834–837.
4. Chmielewski, R. A. N., and J. F. Frank. 1995. Formation of viable but nonculturable *Salmonella* during starvation in chemically defined solutions. Lett. Appl. Microbiol. 20: 380–284.
5. Enriquez, C. E., V. E. Enriquez, and C. P. Gerba. 1997a. Reduction of bacterial contamination in the household kitchen environment through the use of self-disinfecting sponges. Dairy Food Environ. Sanit. 17:550–554.
6. Enriquez, C. E., R. Enriquez-Gordillo, D. I. Kennedy, and C. P. Gerba. 1997b. Bacteriological survey of used cellulose sponges and cotton dishcloths from domestic kitchens. Dairy Food Environ. Sanit. 17:20–24.
7. Food and Drug Administration. 2000. FDA releases report of the FDA retail food program database of foodborne illness risk factors. Food Safety Issues 2:1.
8. Frank, J. F., M. A. Gassem, and R. A. N. Gillett. 1992. A direct viable count method suitable for use with *Listeria monocytogenes*. J. Food Protect. 55:697–700.
9. Käferstein, F. K., Y. Motarjemi, and D. W. Bettcher. 1997. Foodborne disease control: A transnational challenge. Emerg. Infect. Dis. 3:503–510.
10. Mead, P. S., L. Slutsker, V. Dietz, L. F. McCaig, J. S. Bresee, C. Shapiro, P. M. Griffin, and R. V. Tauxe. 1999. Food-related illness and death in the United States. Emerg. Infect. Dis. 5: 607–625.
11. Olsen, S. J., L. C. MacKinon, J. S. Goulding, N. H. Bean, and L. Slutsker. 2000. Surveillance for foodborne disease outbreaks – United States, 1993–1997. MMWR 49 (SS1):1-51.
12. Rusin, P., P. Orosz-Coughlin, and C. Gerba. 1998. Reduction of faecal coliform, coliform and heterotrophic plate count bacteria in the household kitchen and bathroom by disinfection with hypochlorite cleaners. J. Appl. Microbiol. 85: 819–828.
13. Scott, E., and S. F. Bloomfield. 1990. The survival and transfer of microbial contamination via cloths, hands and utensils. J. Appl. Bacteriol. 68: 271–278.
14. Scott, E. and S. F. Bloomfield. 1993. An in-use study of the relationship between bacterial contamination of food preparation surfaces and cleaning cloths. Lett. Appl. Microbiol. 16:173–177.
15. Scott, E., S. F. Bloomfield, and C. G. Barlow. 1982. An investigation of microbial contamination in the home. J. Hyg. Camb. 89:279–293.
16. Tauxe, R. V. 1997. Emerging foodborne diseases: An evolving public health challenge. Emerg. Infect. Dis. 3:425–434.

Congratulations

At IAFP 2006, we offered a drawing for a one-year Membership with our Association and a free registration to our Annual Meeting. We are pleased to announce the following winners of the drawing:

IAFP Membership

Jack Bozzuffi
Bozzuffi Consulting Services LLC
Oxford, NJ

IAFP 2007 Annual Meeting Registration

Raylene Keith
Canadian Food Inspection Agency
Calgary, Alberta, Canada

Journal of Food Protection, Vol. 83, No. 7, 2020, Pages 1248–1260
https://doi.org/10.4315/JFP-20-025
Published 2020 by the International Association for Food Protection

Research Paper

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

BINAIFER BEDFORD,[1] GIRVIN LIGGANS,[2] LAURIE WILLIAMS,[2] AND LAUREN JACKSON[1]*

[1]*Division of Food Processing Science and Technology, Office of Food Safety, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, 6502 South Archer Road, Bedford Park, Illinois 60501 (ORCID: https://orcid.org/0000-0001-6246-700X [L.J.])* [2]*Retail Food Protection Staff, Office of Food Safety, Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration, 5001 Campus Drive, College Park, Maryland 20740, USA*

MS 20-025: Received 17 January 2020/Accepted 19 March 2020/Published Online 23 June 2020

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

* Author for correspondence. Tel: 708-924-0616; Fax: 708-924-0690; E-mail: Lauren.Jackson@fda.hhs.gov.

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]

Coupon type	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 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]

Coupon type	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 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]

Coupon type	Food soil on coupon: 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.

ACKNOWLEDGMENT

The authors appreciate the conversations and insights provided by Dr. Hal King and his suggestion on expanding the scope of the study to include alcohol quat sanitizer wipes (Table Turners) on the basis of current retail food establishment practices.

SUPPLEMENTAL MATERIAL

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

REFERENCES

1. Acker, W. W., J. Plasek, K. G. Blumenthal, K. H. Lai, M. Topaz, D. L. Seger, F. R. Goss, S. P. Slight, P. G. Dip, D. W. Bates, and L. Zhou. 2017. Prevalence of food allergies and intolerances documented in electronic health records. *J. Allergy Clin. Immunol*. 140:1587–1591.
2. Ak, N. O., D. O. Cliver, and C. W. Kaspar. 1994. Cutting boards of plastic and wood contaminated experimentally with bacteria. *J. Food Prot*. 57:16–22.
3. Ak, N. O., D. O. Cliver, and C. W. Kaspar. 1994. Decontamination of plastic and wooden cutting boards for kitchen use. *J. Food Prot*. 57:23–30.
4. Aviat, F., and C. Gerhards. 2016. Microbial safety of wood in contact with food: a review. *Compr. Rev. Food Sci. Food Saf*. 15:491–506.
5. Boyce, J. A., A. Assa'ad, A. W. Burks, S. M. Jones, H. A. Sampson, R. A. Wood, M. Plaut, S. F. Cooper, M. J. Fenton, S. H. Arshad, S. L. Bahna, L. A. Beck, C. Byrd-Bredbenner, C. A. Camargo, Jr., L. Eichenfield, G. T. Furuta, J. M. Hanifin, C. Jones, M. Kraft, B. D. Levy, P. Lieberman, S. Luccioli, K. M. McCall, L. C. Schneider, R. A. Simon, F. E. Simons, S. J. Teach, B. P. Yawn, and J. M. Schwaninger. 2010. Guidelines for the diagnosis and management of food allergy in the United States: report of the NIAID-sponsored expert panel. *J. Allergy Clin. Immunol*. 126(Suppl):S1–58.
6. Brough, H. A., K. Makinson, M. Penagos, S. J. Maleki, H. Cheng, A. Douiri, A. C. Stephens, V. Turcanu, and G. Lack. 2013. Distribution of peanut protein in the home environment. *J. Allergy Clin. Immunol*. 132:623–629.
7. Gehrig, M., C. Schnell, E. Zurcher, and L. Kucera. 2000. Hygienic aspects of wood and polyethylene cutting boards regarding food contaminations. A comparison. *Holz Roh Werkst*. 58:265–269.
8. Gupta, R. S., E. E. Springston, M. R. Warrier, B. Smith, R. Kumar, J. Pongracic, and J. L. Holl. 2011. The prevalence, severity, and distribution of childhood food allergy in the United States. *Pediatrics* 128:e9–e17.
9. Jackson, L. S., F. M. Al-Taher, M. Moorman, J. W. DeVries, R. Tippett, K. M. J. Swanson, T.-J. Fu, R. Salter, G. Dunaif, S. Estes, S. Albillos, and S. M. Gendel. 2008. Cleaning and other control and validation strategies to prevent allergen cross-contact in food-processing operations. *J. Food Prot*. 71:445–458.
10. Little, C., and S. Sagoo. 2009. Evaluation of the hygiene of ready-to-eat food preparation areas and practices in mobile food vendors in the UK. *Int. J. Environ. Health Res*. 19:431–443.
11. Lucke, F., and A. Skowyrska. 2015. Hygienic aspects of using wooden and plastic cutting boards, assessed in laboratory and small gastronomy units. *J. Consum. Prot. Food Saf*. 10:317–322.
12. Miller K., N. McGough, and H. Urwin. 2016. Catering gluten-free when simultaneously using wheat flour. *J. Food Prot*. 79:282–287.
13. Ortiz, J. C., P. Galan-Malo, M. Garcia-Galvez, A. Mateos, M. Ortiz-Ramos, P. Razquin, and L. Mata. 2018. Survey on the occurrence of allergens on food-contact surfaces from school canteen kitchens. *Food Control* 84:449–454.
14. Perry, T. T., M. K. Conover-Walker, A. Pomés, M. D. Chapman, and R. A. Wood. 2004. Distribution of peanut allergen in the environment. *J. Allergy Clin. Immunol*. 113:973–976.
15. Röder, M., A. Ibach, I. Baltruweit, H. Gruyters, A. Janise, C. Suwelack, R. Matissek, S. Vieths, and T. Holzhauser. 2008. Pilot plant investigations on cleaning efficiencies to reduce hazelnut cross-contamination in industrial manufacture of cookies. *J. Food Prot*. 71:2263–2271.
16. Schmidt, R. H. 1997. Basic elements of equipment cleaning and sanitizing in food processing and handling operations. University of Florida Cooperative Extension Service, Institute of Food and Agricultural Sciences. Available at: http://edis.ifas.ufl.edu/FS077. Accessed 16 October 2019.
17. Sicherer, S., and H. A. Sampson. 2014. Food allergy: epidemiology, pathogenesis, diagnosis, and treatment. *J. Allergy Clin. Immunol*. 133:291–307.
18. Sicherer, S., and H. A. Sampson. 2018. Food allergy: a review and update on epidemiology, pathogenesis, diagnosis, prevention, and management. *J. Allergy Clin. Immunol*. 141:41–58.
19. Tebbutt, G. M. 1991. An assessment of cleaning and sampling methods for food-contact surfaces in premises preparing and selling high-risk foods. *Epidemiol. Infect*. 106:319–327.
20. U.S. Department of Agriculture, Economic Research Service. 2019. U.S. food-away-from-home spending continued to outpace food-at-home spending in 2018. Available at: www.ers.usda.gov/data-products/chart-gallery/chart-detail/?chartid=58364. Accessed 23 September 2019.
21. U.S. Department of Agriculture, Food Safety and Inspection Service. 2013. Cutting boards and food safety. Available at: www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/cutting-boards-and-food-safety. Accessed 15 January 2019.
22. U.S. Food and Drug Administration. 2004. Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). Public law 108-282. Title II. U.S. Food and Drug Administration, Silver Spring, MD. Available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm. Accessed 12 January 2017.
23. U.S. Food and Drug Administration. 2017. Food Code. Available at: https://www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/ucm595139.htm. Accessed 10 October 2019.
24. Wang, X., O. A. Young, and D. P. Karl. 2010. Evaluation of cleaning procedures for allergen control in a food industry environment. *J. Food Sci*. 75:T149–T155.
25. Watrous, G. H. 1975. Food soils, water hardness, and alkaline cleaner formulations. *J. Milk Food Technol*. 38:163–165.
26. Watson, W. T. A., A. Woodrow, and A. W. Stadnyk. 2015. Removal of peanut allergen Ara h 1 from common hospital surfaces, toys and books using standard cleaning methods. *Allergy Asthma Clin. Immunol.* 11:1–4. https://doi.org/doi:10.1186/s13223-015-0069-x
27. Welker, C., N. Faiola, S. Davis, I. Maffatore, and C. A. Batt. 1997. Bacterial retention and cleanability of plastic and wood cutting boards with commercial food service maintenance practices. *J. Food Prot*. 60:407–413.

PEER-REVIEWED ARTICLE

Food Protection Trends, Vol 40, No. 6, p. 392–401

2900 100th Street, Suite 309, Des Moines, IA 50322-3855

Rebecca M. Goulter,[1*] James S. Clayton,[2] Robin Grant Moore,[1] Justin M. Bradshaw,[1a] Jason W. Frye,[1] Esa J. Puntch[1] and Lee-Ann Jaykus[1]

[1]Dept. of Food, Bioprocessing and Nutrition Sciences, North Carolina State University, Raleigh, NC 27603, USA
[2]PDI Inc., 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677, USA
[a]Current Affiliation: Johnston Community College, Smithfield, NC 27577, USA

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 ($\geq$ 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

*Author for correspondence: Phone: +1 919.515.3019; Fax: +1.919.5157124; Email: rebecca_goulter@ncsu.edu

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

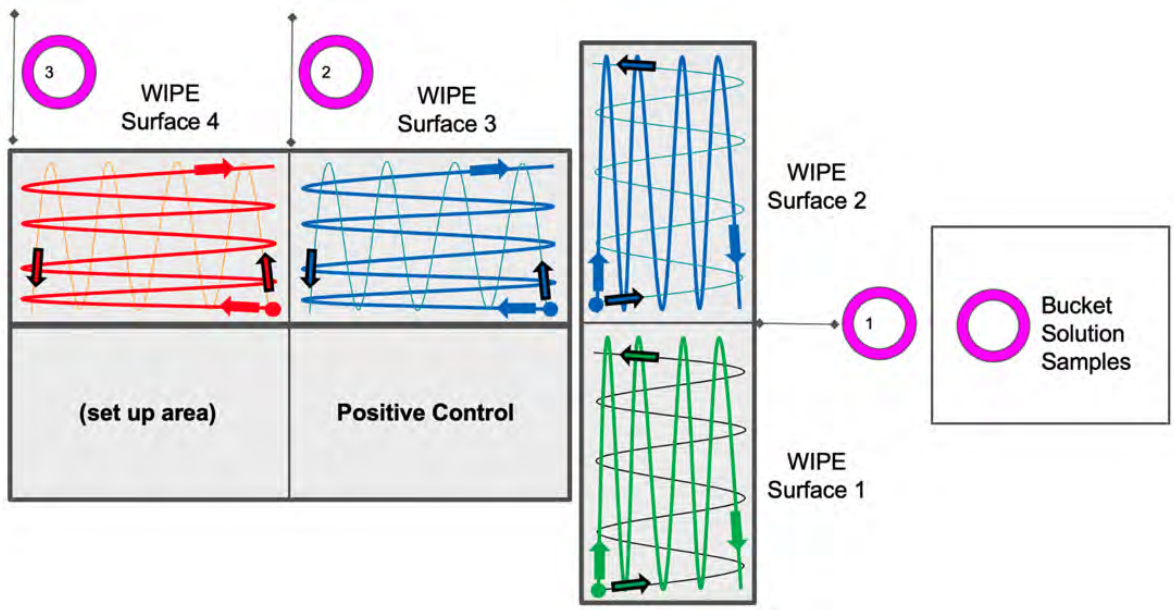


FIGURE B

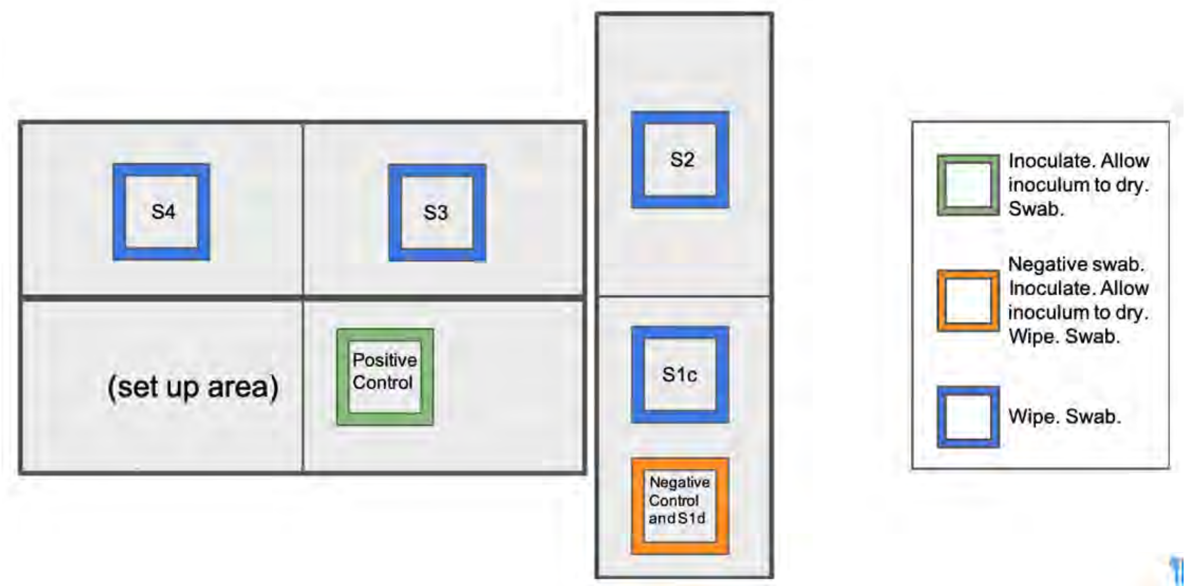


FIGURE 1. Overall experimental design. (a) A diagram of the wiping protocol, including the timing for collection of water samples drawn from the wiping bucket solution. (b) Diagram of the swabbing locations for each of the individual laminate surfaces.

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

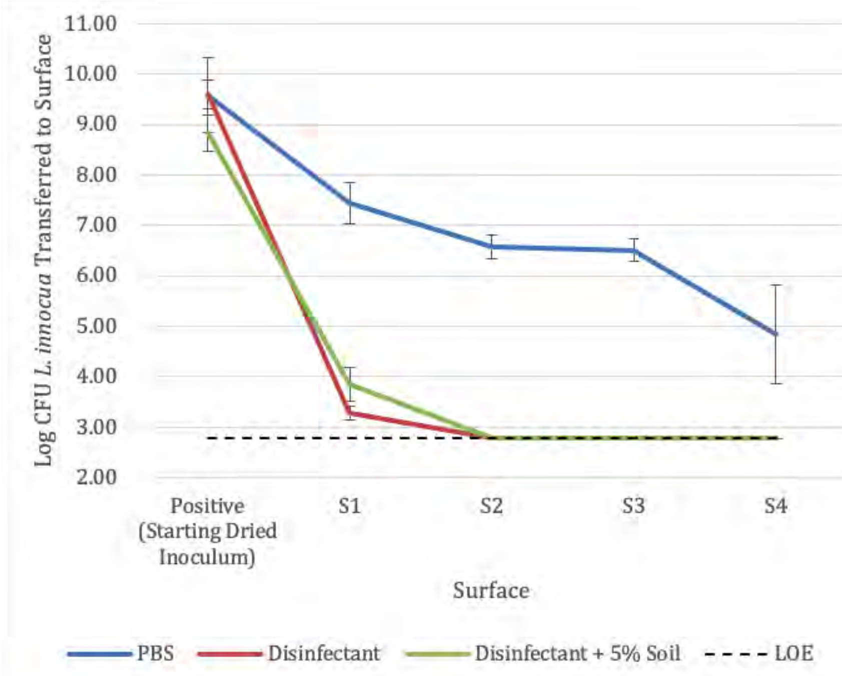


FIGURE 2. Log CFU of *Listeria innocua* transferred to, and remaining on, laminate surfaces during wiping experiments. Surface 1 was inoculated at the same level as the positive surface (starting dried inoculum) before wiping experiments. Cloth was used to wipe surfaces sequentially from surface 1 through 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.

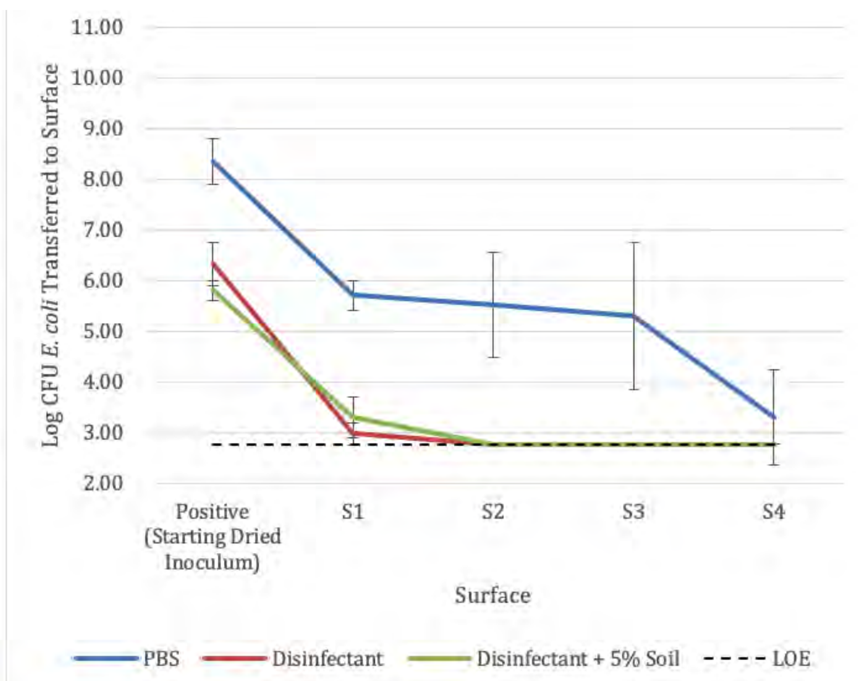


FIGURE 3. Log CFU of *Escherichia coli* transferred to, and remaining on, laminate surfaces during wiping experiments. Surface 1 was inoculated at the same level as the positive surface (starting dried inoculum) before wiping experiments. Cloth was used to wipe surfaces sequentially from surface 1 through 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.

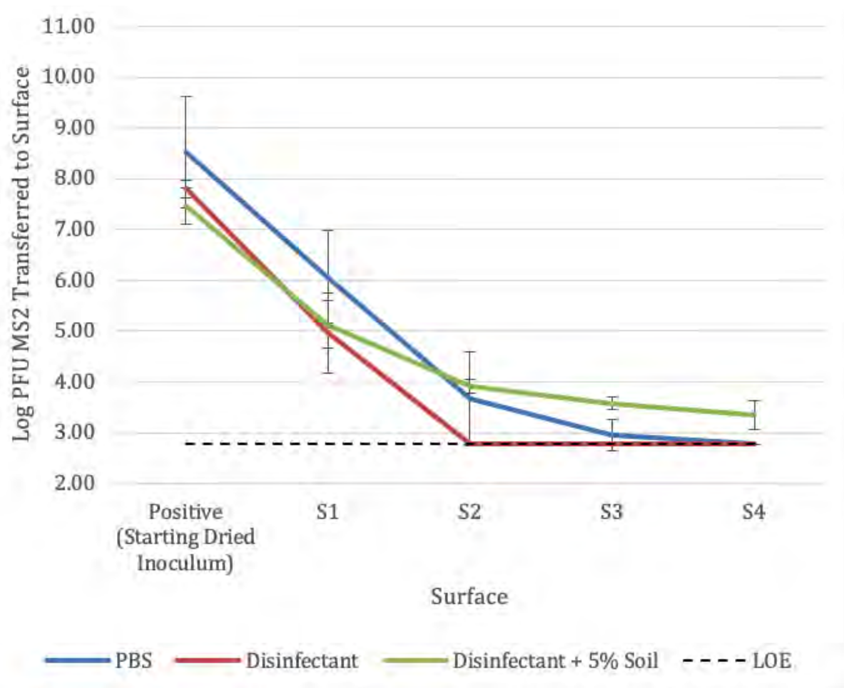


FIGURE 4. Log PFU of MS2 bacteriophage transferred to, and remaining on, laminate surfaces during wiping experiments. Surface 1 was inoculated at the same level as the positive surface (starting dried inoculum) before wiping experiments. Cloth was used to wipe surfaces sequentially from surface 1 through 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.

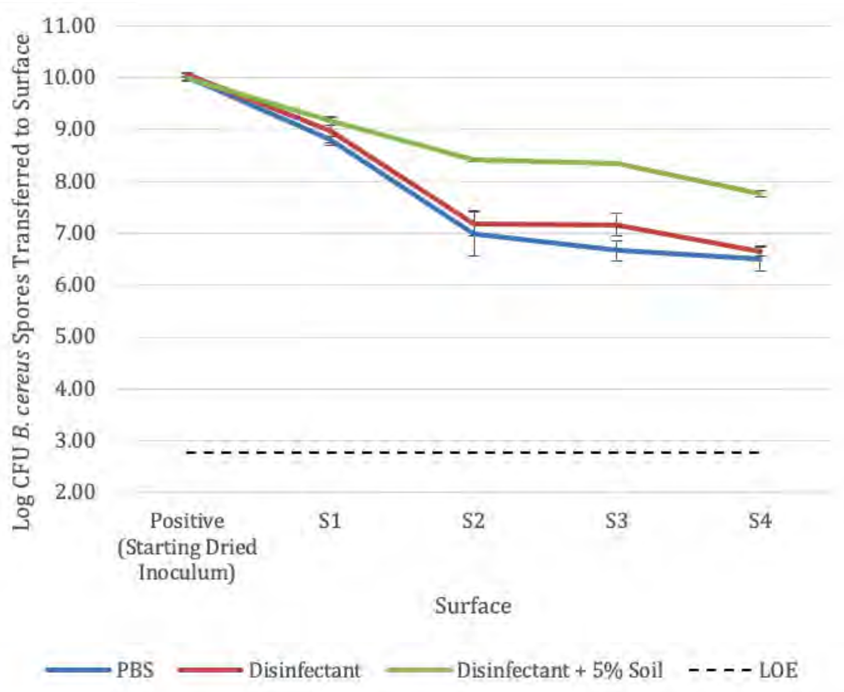


FIGURE 5. Log CFU of *Bacillus cereus* spores transferred to, and remaining on, laminate surfaces during wiping experiments. Surface 1 was inoculated at the same level as the positive surface (starting dried inoculum) before wiping experiments. Cloth was used to wipe surfaces sequentially from surface 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.

ACKNOWLEDGMENT

This work was possible thanks to funding from PDI, Incorporated.

REFERENCES

1. ASTM International. 2011. E1053-11 standard test method to assess virucidal activity of chemicals intended for disinfection of inanimate, nonporous environmental surfaces. ASTM International, West Conshohocken, PA. https://doi.org/10.1520/E1053-11.
2. ASTM International. 2015. E2967-15 standard test method for assessing the ability of pre-wetted towelettes to remove and transfer bacterial contamination on hard, non-porous environmental surfaces using the Wiperator. ASTM International, West Conshohocken, PA. https://doi.org/10.1520/E2967-15.
3. Badman, L. 2001. Water matters: proposed changes to ANSI/NSF standard 55—ultraviolet microbiological water treatment systems. *Water Cond. Purif. Mag.* 43.
4. Bergen, L. K., M. Meyer, M. Høg, B. Rubenhagen, and L. P. Andersen. 2009. Spread of bacteria on surfaces when cleaning with microfibre cloths. *J. Hosp. Infect.* 71:132–137.
5. Engelbrecht, K., D. Ambrose, L. Sifuentes, C. Gerba, I. Weart, and D. Koenig. 2013. Decreased activity of commercially available disinfectants containing quaternary ammonium compounds when exposed to cotton towels. *Am. J. Infect. Control* 41:908–911.
6. Gerba, C. P. 2015. Quaternary ammonium biocides: efficacy in application. *Appl. Environ. Microbiol.* 81:464–469.
7. Gerding, D. N., C. A. Muto, and R. C. Owens, Jr. 2008. Measures to control and prevent *Clostridium difficile* infection. *Clin. Infect. Diseases* 46:S43–S49.
8. Gibson, K. E., P. G. Crandall, and S. C. Ricke. 2012. Removal and transfer of viruses on food contact surfaces by cleaning cloths. *Appl. Environ. Microbiol.* 78:3037–3044.
9. Johnson, K. M., C. L. Nelson, and F. F. Busta. 1982. Germination and heat resistance of *Bacillus cereus* spores from strains associated with diarrheal and emetic foodborne illnesses. *J. Food Sci.* 47:1268–1271.
10. Medrano-Félix, A., C. Martinez, N. Castro-del Campo, J. León-Félix, F. Peraza-Garay, C. P. Gerba, and C. Chaidez. 2011. Impact of prescribed cleaning and disinfectant use on microbial contamination in the home. *J. Appl. Microbiol.* 110:463–471.
11. Ramm, L., H. Siani, R. Westgate and Maillard, J. Y. 2015. Pathogen transfer and high variability in pathogen removal by detergent wipes. *Am. J. Infect. Control* 43:724–728.
12. Rossi, E. M., D. Scapin, W. F. Grando, and E. C. Tondo. 2012. Microbiological contamination and disinfection procedures of kitchen sponges used in food services. *Food Nutr. Sci.* 3:975–908.
13. Sattar, S. A., C. Bradley, R. Kibbee, R. Westgate, M. A. C. Wilkinson, T. Sharpe, and J. Y. Maillard. 2015. Disinfectant wipes are appropriate to control microbial bioburden from surfaces: use of a new ASTM standard test protocol to demonstrate efficacy. *J. Hosp. Infect.* 91:319–325.
14. Sattar, S. A., and J. Y. Maillard. 2013. The crucial role of wiping in decontamination of high-touch environmental surfaces: Review of current status and directions for the future. *Am. J. Inf. Cont.* 41:S97–S104.
15. Scott, E., and S. F. Bloomfield. 1993. An in-use study of the relationship between bacterial contamination of food preparation surfaces and cleaning cloths. *Lett. Appl. Microbiol.* 16:173–177.
16. Smith, D. L., S. Gillanders, J. T. Holah, and C. Gush. 2011. Assessing the efficacy of different microfibre cloths at removing surface microorganisms associated with healthcare-associated infections. J. *Hosp. Infect.* 78:182–186.
17. Su, X., and D. H. D'Souza. Grape seed extract for control of human enteric viruses. 2011. *Appl. Environ. Microbiol.* 77:3982–3987.
18. Trajtman, A. N., K. Manickam, and M. J. Alpha. 2015. Microfiber cloths reduce the transfer of *Clostridium difficile* spores to environmental surfaces compared with cotton cloths. *Am. J. Infect. Control* 43:686–689.
19. Tung, G., D. Macinga, J. Arbogast, and L. A. Jaykus. 2013. Efficacy of commonly used disinfectants for inactivation of human noroviruses and their surrogates. *J. Food Prot.* 76:1210–1217.

AEM
Journals.ASM.org

Removal and Transfer of Viruses on Food Contact Surfaces by Cleaning Cloths

Kristen E. Gibson, Philip G. Crandall, and Steven C. Ricke

University of Arkansas, Division of Agriculture, Department of Food Science, and Center for Food Safety, Fayetteville, Arkansas, USA

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

Received 4 January 2012 Accepted 6 February 2012
Published ahead of print 10 February 2012
Address correspondence to Kristen E. Gibson, keg005@uark.edu.

doi:10.1128/AEM.00027-12

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′-CGGCCAAAAGGTGGTGGATG-3′	185	5′ UTR[d]	40
		HepG-R	400	5′-CGACGAGCCTGACGTCGGG-3′			
		HepG probe	200	5′ AGGTCCCTCTGGCGCTTGTGGCGAG-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 $\leq$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 $\leq$10 PFU ($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

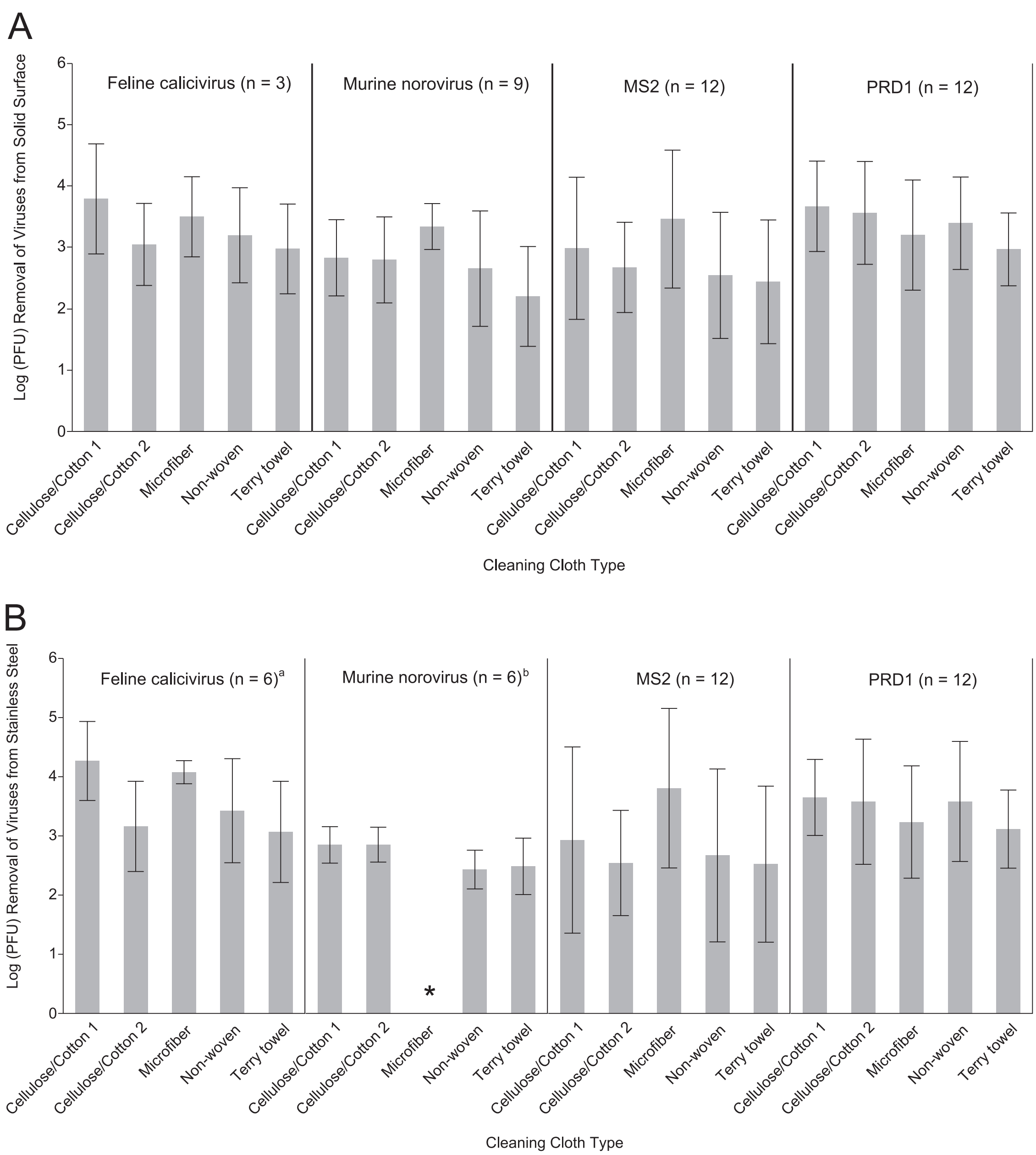


FIG 1 Virus removal from solid surface (A) and stainless steel (B) by cleaning cloth and virus type. Error bars indicate standard deviations. *, only dry microfiber was included in these data for MNV removal, and thus, the data were excluded from statistical analyses, as dry microfiber was determined 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

	Average C_T value (SD)[a]					
	Solid surface			Stainless steel		
Cleaning cloth type	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

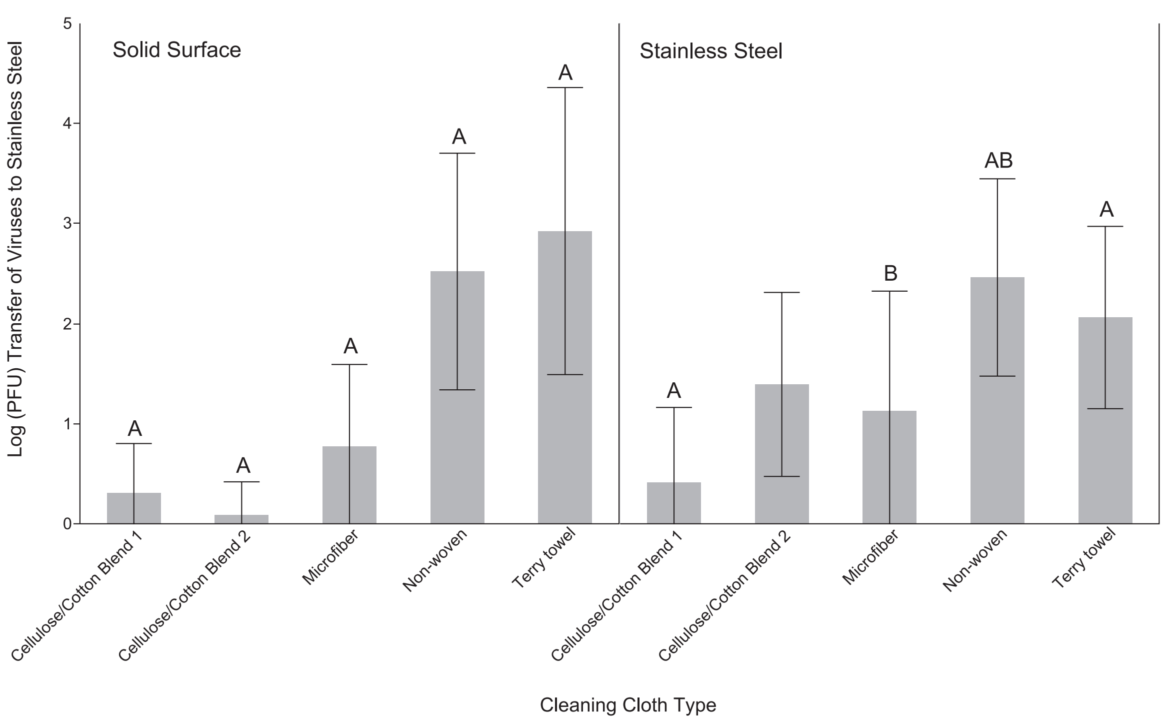


FIG 2 Total virus (FCV, MS2, PRD1) transfer to solid surface and stainless steel by cleaning cloths. Error bars indicate standard deviations. Letters above the bars represent statistically significant differences ($P \leq 0.05$) between cloth types for virus transfer within each surface type.

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.

ACKNOWLEDGMENTS

We especially thank Kim Buldoc and Jesse Kay for their assistance in the lab. We also thank S. R. Milillo for her critical review of the manuscript. We acknowledge John Lample for providing the cleaning cloths used for evaluation.

This research was funded by a USDA NIFSI grant (award no. 10507316) to P. G. Crandall and S. C. Ricke.

REFERENCES

1. **Bae J, Schwab K.** 2008. Evaluation of murine norovirus, feline calicivirus, poliovirus, and MS2 as surrogates for human norovirus in a model of viral persistence in surface water and groundwater. Appl. Environ. Microbiol. **74**:477–484.
2. **Baert L, Uyttendaele M, Debevere J.** 2008. Evaluation of viral extraction methods on a broad range of ready-to-eat foods with conventional and real-time RT-PCR for norovirus GII detection. Int. J. Food Microbiol. **123**:101–108.
3. **Barker J, Vipond IB, Bloomfield SF.** 2004. Effects of cleaning and disinfection in reducing the spread of norovirus contamination via environmental surfaces. J. Hosp. Infect. **58**:42–49.
4. **Belliot G, Lavaux A, Souihel D, Agnello D, Pothier P.** 2008. Use of murine norovirus as a surrogate to evaluate resistance of human norovirus to disinfectants. Appl. Environ. Microbiol. **74**:3315–3318.
5. **Bidawid S, Malik N, Adegbunrin O, Sattar SA, Farber JM.** 2004. Norovirus cross-contamination during food handling and interruption of virus transfer by hand antisepsis: experiments with feline calicivirus as a surrogate. J. Food Prot. **67**:103–109.
6. **Boone SA, Gerba CP.** 2007. Significance of fomites in the spread of

respiratory and enteric viral disease. Appl. Environ. Microbiol. **73**:1687–1696.
7. **Diab-Elschahawi M, et al.** 2010. Evaluation of the decontamination efficacy of new and reprocessed microfiber cleaning cloth compared with other commonly used cleaning cloths in the hospital. Am. J. Infect. Control **38**:289–292.
8. **D'Souza D, Su X.** 2010. Efficacy of chemical treatments against murine norovirus, feline calicivirus, and MS2 bacteriophage. Foodborne Pathog. Dis. **7**:319–326.
9. **D'Souza DH, et al.** 2006. Persistence of caliciviruses on environmental surfaces and their transfer to food. Int. J. Food Microbiol. **108**:84–91.
10. **Duizer E, et al.** 2004. Laboratory efforts to cultivate noroviruses. J. Gen. Virol. **85**:79–87.
11. **Farrah SR, Shah DO, Ingram LO.** 1981. Effects of chaotropic and antichaotropic agents on elution of poliovirus adsorbed on membrane filters. Proc. Natl. Acad. Sci. U. S. A. **78**:1229–1232.
12. **Ferguson C, et al.** 2007. Field scale quantification of microbial transport from bovine faeces under simulated rainfall events. J. Water Health **5**:83–95.
13. **Gerba C.** 1984. Applied and theoretical aspects of virus adsorption to surfaces. Adv. Appl. Microbiol. **30**:133–168.
14. **Gibson KE, Schwab KJ.** 2011. Thermal inactivation of human norovirus surrogates. Food Environ. Virol. **3**:74–77.
15. **Gibson KE, Schwab KJ.** 2011. Tangential-flow ultrafiltration with integrated inhibition detection for recovery of surrogates and human pathogens from large-volume source water and finished drinking water. Appl. Environ. Microbiol. **77**:385–391.
16. **Girard M, Ngazoa S, Mattison K, Jean J.** 2010. Attachment of noroviruses to stainless steel and their inactivation, using household disinfectants. J. Food Prot. **73**:400–404.
17. **Glass RI, Parashar UD, Estes MK.** 2009. Norovirus gastroenteritis. N. Engl. J. Med. **361**:1776–1785.
18. **Isakbaeva ET, et al.** 2005. Norovirus transmission on cruise ship. Emerg. Infect. Dis. **11**:154–158.
19. **Jones EL, Kramer A, Gaither M, Gerba CP.** 2007. Role of fomite contamination during an outbreak of norovirus on houseboats. Int. J. Environ. Health Res. **17**:123–131.
20. **Julian TR, Leckie JO, Boehm AB.** 2010. Virus transfer between fingerpads and fomites. J. Appl. Microbiol. **109**:1868–1874.
21. **Kageyama T, et al.** 2003. Broadly reactive and highly sensitive assay for Norwalk-like viruses based on real-time quantitative reverse transcription-PCR. J. Clin. Microbiol. **41**:1548–1557.
22. **Lalla F, Dingle P.** 2004. The efficacy of cleaning products on food industry surfaces. J. Environ. Health **67**:17–22.
23. **Lalla F, Dingle P, Cheong C.** 2005. The antibacterial action of cloths and sanitizers and the use of environmental alternatives in food industries. J. Environ. Health **68**:31–35.
24. **Lamhoujeb S, Fliss I, Ngazoa SE, Jean J.** 2009. Molecular study of the persistence of infectious human norovirus on food-contact surfaces. Food Environ. Virol. **1**:51–56.
25. **Malek M, et al.** 2009. Outbreak of norovirus infection among river rafters associated with packaged delicatessen meat, Grand Canyon, 2005. Clin. Infect. Dis. **48**:31–37.
26. **Mattison K, et al.** 2007. Survival of calicivirus in foods and on surfaces: experiments with feline calicivirus as a surrogate for norovirus. J. Food Prot. **70**:500–503.
27. **Mokhtari A, Jaykus LA.** 2009. Quantitative exposure model for the transmission of norovirus in retail food preparation. Int. J. Food Microbiol. **133**:38–47.
28. **Moore G, Griffith C.** 2006. A laboratory evaluation of the decontamination properties of microfibre cloths. J. Hosp. Infect. **64**:379–385.
29. **Nilsen SK, Dahl I, Jorgensen O, Schneider T.** 2002. Micro-fibre and ultra-micro-fibre cloths, their physical characteristics, cleaning effect, abrasion on surfaces, friction, and wear resistance. Build Environ. **37**: 1373–1378.
30. **Oikarinen S, et al.** 2009. PCR inhibition in stool samples in relation to age of infants. J. Clin. Virol. **44**:211–214.
31. **Park GW, Sobsey MD.** 2011. Simultaneous comparison of murine norovirus, feline calicivirus, coliphage MS2, and GII.4 norovirus to evaluate the efficacy of sodium hypochlorite against human norovirus on a fecally soiled stainless steel surface. Foodborne Pathog. Dis. **8**:1005–1010.
32. **Park H, Kim M, Ko G.** 2010. Evaluation of various methods for recovering human norovirus and murine norovirus from vegetables and ham. J. Food Prot. **73**:1651–1657.
33. **Patel MM, Hall AJ, Vinjé J, Parashar UD.** 2009. Noroviruses: a comprehensive review. J. Clin. Virol. **44**:1–8.
34. **Riddle MS, et al.** 2006. Epidemic infectious gastrointestinal illness aboard U.S. Navy ships deployed to the Middle East during peacetime operations—2000-2001. BMC Gastroenterol. **6**:9.
35. **Rusin P, Maxwell S, Gerba CP.** 2002. Comparative surface-to-hand and fingertip-to-mouth transfer efficiency of gram-positive bacteria, gram-negative bacteria, and phage. J. Appl. Microbiol. **93**:585–592.
36. **Rzezutka A, Cook N.** 2004. Survival of human enteric viruses in the environment and food. FEMS Microbiol. Rev. **28**:441–453.
37. **Scallan E, et al.** 2011. Foodborne illness acquired in the United States—major pathogens. Emerg. Infect. Dis. **17**:7–15.
38. **Schaldach CM, Bourcier WL, Shaw HF, Viani BE, Wilson WD.** 2006. The influence of ionic strength on the interaction of viruses with charged surfaces under environmental conditions. J. Colloid Interface Sci. **294**:1–10.
39. **Scharff RL.** 2012. The economic burden from health losses due to foodborne illness in the United States. J. Food Prot. **75**:123–131.
40. **Schlueter V, et al.** 1996. Reverse transcription-PCR detection of hepatitis G virus. J. Clin. Microbiol. **34**:2660–2664.
41. **Schwab KJ, Estes MK, Neill FH, Atmar RL.** 1997. Use of heat release and an internal RNA standard control in reverse transcription-PCR detection of Norwalk virus from stool samples. J. Clin. Microbiol. **35**:511–514.
42. **Scott E, Bloomfield SF.** 1990. The survival and transfer of microbial contamination via cloths, hands and utensils. J. Appl. Bacteriol. **68**:271–278.
43. **Shieh Y, Wait D, Tai L, Sobsey MD.** 1995. Methods to remove inhibitors in sewage and other fecal wastes for enterovirus detection by the polymerase chain reaction. J. Virol. Methods **54**:51–66.
44. **Smith D, Gillanders S, Holah J, Gush C.** 2011. Assessing the efficacy of different microfibre cloths at removing surface microorganisms associated with healthcare-associated infections. J. Hosp. Infect. **78**:182–186.
45. **Solomon EB, Fino V, Wei J, Kniel KE.** 2009. Comparative susceptibilities of hepatitis A virus, feline calicivirus, bacteriophage MS2 and bacteriophage phiX-174 to inactivation by quaternary ammonium and oxidative disinfectants. Int. J. Antimicrob. Agents **33**:288–289.
46. **Takahashi H, Ohuchi A, Miya S, Izawa Y, Kimura B.** 2011. Effect of food residues on norovirus survival on stainless steel surfaces. PLoS One **6**:e21951.
47. **Taku A, et al.** 2002. Concentration and detection of caliciviruses from food contact surfaces. J. Food Prot. **65**:999–1004.
48. **Tebbutt GM.** 1988. Laboratory evaluation of disposable and reusable disinfectant cloths for cleaning food contact surfaces. Epidemiol. Infect. **101**:367–375.
49. **Teunis PF, et al.** 2008. Norwalk virus: how infectious is it? J. Med. Virol. **80**:1468–1476.
50. **U.S. Department of Health and Human Services.** 2009. Food code. U.S. Department of Health and Human Services, Washington, DC. http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/default.htm. 3 January 2012.
51. **Vega E, Garland J, Pillai SD.** 2008. Electrostatic forces control nonspecific virus attachment to lettuce. J. Food Prot. **71**:522–529.
52. **Vega E, Smith J, Garland J, Matos A, Pillai SD.** 2005. Variability of virus attachment patterns to butterhead lettuce. J. Food Prot. **68**:2112–2117.
53. **White LJ, et al.** 1996. Attachment and entry of recombinant Norwalk virus capsids to cultured human and animal cell lines. J. Virol. **70**:6589–6597.
54. **Wu HM, et al.** 2005. A norovirus outbreak at a long-term-care facility: the role of environmental surface contamination. Infect. Control Hosp. Epidemiol. **26**:802–810.